IN THE UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF OHIO
EASTERN DIVISION

Putnam County School Board, Individually, and on Behalf of All Others Similarly Situated, **Plaintiff,** **v.** **Cephalon, Inc., Teva Pharmaceutical Industries Ltd., Teva Pharmaceuticals USA, Inc., Endo International Plc, Endo Health Solutions Inc., Endo Pharmaceuticals Inc., Janssen Pharmaceuticals, Inc., Orth-McNeil-Janssen Pharmaceuticals, Inc., n/k/a/ Janssen Pharmaceutica, Inc., n/k/a Janssen Pharmaceuticals, Inc., Johnson & Johnson, Inc, AbbVie, Inc., Allergan plc f/k/a Actavis plc, Watson Pharmaceuticals, Inc. n/k/a Actavis, Inc., Watson Laboratories, Inc., Actavis LLC, Actavis Pharma, Inc. f/k/a/ Watson Pharma, Inc., KVK-Tech, Inc., Viatris, Inc. f/k/a Mylan N.V., Assertio Holdings, Inc., AmerisourceBergen Corporation, Cardinal Health, Inc., McKesson Corporation, CVS Health Corporation, CVS Indiana L.L.C., CVS Rx Services, Inc., CVS TN Distribution, LLC, CVS Pharmacy, Inc., Holiday CVS, LLC, Omnicare Distribution Center LLC, Walgreens Boots Alliance, Inc., a/k/a Walgreen Co., Walgreen Eastern Co., Inc., Walmart Inc., f/k/a Wal-Mart Stores, Inc., Wal-Mart Stores East, LP, WSE Management, LLC, WSE Investment, LLC, Wal-Mart Stores East, Inc.,** **Defendants.**	**Civil Action No. _____** **MDL 2804** **Judge Dan Aaron Polster** **CLASS ACTION COMPLAINT AND JURY REQUEST**

CLASS ACTION COMPLAINT AND JURY REQUEST

I. INTRODUCTION.

1. American public schools perform an indispensable function central to the health of American democracy, by providing free education to every student who comes through their doors. For the last two decades, in addition to providing this essential and challenging governmental function, public schools have been shouldering perhaps the most profound and

enduring consequences of the nationwide opioid epidemic. Children who are exposed to opioids *in utero* frequently develop cognitive and behavioral disabilities as a result, and they require extra interventions and supports throughout their education. Children living in households battling opioid addiction and children addicted to opioids require special education interventions as well. Public schools are, in turn, required to provide special education and related services to multiple generations of children born with prenatal opioid exposure and children exposed to opioid addiction.

2. Because of Defendants' horrific wrongdoing, which created the worst man-made epidemic in history, births of children with prenatal opioid exposure have increased exponentially since the onslaught of the opioid epidemic, and they show no signs of slowing down. As a result, our nation's public schools will be saddled with the extra costs of education of children with prenatal opioid exposure and postnatal opioid exposure for years to come.

3. The opioid crisis has had a particularly profound effect on women, who are more likely than men to suffer from chronic pain, and who receive prescriptions for pain relievers in higher doses and use them for longer periods of time.[1] Women may become more dependent on prescription pain relievers more quickly than men.[2] Prescription pain reliever overdose deaths among women increased more than 400% from 1999 to 2010, compared to 237% among men.[3] The rates of Neonatal Opioid Withdrawal Syndrome ("NOWS"), often referred to as Neonatal Abstinence Syndrome ("NAS"), which occurs when a baby is born addicted to opioids as a result

[1] *Opioid Addiction 2016 Facts & Figures,* American Society of Addiction Medicine, https://www.asam.org/docs/default-source/advocacy/opioid-addiction-disease-facts-figures.pdf.
[2] *Id.*
[3] *Id.*

of use by the mother during pregnancy, have also increased dramatically.[4] Nationally, the cost of treating NOWS increased from $61 million in 2003 to nearly $316 million in 2012.[5]

4. Plaintiff brings this action on behalf of itself and a state class of all independent public school districts in Florida. Plaintiff and the proposed Class bear the steadily rising costs of providing special education and related services to children who were exposed to opioid use *in utero*, making them more than twice as likely to exhibit learning and developmental disabilities than children who were not,[6] to children damaged by living in households afflicted by opioids, and to children addicted to opioids.

5. Plaintiff and the proposed Class are often the first to identify a student in crisis and the first point of contact for the students who need support in the face of crisis. Plaintiff and the proposed Class have also borne costs including, but no limited to, providing resources to teachers and administrators who are on the front lines helping students, and by providing specialized health and/or counseling programs for opioid-affected students.

6. Even if the opioid crisis were abated today, Plaintiff and the proposed Class will incur considerable costs in the years to come as the current cohort of adversely-impacted children advance from lower school to high school with special needs all along the way.

7. Plaintiff and the proposed Class also bear opioid-related costs associated with their workers' and their families' health expenses and insurance, including their workers' and

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[4] Hannah Rappleye et al., *Born Addicted: The Number of Opioid-Addicted Babies is Soaring*, NBC News, Oct. 9, 2017, https://www.nbcnews.com/storyline/americas-heroin-epidemic/born-addicted-number-opioid-addicted-babies-soaring-n806346. *Dramatic Increases in Maternal Opioid Use and Neonatal Abstinence Syndrome*, Nat'l Inst. on Drug Abuse, https://www.drugabuse.gov/related-topics/trends-statistics/infographics/dramatic-increases-in-maternal-opioid-use-neonatal-abstinence-syndrome (last updated Sept. 2015).

[5] T.E. Corr & C.S. Hollenbeak, *The economic burden of neonatal abstinence syndrome in the United States*, 112 Addiction 1590 (Sept. 2017), *at* https://onlinelibrary.wiley.com/doi/abs/10.1111/add.13842.

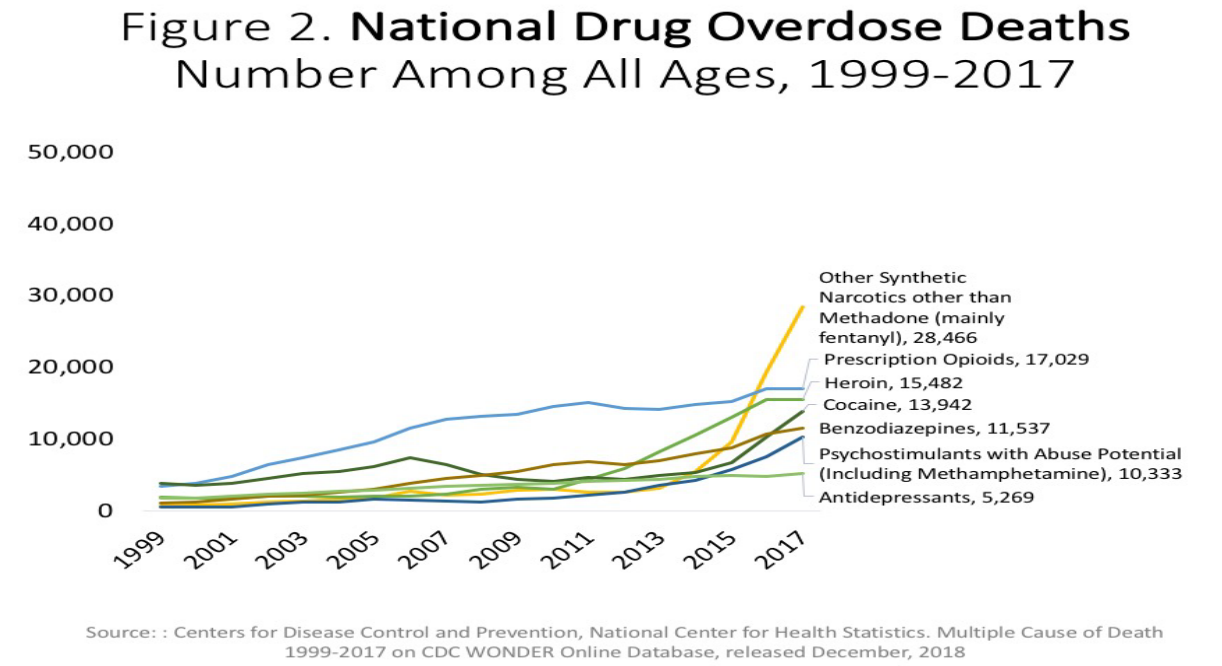
[6] Paul Morgan & Yangyang Wang, *The Opioid Epidemic, Neonatal Abstinence Syndrome, and Estimated Costs for Special Education Services*, 25 American Journal of Managed Care 13 (2019).

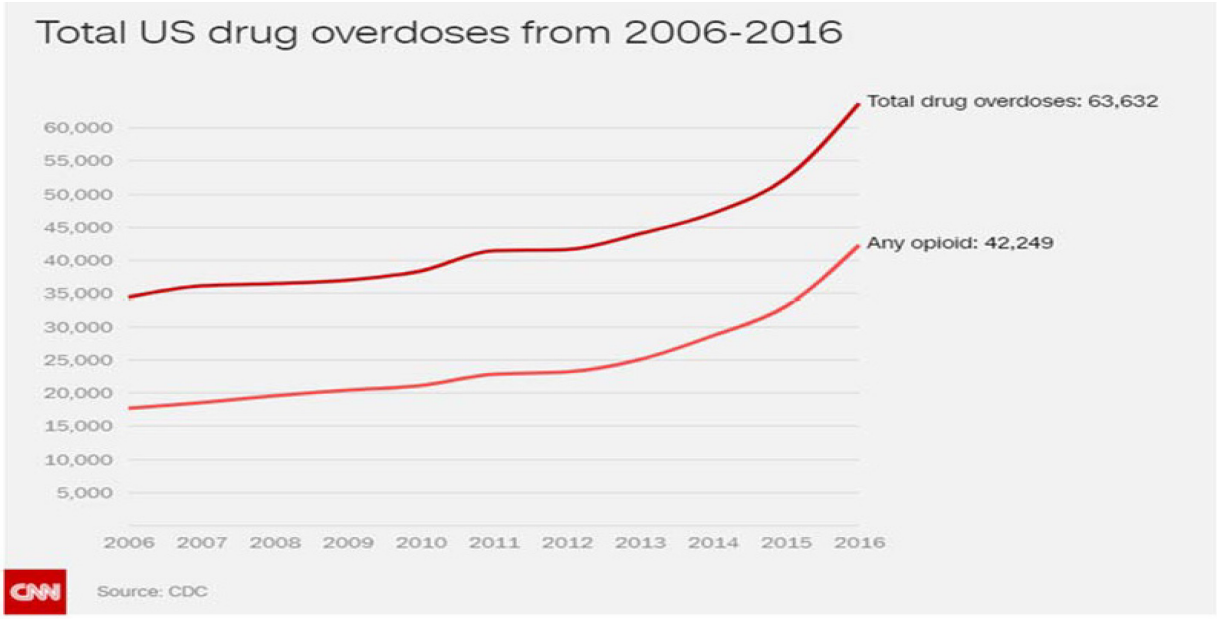
their families' increased use of prescription opioids, and the treatments required as a result of their workers' and their families' opioid addictions, including treatment for overdoses and leaves of absences.

8. Public health officials have called the current opioid epidemic the worst drug crisis in American history.[7] On October 26, 2017, the President of the United States declared it a public health emergency. That year, opioid overdoses were responsible for more than 47,000 American deaths, and around 1.7 million people suffered from addiction related to prescription opioids.[8] According to recent estimates, as many as 130 people in the United States die every day from opioid overdoses, with as many as 35% of fatal overdoses involving prescription opioids.[9]

[7] Julie Bosman, *Inside a Killer Drug Epidemic: A Look at America's Opioid Crisis*, N.Y. Times (Jan. 6, 2017), https://www.nytimes.com/2017/01/06/us/opioid-crisis-epidemic.html.
[8] *Opioid Overdose Crisis*, NIH: National Institute on Drug Abuse (Jan. 2019), https://www.drugabuse.gov/drugs-abuse/opioids/opioid-overdose-crisis#one.
[9] *Id.* Overdose Deaths Involving Prescription Opioids, Centers for Disease Control and Prevention, https://www.cdc.gov/drugoverdose/data/prescribing/overdose-death-maps.html (last visited May 5, 2022).

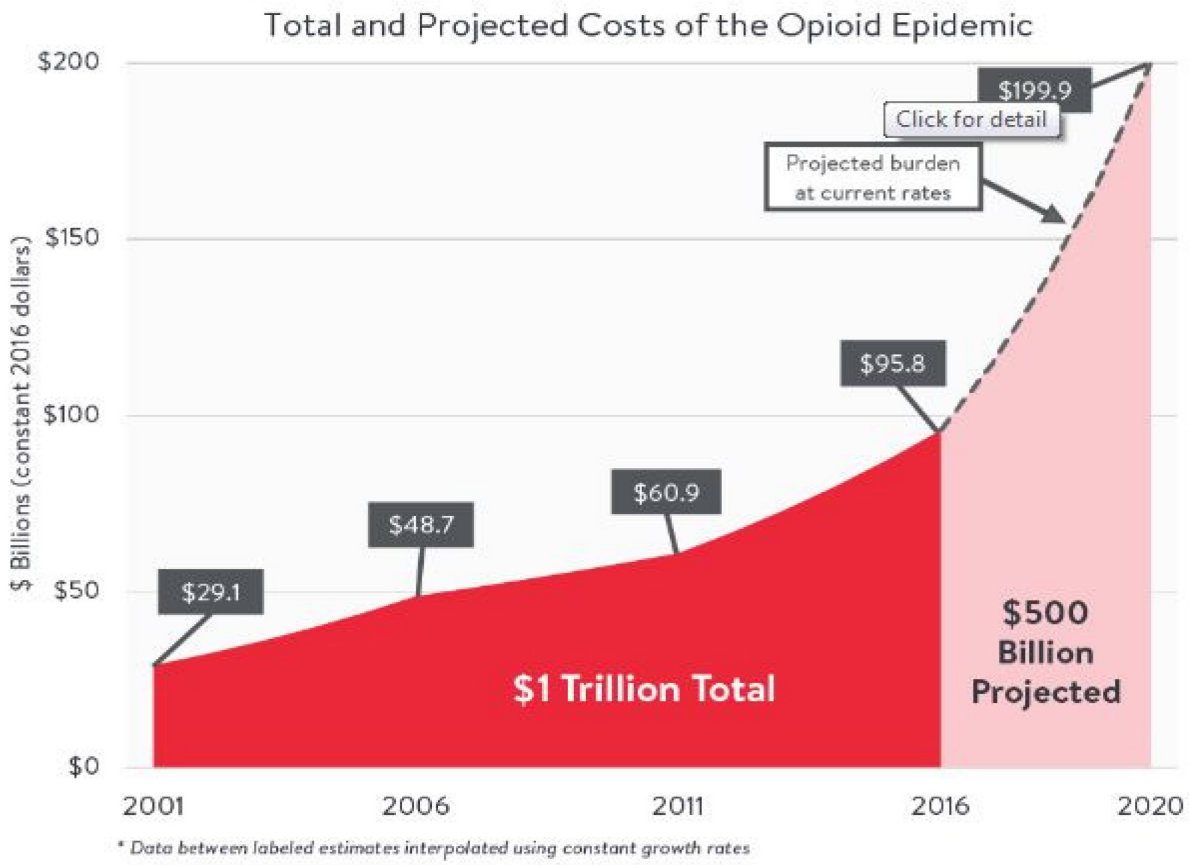
9. The following charts illustrate the rise of opioid-related overdose deaths in the United States:[10]





[10] *Overdose Death Rates*, National Institute of Drug Abuse, https://www.drugabuse.gov/related-topics/trends-statistics/overdose-death-rates (hereinafter, "*Overdose Death Rates*") (last visited May 5, 2022). *Opioids now kill more people than breast cancer*, CNN (Dec. 21, 2017), https://wtvr.com/2017/12/21/opioids-now-kill-more-people-than-breast-cancer/.

10. The opioid crisis and related expenses continue to grow. According to a report issued on February 13, 2018, by Altarum, a nonprofit health systems research and consulting organization, the cost of the country's opioid crisis is estimated to have exceeded $1 trillion from 2001 to 2017, and was projected to have cost an additional $500 billion by 2020:[11]



[11] *Economic Toll Of Opioid Crisis In U.S. Exceeded $1 Trillion Since 2001*, Altarum (Feb. 13, 2018), https://altarum.org/news/economic-toll-opioid-crisis-us-exceeded-1-trillion-2001.

11. According to a Centers for Disease Control and Prevention ("CDC") report issued in March 2018, hospital emergency room visits for opioid overdoses rose 30% nationwide between July 2016 and September 2017. Over the same period, emergency room visits for opioid overdoses in large cities increased by 54%:

12. Drug manufacturers' deceptive marketing and sale of opioids to treat chronic pain is a key driver of the opioid epidemic. Prescription opioids are powerful pain medications that historically have been used for short-term, post-surgical and trauma-related pain, and for palliative end-of-life care primarily in cancer patients. Because opioids are highly addictive and dangerous, the U.S. Food and Drug Administration ("FDA") regulates them as Schedule II Controlled Substances, a classification reserved for drugs that have a high potential for abuse and that may lead to severe psychological or physical dependence.

13. This demonstrated need for caution reflects the historical understanding of both the medical community and American culture at large about the serious consequences of opioid

use and misuse. Opioids' powerful ability to relieve pain comes at a steep price; opioids are dangerously addictive and often lethal substances. For generations, physicians were taught that opioid painkillers were highly addictive and should be used sparingly and primarily for patients near death.[12] The medical community also understood that opioids were poorly suited for long-term use because tolerance would require escalating doses, and dependence would make it extremely difficult to stop their use.

14. The prevailing and accurate understanding of the enormous risks and limited benefits of long-term opioid use constrained drug manufacturers' ability to drive sales. In order to suppress reasonable concerns about opioids and to maximize profits, opioid manufacturers, Defendants Janssen, Endo, Cephalon, Actavis, KVK, Viatris, and Assertio (individually defined in §II (B) and hereinafter collectively referred to as the "Manufacturer Defendants") and non-joined manufacturers Insys, Mallinckrodt, and Purdue and its owners, the Sacklers,[13] engaged in a concerted, coordinated strategy to recast how doctors and patients think about pain and, specifically, to encourage the use of opioids to treat not just the relative few who suffer from such things as acute post-surgical pain and end-stage cancer pain, but the masses who suffer from common chronic pain conditions.

15. Borrowing from the tobacco industry's playbook, the Manufacturer Defendants and the non-joined manufacturers employed ingenious marketing strategies, as detailed below, designed to "reeducate" the public and prescribers. They deliberately conceived these strategies to create, and in fact, did create, an entirely new "health care" narrative – one in which opioids

[12] Harriet Ryan et al., *OxyContin goes global –"We're only just getting started*," L.A. Times (Dec. 18, 2016), http://www.latimes.com/projects/la-me-oxycontin-part3/ (hereinafter, "Ryan, *OxyContin goes global*").

[13] Purdue, Mallinckrodt, and Insys entities are not joined as defendants due to bankruptcy filings. Under the Purdue bankruptcy stay, the Sacklers are also currently prevented from being joined as defendants.

would be considered safe and effective for long-term use, and pain would be aggressively treated at all costs. According to this newly fabricated narrative, pain had been seriously under-treated throughout the United States because opioids were under-prescribed, and doctors came under enormous pressure to treat all kinds of pain with opioids.

16. The Manufacturer Defendants' and non-joined manufacturers' intention was to normalize aggressively prescribing opioids for many kinds of pain that had been treated without opioids by downplaying the very real and serious risks of opioids, especially the risk of addiction, and by misstating and exaggerating the benefits of their use. To accomplish this goal, they intentionally misled doctors and patients about the appropriate uses, risks, safety, and efficacy of prescription opioids. They did so directly through sales representatives and marketing materials and indirectly through financial relationships with academic physicians, professional societies, hospitals, trade associations for state medical boards, and seemingly neutral third-party foundations.

17. False messages about the safety, addictiveness, and efficacy of opioids were disseminated by infiltrating professional medical societies and crafting and influencing industry guidelines to disseminate false and deceptive pro-opioid information under the guise of science and truth. According to a February 2018 report issued by U.S. Senator Claire McCaskill, opioid manufacturers, including several of the Manufacturer Defendants, paid nearly $9 million to advocacy groups and professional societies operating in the area of opioids policy between 2012 and 2017.[14] The opioid manufacturers got their money's worth:

[14] *Fueling an Epidemic, Report Two: Exposing the Financial Ties Between Opioid Manufacturers and Third-Party Advocacy Groups*, U.S. Senate Homeland Security & Governmental Affairs Committee, Ranking Member's Office at 1 (Feb. 13, 2018), https://www.hsgac.senate.gov/imo/media/doc/REPORT-Fueling%20an%20EpidemicExposing%20the%20Financial%20Ties%20Between%20Opioid%20Manufacturers%20and%20Third%20Party%20Advocacy%20Groups.pdf (hereinafter, "*February 2018 McCaskill Report*").

> Initiatives ***from the groups in this report often echoed and amplified messages favorable to increased opioid use*** – and ultimately, the financial interests of opioid manufacturers. ***These groups have issued guidelines and policies minimizing the risk of opioid addiction and promoting opioids*** for chronic pain, lobbied to change laws directed at curbing opioid use, and argued against accountability for physicians and industry executives responsible for overprescription and misbranding.[15]

18. When, in 2016, the CDC recommended limits on prescribing opioids for chronic pain, the purportedly neutral medical societies also strongly criticized those guidelines. Based on that and other similar conduct, the *February 2018 McCaskill Report* concluded there was "a direct link between corporate donations and the advancement of opioids-friendly messaging."

19. The Manufacturer Defendants and non-joined manufacturers falsely assured the public and prescribers that the risk of becoming addicted to prescription opioids among patients being treated for pain was less than 1%. In reality, many people with no addiction history can become addicted after just weeks or even days of use.[16] As many as 56% of patients receiving long-term prescription opioid painkillers become addicted.[17] Indeed, almost one in five people who receive an opioid prescription with a ten days' supply will still be taking opioids one year later.[18]

20. The Manufacturer Defendants' and non-joined manufacturers' focus on driving opioid sales growth led to concomitant growth both in the deaths resulting from opioid use and in hospital admissions for opioid-related addiction treatment:[19]

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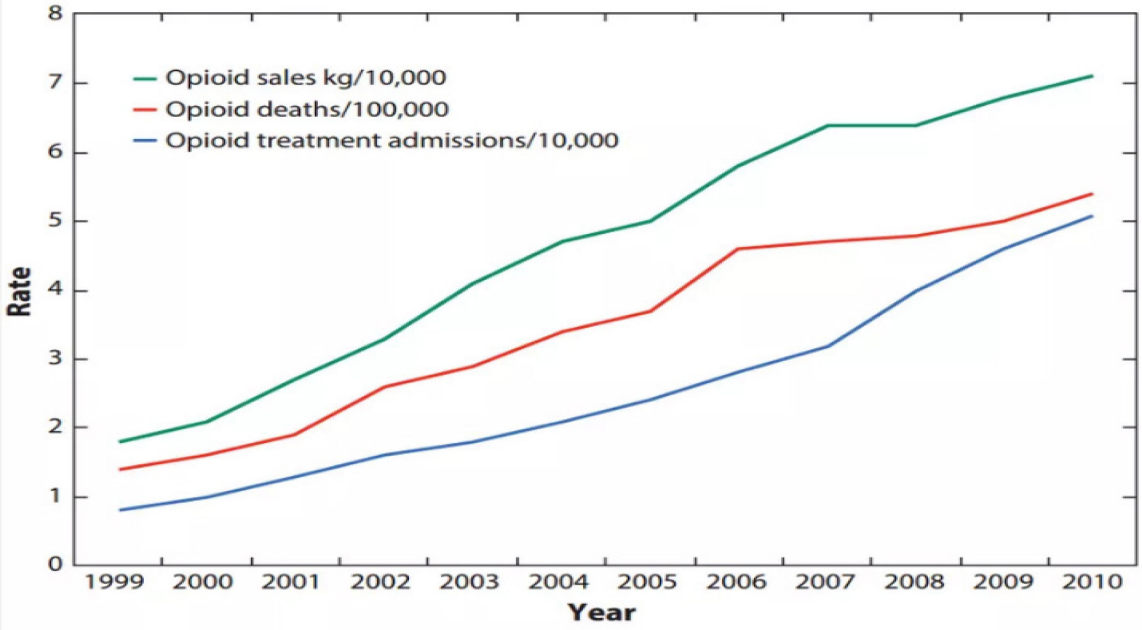
[15] Emphasis is added throughout unless otherwise noted.
[16] Anna Lembke, *Drug Dealer, MD: How Doctors Were Duped, Patients Got Hooked, and Why It's So Hard to Stop*, 22 (Johns Hopkins University Press 2016) (hereinafter, "Lembke (2016)").
[17] Bridget A. Martell et al., *Systematic Review: Opioid Treatment for Chronic Back Pain: Prevalence, Efficacy, and Association with Addiction*, 146(2) Ann. Intern. Med. 116-27 (2007), http://annals.org/aim/article/732048/systematic-review-opioid-treatment-chronic-back-painprevalence-efficacy-association (hereinafter, "Martell, *Systematic Review*").
[18] Sarah Frostenson, *The risk of a single 5-day opioid prescription, in one chart*, Vox (Mar. 18, 20107, 7:30 AM), www.vox.com/2017/3/18/14954626/one-simple-way-to-curb-opioidoveruse-prescribe-them-for-3-days-or-less.
[19] Andrew Kolodny et al., *The Prescription Opioid and Heroin Crisis: A Public Health*



Put simply, they manipulated and misrepresented medical science to increase sales and profits—at great human cost.

21. In a study published on March 6, 2018, in the *Journal of the American Medical Association* ("*JAMA*"),[20] researchers conducting the first randomized clinical trial designed to compare the efficacy of opioids and non-opioids (including acetaminophen, ibuprofen, and lidocaine) for the treatment of moderate to severe back pain, hip pain, and knee osteoarthritis pain concluded that patients who took opioids over the long term experienced no better improvement in pain-related function than patients who used safer alternatives.

22. Defendants McKesson, Cardinal Health, and AmerisourceBergen (individually defined in §II (D) and collectively referred herein as the "Distributor Defendants") are major

Approach to an Epidemic of Addiction, 36 Annu. Rev. Public Health 559-74 (2015), http://www.annualreviews.org/doi/pdf/10.1146/annurev-publhealth-031914-122957.

[20] Erin E. Krebs et al., *Effect of Opioid vs. Nonopioid Medications on Pain-Related Function in Patients with Chronic Back Pain or Hip or Knee Osteoarthritis Pain, The SPACE Randomized Clinical Trial*, 319(9) JAMA 872-82 (2018) (hereinafter, "Krebs, *Effect of Opioid vs. Nonopioid Medications*").

distributors of controlled substances, acting as middlemen between drug manufacturers and pharmacies. Like the Manufacturer Defendants, the Distributor Defendants were also aware of a growing epidemic of addiction to, and abuse of, the prescription opioids they supplied. The Manufacturer Defendants and the Distributor Defendants were aware of the quantities and frequency with which those drugs were distributed nationwide. Yet, both the Manufacturer Defendants and the Distributor Defendants persisted in failing to report suspicious sales as required by state and federal law. Their failures to follow the law significantly contributed to rising addiction and overdose rates nationwide.

23. Released data on the sale of prescription pain pills shows the full extent of Defendants' scheme to saturate the market with opioid medications. The Drug Enforcement Administration ("DEA") tracks the manufacturing and distribution of oxycodone and hydrocodone pills, which represent 75% of all opioid pill shipments distributed to pharmacies.[21] Between 2006 and 2014, that percentage translates to more than 12 billion prescription opioid pills.

24. Distributor Defendants were key players in the spread of opioid pain relievers, responsible for 44% of the nation's supply of prescription pain pills.

25. The production and distribution of massive quantities of prescription opioid pills was not an accident. Defendants' decision to ignore red flags, and their consistent failure to report suspicious orders, created a market flooded with prescription opioids. From 2006 to 2012, the volume of opioid pills handled by the 10 largest companies increased by 51%. During this

[21] The following statistics are available through the *Washington Post*'s interactive DEA pain pill database. *Drilling into the DEA's pain pill database,* The Washington Post (Updated July 21, 2019), https://www.washingtonpost.com/graphics/2019/investigations/dea-pain-pill-database/.

time, there were 36 opioid pills for every person in the country, and nationwide sales of prescription opioid pain pills increased from $6.1 billion to $8.5 billion.[22]

26. The country's major opioid distributors have paid hefty fines for their respective failures to report suspicious orders of opioids as required by law. Defendant McKesson, the largest prescription drug wholesale company in the United States, agreed on January 17, 2017, to pay a $150 million fine to the federal government. In December 2016, Defendant Cardinal Health reached a $44 million settlement with the federal government.[23] As of 2019, corporations have paid almost $500 million in fines to the Justice Department for "failing to report and prevent suspicious [opioid] drug orders."[24]

27. These fines, however, are dwarfed by Defendants' profits from their scheme. According to *Fortune* magazine, Distributor Defendants are each among the top 15 companies in the Fortune 500.

28. The impact of opioid addiction has devastated the nation. Former FDA Commissioner David A. Kessler has called the failure to recognize the dangers of painkillers "one of the greatest mistakes of modern medicine." As alleged herein, that "mistake" was not a mistake at all. Instead, it directly resulted in large part from the Manufacturer Defendants' and non-joined manufacturers' false and misleading messaging, which was carefully calculated to

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[22] Scott Higham et al., *76 billion opioid pills: Newly released federal data unmasks the epidemic*, The Washington Post (July 16, 2019), https://www.washingtonpost.com/investigations/76-billion-opioid-pills-newly-released-federal-data-unmasks-the-epidemic/2019/07/16/5f29fd62-a73e-11e9-86dd-d7f0e60391e9_story.html (hereinafter, "Higham et al., *76 billion opioid pills*").

[23] Nate Raymond, *McKesson to pay $37 million to resolve West Virginia opioid lawsuit*, Reuters (May 2, 2019), https://www.reuters.com/article/us-usa-opioids-litigation/mckesson-to-pay-37-million-to-resolve-west-virginia-opioid-lawsuit-idUSKCN1S81HO; Press Release, U.S. Department of Justice, Cardinal Health Agrees to $44 Million Settlement for Alleged Violations of Controlled Substances Act (Dec. 23, 2016), https://www.justice.gov/usao-md/pr/cardinalhealth-agrees-44-million-settlement-alleged-violations-controlled-substances-act.

[24] Higham et al., *76 billion opioid pills, supra* n.22.

reach as many prescribers as possible, as well as their willingness to turn a blind eye to suspicious orders.

29. Even when some defendants were forced to admit the unlawful marketing and sale of opioids and/or the failure to report suspicious orders, the conduct did not abate because profits realized by the aggressive marketing and prescribing of opioids dwarf the penalties imposed as a result of violations found. The fines were absorbed as part of the overhead for engaging in this lawless and immoral behavior as the incentive to push opioids remained.

30. While great attention has been paid to the strain placed on states and local governments for their vast public health expenditures to respond to the opioid epidemic, the astounding harm caused to our nation's public schools has gone largely unnoticed. Children born with opioid exposure *in utero* are tragic victims of the opioid epidemic, and they suffer from a host of developmental and behavioral problems for the rest of their lives. Children exposed to family members' addiction to or death from opioids suffer from developmental and behavioral problems as well, as do children addicted to opiods. Public schools are tasked with finding the resources to provide special support and education to these children.

31. Public schools are also the country's largest public employer, and most provide health insurance and other benefits to their employees. Thus, public schools have footed the bills for their employees' prescription opioids—including those prescribed inappropriately—and for the resulting healthcare costs, including addiction treatment and workers' compensation.

II. PARTIES.

A. Plaintiff.

32. Plaintiff brings this civil action against Defendants on behalf of itself and other similarly situated independent public school districts in Florida to recoup monies they have spent because of Defendants' actions and inactions and to abate the effects caused to Florida public

schools from the opioid epidemic caused by the Defendants.

33. Putnam County School Board, for the Putnam County School District, is located at 200 Reid Street, Palatka, FL 32177.

34. Plaintiff directly and foreseeably sustained all economic damages alleged herein. Defendants' conduct has exacted a financial burden for which Plaintiff seeks relief. Plaintiff's past and continuing damages sustained include, and will continue to include, but are not limited to: (1) costs associated with special education and related programs, including special programs for children with learning disabilities related to *in utero* opioid exposure; (2) costs associated with providing special education and related services to children damaged by living in households afflicted by opioids; (3) costs associated with providing special education and related services for children addicted to opioids; (4) costs associated with increased school security in all facilities of the school district; (5) costs for providing medical care, additional therapeutic and prescription drug purchases, and other treatments for covered school district employees and family members suffering from opioid-related addiction or disease, including overdoses; (6) costs associated with increased healthcare and healthcare insurance for school district employees and their families; and (7) costs of disability payments. These damages have been suffered and continue to be suffered directly by Plaintiff.

35. Plaintiff seeks the means to abate the damages caused to Florida independent public school districts by Defendants' wrongful and unlawful conduct.

B. Manufacturer Defendants

36. Defendant Cephalon, Inc. is a Delaware corporation with its headquarters and principal place of business in Frazer, Pennsylvania. In October 2011, Cephalon, Inc. was acquired by Defendant Teva Pharmaceutical Industries Ltd. ("Teva Ltd."), which is incorporated

under the laws of Israel, with its principal place of business in Petah Tikva, Israel. Since Defendant Teva Ltd. acquired Cephalon, Inc., its United States sales and marketing activities have been conducted by Defendant Teva Pharmaceuticals USA, Inc. ("Teva USA"), a wholly-owned operating subsidiary of Teva Ltd. Teva USA's headquarters and principal place of business are in North Wales, Pennsylvania. Defendant Cephalon, Inc. and the above-named entities are collectively referred to herein as "Cephalon," and manufactured, marketed and sold opioids in the United States and Florida.

37. Defendant Endo International plc is an Irish public limited company with its headquarters in Dublin, Ireland. Defendant Endo Health Solutions Inc. is a Delaware corporation with its headquarters and principal place of business in Malvern, Pennsylvania. Defendant Endo Pharmaceuticals Inc. is also a Delaware corporation with its headquarters and principal place of business in Malvern, Pennsylvania. Endo Pharmaceuticals Inc. is an indirectly, wholly-owned subsidiary of Endo International plc. Endo International plc and Endo Health Solutions Inc., are collectively referred to herein as "Endo."

38. Defendant Janssen Pharmaceuticals, Inc. ("Janssen")—which was formerly known as Ortho-McNeil-Janssen Pharmaceuticals, Inc., which, in turn, was formerly known as Janssen Pharmaceutica, Inc.—is a Pennsylvania corporation headquartered in Titusville, New Jersey, and Raritan, New Jersey. Janssen is a wholly-owned subsidiary of Johnson & Johnson, Inc.

39. Defendant Johnson & Johnson, Inc. is a New Jersey corporation that is headquartered in New Brunswick, New Jersey.

40. Defendant Allergan plc is a public limited company incorporated in Ireland with its principal place of business in Dublin, Ireland. Actavis plc acquired Allergan plc in 2015, and

the combined company changed its name to Allergan plc. Defendant Actavis, Inc. was acquired by Defendant Watson Pharmaceuticals, Inc. in October 2012, and the combined company changed its name to Actavis, Inc. as of January 2013, and then to Actavis plc in October 2013.

41. Defendant Watson Laboratories, Inc. is a Nevada corporation with its principal place of business in Corona, California, and is a wholly-owned subsidiary of Allergan plc (f/k/a Actavis, Inc. f/k/a Watson Pharmaceuticals, Inc.).

42. Defendant Actavis Pharma, Inc. is a Delaware corporation with its principal place of business in New Jersey and was formerly known as Watson Pharma, Inc.

43. Defendant Actavis LLC is a Delaware limited liability company with its principal place of business in Parsippany, New Jersey.

44. Each of the Defendants and entities in paragraphs 41-44 was owned by Defendant Allergan plc, which used them to market and sell its drugs, including opioids, in the United States and Florida. Defendant AbbVie, Inc. is a Delaware biopharmaceutical corporation with its principal place of business in North Chicago, Illinois, and is the owner of Allergan, plc. These Defendants and entities are collectively referred to herein as "Actavis."

45. Defendant KVK-Tech, Inc. ("KVK") is a pharmaceutical company of generic and specialty drugs founded in 2004. Its principal place of business is in Newton, Pennsylvania. At all times relevant to this Complaint, KVK manufactured, marketed, and distributed opioids that were sold in the United States and Florida.

46. In November 2020, Viatris, Inc. ("Viatris") was created by a merger of Mylan N.V., and its subsidiaries, with Upjohn. Defendant Viatris' principal place of business is 1000 Mylan Boulevard, Canonsburg, Pennsylvania, 15317, which is with one of its three "global centers. Mylan N.V., with its numerous wholly-owned subsidiaries including Mylan

Laboratories Inc., Mylan Technologies, Inc., and Mylan Institutional, Inc. (hereinafter collectively referred to as "Mylan") was a global generic and specialty pharmaceuticals company which developed, licensed, manufactured, marketed and distributed generic specialty pharmaceuticals, including opioids, nationwide and in Florida. Mylan N.V. group's global headquarters was in Canonsburg, Pennsylvania.

47. Defendant Assertio Holdings, Inc. ("Assertio") is the successor pharmaceutical corporation of Assertio Therapeutics, Inc. after Assertio Therapeutics, Inc. merged with Zyla Life Sciences in May 2020. Defendant Assertio Holdings, Inc. is headquartered in Lake Forest, Illinois, just as Assertio Therapeutics, Inc. was. On August 14, 2018, Assertio Therapeutics, Inc. became the new name of Depomed, Inc. ("Depomed"), an American pharmaceutical manufacturer of pain and neurological drugs, including opioids, marketed, distributed and sold nationwide and in Florida, that had been headquartered in Newark, California. In addition, Depomed also acquired the opioid franchise (Nucynta) from Defendants Johnson & Johnson and Janssen for 1.05 billion dollars.

C. Distributor Defendants

48. Defendant AmerisourceBergen Corporation ("AmerisourceBergen") is a Delaware corporation with its headquarters and principal place of business in Chesterbrook, Pennsylvania.

49. Defendant Cardinal Health, Inc. ("Cardinal Health") is an Ohio corporation with its headquarters and principal place of business in Dublin, Ohio.

50. Defendant McKesson Corporation ("McKesson") is a Delaware corporation with its headquarters and principal place of business in San Francisco, California.

D. National Retail Pharmacy Defendants

a) CVS

51. Defendant CVS Health Corporation ("CVS Health") is a Delaware corporation with its principal place of business in Rhode Island. Through its various DEA registrant subsidiaries and affiliated entities, CVS Health conducts business as a licensed wholesale distributor and pharmacy operator. At all times relevant to this Complaint, CVS Health distributed prescription opioids throughout the United States, including Florida.

52. Defendant CVS Indiana LLC is an Indiana limited liability company with its principal place of business in Indianapolis, Indiana. Defendant CVS Rx Services, Inc. is a New York corporation with its principal place of business in Chemung, New York. Defendant CVS TN Distribution, LLC is a Tennessee corporation with its principal place of business in Knoxville, Tennessee.

53. Defendant CVS Pharmacy, Inc. is a Rhode Island corporation with its principal place of business in Woonsocket, Rhode Island. CVS Pharmacy, Inc. is a wholly-owned subsidiary of CVS Health. Defendant CVS Pharmacy, Inc. is both a DEA registered "distributor"[25] and a DEA registered "dispenser"[26] of prescription opioids.

54. Defendant Holiday CVS, LLC is a Florida limited liability corporation with its principal place of business also in Woonsocket, Rhode Island, the same address as Defendant CVS Pharmacy, Inc., which owns 100% of Holiday CVS, Inc. On December 20, 2005, 200 additional individual Florida CVS pharmacies merged into Holiday CVS, Inc.

55. Defendant Omnicare Distribution Center LLC is a Delaware corporation with its principal place of business in Ohio. Omnicare Distribution Center LLC, a CVS Health company,

[25] 21 U.S.C. § 802(11) and § 822(a)(1).
[26] 21 U.S.C. § 802(1) and § 822(a)(2).

portrays itself as an industry leading long-term care pharmacy services provider focused on supporting assisted living community residents.

56. Defendants CVS Health Corporation; CVS Indiana LLC.; CVS Rx Services, Inc.; CVS TN Distribution, LLC; CVS Pharmacy, Inc.; Holiday CVS, Inc. and Omnicare Distribution Center, LLC are collectively referred to as "CVS." CVS conducts business as a licensed wholesale distributor and dispenser. At all times relevant to this Complaint, CVS distributed and/or dispensed prescription opioids throughout the United States, including in Florida, where it operates 883 pharmacies.

b) Walgreens

57. Defendant Walgreen Co., an Illinois corporation with its principal place of business at 200 Wilmot Rd.; Deerfield, Illinois 60015 acted as a retail pharmacy in the United States until Walgreen Co. completed the acquisition of Alliance Boots, a British pharmacy giant, in 2014. After this acquisition, the company simply became Walgreens Boots Alliance, Inc. However, Walgreen Co. continues to this day as a registered for-profit corporation doing business in Florida.

58. Defendant Walgreens Boots Alliance, Inc. is a Delaware corporation with its principal place of business also at 200 Wilmot Rd.; Deerfield, Illinois 60015. Walgreens Boots Alliance, Inc. describes itself as the successor of Walgreen Co.

59. Defendant Walgreen Eastern Co., Inc. is a New York corporation with its principal place of business also at 200 Wilmot Rd.; Deerfield, Illinois 60015 and is a registered for-profit corporation doing business in Florida. Walgreen Eastern Co., Inc. is a subsidiary of Walgreens Boots Alliance, Inc.

60. Defendants Walgreens Boots Alliance, Inc.; Walgreen Co.; and Walgreen Eastern Co., Inc. are collectively referred to as "Walgreens."

61. Through its various DEA registrant subsidiaries and affiliated entities, Walgreens conducted and conducts business as a licensed wholesale distributor and pharmacy operator. At all times relevant to this Complaint, Walgreens distributed and sold prescription opioids throughout the United States, including in Florida, where it operates 816 pharmacies.

c) Walmart

62. Defendant Walmart Inc., formerly known as Wal-Mart Stores, Inc., is a Delaware corporation with its principal place of business in Bentonville, Arkansas.

63. Defendant Wal-Mart Stores East, LP is a Delaware limited partnership with its principal place of business in Arkansas.

64. Defendant WSE Management, LLC, is a Delaware limited liability company and owns 1% of Wal-Mart Stores East, LP.

65. Defendant WSE Investment, LLC, is a Delaware limited liability company, and owns 99% of Wal-Mart Stores East, LP.

66. The sole owner of both WSE Management, LLC and WSE Investment, LLC is Wal-Mart Stores East Inc., an Arkansas corporation.

67. The sole shareholder of Wal-Mart Stores East, Inc. is Walmart Inc., f/k/a Wal-Mart Stores, Inc.

68. Defendants Walmart Inc., f/k/a Wal-Mart Stores, Inc.; Wal-Mart Stores East, LP; WSE Management, LLC; WSE Investment, LLC; and Wal-Mart Stores East, Inc. are collectively referred to as "Walmart."

69. Through its various DEA registrant subsidiaries and affiliated entities, Walmart conducts business as a licensed wholesale distributor and pharmacy operator. At all times relevant to this Complaint, Walmart distributed and sold prescription opioids throughout the United States, including in Florida where it operates 341 pharmacies.

70. Collectively, Defendants CVS, Walgreens, and Walmart are referred to as "National Retail Pharmacy Defendants."

III. JURISDICTION AND VENUE

71. This Court has subject matter jurisdiction pursuant to 28 U.S.C. §1331, based on Defendants' violations of federal law, specifically 18 U.S.C. §1961, *et seq.* ("Racketeer Influenced and Corrupt Organizations Act" or "RICO"), 18 U.S.C. §1965 pertaining to RICO jurisdiction, and 28 U.S.C. §1332(d) because: (a) this action is brought as a proposed class action under Fed. R. Civ. P. 23; (b) at least one member of the class is a citizen of a state different from at least one Defendant; (c) the amount in controversy exceeds $5 million exclusive of interest and costs; (d) the proposed class contains more than 100 members; and (e) no relevant exceptions apply. This Court also has supplemental jurisdiction over the state law claims set forth below pursuant to 28 U.S.C. §1367 because those state law claims are so related to Plaintiff's federal claims that they form part of the same case or controversy.

72. The U.S. District Court for the Northern District of Ohio has personal jurisdiction over Defendants, because they conduct business in Ohio, purposefully direct or directed their actions toward Ohio, as well as Florida, and have the requisite minimum contacts with Ohio necessary to constitutionally permit this Court to exercise jurisdiction. This Court also has personal jurisdiction over all Defendants under 18 U.S.C. §1965(b). This Court may exercise nationwide jurisdiction over the named Defendants where the "ends of justice" require national service, and Plaintiff demonstrates national contacts. Here, the interests of justice require that

Plaintiff be allowed to bring all members of the opioid enterprise before this Court in a single trial.

73. Venue in the Northern District of Ohio is proper, as various Defendants herein conduct business in this judicial district, conducted the same business activities described herein in this judicial district, and various actions and/or inactions sued upon also affected this judicial district. 18 U.S.C. §1965(a); 28 U.S.C. §1391(b)(2).

IV. FURTHER FACTUAL ALLEGATIONS

A. Prescription Opioids

74. The term opioid refers to (a) all drugs derived in whole or in part from the morphine-containing opium poppy plant such as morphine, laudanum, codeine, thebaine, hydrocodone, oxycodone, and oxymorphone, and (b) synthetic opioids like fentanyl or methadone.

75. Opioids are derived from or possess properties similar to opium and heroin and are highly addictive, dangerous, and therefore are regulated by the federal government as controlled substances.

76. Since passage of the Controlled Substances Act ("CSA") in 1970, 21 U.S.C. §801, *et seq*., controlled substances have been categorized in five schedules, ranked in order of their potential for abuse, with Schedule I being the highest.[27] Opioids are generally categorized as Schedule II or Schedule III drugs. Schedule II drugs have "a high potential for abuse," and "may lead to severe psychological or physical dependence."[28] Schedule II drugs may not be dispensed without an original copy of a manually signed prescription, which may not be refilled,

[27] Schedule I drugs are defined by the CSA as drugs with no currently accepted medical use and a high potential for abuse.
[28] 21 U.S.C. § 812(b)(2).

from a doctor and filled by a pharmacist who both must be licensed by their state and registered with the DEA.[29] The labels for scheduled opioid drugs carry black box warnings of potential addiction, abuse, and misuse, including "[s]erious, life-threatening, or fatal respiratory depression." [30]

77. When under the continuous influence of opioids over time, patients grow tolerant to their analgesic effects. As tolerance increases, a patient typically requires progressively higher doses to obtain the same levels of pain reduction to which he has become accustomed –including doses that are "frighteningly high."[31] At higher doses, the effects of withdrawal are more substantial, thus leaving a patient at a much higher risk of addiction. A patient can take the opioids at the continuously escalating dosages to match pain tolerance and still overdose at recommended levels. Studies on opioid use have demonstrated a correlation between high opioid dosage and poor physical function, as well as worsened overall general health.[32] Opioid use also delays injury recovery and increases the risk of permanent disability. In a study of Workers Compensation claims for lower back pain, increasing a patient's opioid dosage was found to correlate with an increased risk of disability compared to non-opioid users.[33] Another study showed that prescribing opioids within six weeks of an injury *doubled* the risks of disability one

[29] 21 U.S.C. § 829.
[30] *See, e.g.*, March 22, 2016, Required Safety Labeling Language for Immediate Release Opioids, FDA, https://www.fda.gov/downloads/Drugs/DrugSafety/InformationbyDrugClass/UCM491594.pdf.
[31] M. Katz, *Long-term Opioid Treatment of Nonmalignant Pain: A Believer Loses His Faith*, 170 ARCHIVES OF INTERNAL MED. 1422 (2010).
[32] Kathryn Sullivan Dillie, et al., *Quality of Life Associated With Daily Opioid Therapy in a Primary Care Chronic Pain Sample*, 21 J. of the Am. Bd. of Fam. Med. 108 (2008).
[33] Id., *The Psychological and Physical Side Effects of Pain Medications*, Nat. Safety Council (2016) (citing Barbara S. Webster, et al., *Relationship Between Early Opioid Prescribing for Acute Occupation Low Back Pain and Disability Duration, Medical Costs, Subsequent Surgery, and Late Opioid Use*, 32 Spine 2127 (Sept. 2007)).

year later.[34] Likewise, studies on opioid use prior to back surgery show poorer outcomes for patients—including increased pain, decreased function, and increased depression.[35]

78. Stopping opioids after more than just a few weeks of therapy will cause most patients to experience withdrawal symptoms. These withdrawal symptoms include severe anxiety, nausea, vomiting, headaches, agitation, insomnia, tremors, hallucinations, delirium, pain, and other serious symptoms, all of which may persist for months after a complete withdrawal from opioids, depending on how long the opioids were used.

79. During much of the latter half of the 20th century, doctors used opioid pain relievers sparingly, and only in the short term, for cases of acute injury or illness, during and immediately after surgery, or for palliative cancer and end-of-life care.

80. Beginning in the late 20th century, however, and continuing through today, the Manufacturer Defendants and the non-joined manufacturers acted to dramatically expand the marketplace for opioids. The market for short-term pain relief is significantly more limited than the market for long-term chronic pain relief. They recognized that if they could sell opioids, not just for short-term pain relief but also for long-term chronic pain relief, they could achieve blockbuster levels of sales and dramatically increase their profits. They also recognized that if they could cause their customers to become physically addicted to their drugs, they would increase the likelihood that their blockbuster profits would continue indefinitely.

[34] Id., *supra* n.38, (citing Gary M. Franklin, et al., *Early Opioid Prescription and Subsequent Disability Among Workers With Back Injuries: the Disability Risk Identification Study Cohort*, 33 Spine 199 (2008)).
[35] Teater, *supra* n.38, (citing Sheyan J. Armaghani, et al., *Preoperative Opioid Use as a Predictor of Adverse Postoperative Self-Reported Outcomes in Patients Undergoing Spine Surgery*, 96 J. Bone & Joint Surgery (American) e89 (2014)).

B. Over the Course of More Than Two Decades, the Manufacturer Defendants and the Non-Joined Manufacturers Misled the Public Regarding the Dangers of Opioid Addiction and the Efficacy of Opioids for Long-Term Use, Causing Sales and Overdose Rates to Soar.

81. Since the mid-90s the Manufacturer Defendants and non-joined manufacturers have aggressively marketed and falsely promoted liberal opioid prescribing as presenting little to no risk of addiction, even when used long term for chronic pain. They infiltrated academic medicine and regulatory agencies to convince doctors that treating chronic pain with long-term opioids was evidence-based medicine when, in fact, they knew it was not. Huge profits resulted from these efforts, as did the present addiction and overdose crisis that has ravaged the nation.

1. Background on Opioid Overprescribing

82. The Manufacturer Defendants' and non-joined manufacturers' scheme to drive their rapid and dramatic expansion of prescription opioids was rooted in two pieces of so-called "evidence." The first was the publication of a five-sentence, 100-word letter to the editor published in 1980 in the *New England Journal of Medicine* ("1980 Letter to the Editor").[36]

> [W]e found that a five-sentence letter published in the *Journal* in 1980 was heavily and uncritically cited as evidence that addiction was rare with long-term opioid therapy. We believe that this citation pattern contributed to the North

[36] This very brief Letter to the Editor by Jane Porter ("Porter") and Dr. Herschel Jick ("Jick"), reported that less than 1% of patients at Boston University Medical Center who received narcotics while hospitalized became addicted. Jane Porter & Hershel Jick, *Addiction rate in patients treated with narcotics*, 302(2) New Eng. J. Med. 123 (Jan. 10, 1980). However, the letter did not support the conclusion that opioids were safe for long-term treatment of chronic pain, the conclusion for which it was often cited by the industry. Harrison Jacobs, *This one-paragraph letter was used to launch the opioid epidemic*, Bus. Insider (May 26, 2016), http://www.businessinsider.com/porter-and-jick-letter-launched-the-opioid-epidemic-2016-5. As discussed in a 2009 article in the *American Journal of Public Health*, the 1980 Letter to the Editor "shed[] some light on the risk of addiction for acute pain, [but did] not help establish the risk of iatrogenic addiction when opioids are used daily for a prolonged time in treating chronic pain. [Indeed, t]here are a number of studies . . . that demonstrate that in the treatment of chronic non-cancer-related pain with opioids, there is a high incidence of prescription drug abuse." Art Van Zee, *The Promotion and Marketing of OxyContin: Commercial Triumph, Public Health Tragedy*, 99(2) Am. J. Pub. Health 221-27 (Feb. 2009) (hereinafter, "Van Zee, *Promotion and Marketing*").

> American opioid crisis by helping to shape a narrative that allayed prescribers' concerns about the risk of addiction associated with long-term opioid therapy.[37]

83. The second piece of "evidence" was a single medical study published by Drs. Russell Portenoy ("Portenoy") and Kathleen Foley ("Foley") ("Portenoy Publication").[38] Portenoy emerged as one of the industry's most vocal proponents of long-term opioid use. He essentially made it his life's work to campaign for the movement to increase the use of prescription opioids. He was one of Big Pharma's[39] "thought leaders" and was paid to travel the country to promote more liberal opioid prescribing for many types of pain. His talks were sponsored by the Manufacturer Defendants and organizations funded by them and non-joined manufacturers, under the guise of continuing medical education ("CME") programs for doctors. Portenoy was a paid propagandist for Big Pharma, with financial relationships with at least a dozen pharmaceutical companies, most of which produced prescription opioids.[40]

84. On November 1, 2017, the President's Commission on Combating Drug Addiction and the Opioid Crisis noted the important and detrimental role played by the 1980

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[37] German Lopez, *A 5-sentence letter helped trigger America's deadliest drug overdose crisis ever,* Vox (June 1, 2017), https://www.vox.com/science-and-health/2017/6/1/15723034/opioidepidemic- letter-1980-study.

[38] In 1986, the medical journal *Pain*, which would eventually become the official journal of the American Pain Society ("APS"), published an article by Portenoy and Foley summarizing the results of a "study" of 38 chronic non-cancer pain patients who had been treated with opioid painkillers. Portenoy and Foley concluded that, for non-cancer pain, opioids "can be safely and effectively prescribed to selected patients with relatively little risk of producing the maladaptive behaviors which define opioid abuse." However, their study was neither scientific nor did it meet the rigorous standards commonly used to evaluate the validity and strength of such studies in the medical community. For instance, there was no placebo control group, and the results were retroactive (asking patients to describe prior experiences with opioid treatment rather than less biased, in-the-moment reports). The authors themselves advised caution, stating that the drugs should be used as an "alternative therapy" and recognizing that longer-term studies of patients on opioids would have to be performed. None were. *See* Lembke (2016), supra n.16.

[39] "Big Pharma" is used herein to refer to large pharmaceutical companies, including, but not limited to, Manufacturer Defendants and non-joined manufacturers, considered especially as a politically influential group.

[40] Lembke (2016), *supra* n.16, at 59 (citing Barry Meier, *Pain Killer: A "Wonder" Drug's Trail of Addiction and Death* (St. Martin's Press, 1st ed. 2003)).

Letter to the Editor and the Portenoy Publication, in a section of the Commission's Report with the header "Contributors to the Current Crisis."[41]

85. Portenoy has now admitted that he intentionally minimized the risks of opioids.[42] In a 2011 interview released by Physicians for Responsible Opioid Prescribing, Portenoy stated that his earlier work purposefully relied on evidence that was not "real" and left real evidence behind:

> I gave so many lectures to primary care audiences in which the Porter and Jick article was just one piece of data that I would then cite, and I would cite six, seven, maybe ten different avenues of thought or avenues of evidence, ***none of which represented real evidence***, and yet what I was trying to do was to create a narrative so that the primary care audience would look at this information in [total] and feel more comfortable about opioids in a way they hadn't before. ***In essence this was education to destigmatize [opioids], and because the primary goal was to destigmatize, we often left evidence behind***.[43]

86. The damage, however, was already done. The Manufacturer Defendants and non-joined manufacturers used the 1980 Letter to the Editor and the Portenoy Publication as the foundation for a massive, far-reaching campaign to dramatically recast the thinking of healthcare providers, patients, policymakers and the public on the risk of addiction presented by opioid therapy. By 1997, the American Pain Society ("APS") and the American Academy of Pain Medicine ("AAPM") (both funded by the Manufacturer Defendants and non-joined manufacturers) issued a "landmark consensus," co-authored by Portenoy, stating that there was little risk of addiction or overdose for pain patients.[44]

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[41] *The President's Commission on Combating Drug Addiction and the Opioid Crisis* at 20 (Nov. 1, 2017), https://www.whitehouse.gov/sites/whitehouse.gov/files/images/Final_Report_Draft_11-1-2017.pdf.
[42] Celine Gounder, *Who Is Responsible for the Pain-Pill Epidemic?*, New Yorker (Nov. 8, 2013), http://www.newyorker.com/business/currency/who-is-responsible-for-the-pain-pill-epidemic (hereinafter, "Gounder, *Who Is Responsible*").
[43] Jacobs, *One-paragraph letter*, *supra* n.35; Andrew Kolodny, *Opioids for Chronic Pain: Addiction is NOT Rare*, YouTube (10/30/11), https://www.youtube.com/watch?v=DgyuBWN9D4w&feature=youtu.be
[44] Jacobs, *One-paragraph letter, supra* n.35.

87. In the years following publication of the 1980 Letter to the Editor and the Portenoy Publication, the Manufacturer Defendants introduced powerful prescription opioids into the market. Defendant Janssen introduced Duragesic in 1990, and Defendant Cephalon's Actiq was first approved by the FDA in 1998. More recently, Defendant Endo's Opana and Opana ER were approved by the FDA in 2006, as were Defendant Janssen's Nucynta in 2008 and Nucynta ER in 2011, and Defendant Cephalon's Fentora in 2006.

88. These branded prescription opioids and their generic counterparts are highly addictive. Between doses, patients can suffer body aches, nausea, sweats, racing heart, hypertension, insomnia, anxiety, agitation, opioid cravings, opioid-induced hyperalgesia (heightened sensitivity to pain) and other symptoms of withdrawal. When the agony is relieved by the next dose, it creates a cycle of dysphoria and euphoria that fosters addiction and dependence.

89. Despite prescription opioids' highly addictive qualities, the Manufacturer Defendants and non-joined manufacturers launched aggressive pro-opioid marketing efforts that caused a dramatic shift in the public's and prescribers' perception of the safety and efficacy of opioids for chronic long-term pain and everyday use. Contrary to what doctors had understood before about opioid risks and benefits, they were encouraged for the last two decades by the Manufacturer Defendants and non-joined manufacturers to prescribe opioids aggressively, and were assured, based on false evidence provided directly by the Manufacturer Defendants, non-joined manufacturers, numerous medical entities funded by them, and others with financial interests in generating more opioid prescriptions, that: (a) the risk of becoming addicted to prescription opioids among patients being treated for pain was low, even under 1%; and (b) great

harm was caused by "undertreated pain." These two foundational falsehoods led directly to the current opioid crisis.

90. The Manufacturer Defendants' and non-joined manufacturers' strategy was a striking marketing success. It was designed to redefine back pain, neck pain, headaches, arthritis, fibromyalgia, and other common conditions suffered by most of the population at some point in their lives as a single malady – chronic pain – that doctors and patients should take seriously and for which opioids were an appropriate, successful, and low-risk treatment. Indeed, studies now show more than 85% of patients taking OxyContin at common doses are doing so for chronic non-cancer pain.[45]

91. This false and misleading marketing strategy continued despite studies revealing that up to 56% of patients receiving long-term prescription opioid painkillers for chronic back pain progress to addictive opioid use, including patients with no history of addiction.[46]

92. Thus, based on false and incomplete evidence, the Manufacturer Defendants and non-joined manufacturers expanded their market exponentially from patients with end-stage cancer and acute pain, a narrow customer base, to anyone suffering from chronic pain, which by some accounts includes approximately 100 million Americans – nearly one-third of the country's population.[47] The treatment of chronic pain includes patients whose general health is good enough to refill prescriptions month after month, year after year, and the promotion, distribution (without reporting suspicious sales) and rampant sale of opioids for such treatment has made

[45] Ryan, *OxyContin goes global*, *supra* n.12.
[46] Lembke (2016), *supra* n.16, at 22 (citing Martell, *Systematic Review*, *supra* n.17); see also Krebs, *Effect of Opioid vs. Nonopioid Medications*, *supra* n.20 (describing JAMA study that concluded opioids were not superior to non-steroidal anti-inflammatory drugs ("NSAIDs") like ibuprofen to treat long-term pain).
[47] *AAPM Facts and Figures on Pain*, The American Academy of Pain Medicine, https://painmed.org/about/position-statements/use-of-opioids-for-the-treatment-of-chronic-pain (last visited Sept. 19, 2019).

Defendants billions of dollars. It has also led to the prevalence of opioid addiction and the overdose crisis nationwide.

2. The Fraudulent Sales Practices.

93. As set forth below, the Manufacturer Defendants and non-joined manufacturers employed various strategies to normalize the use of opioids for chronic long-term pain without informing the public and prescribers about the very significant risks of addiction, overdose, and death.

3. Manufacturer Defendants and Non-Joined Manufacturers Funded Front Organizations that Published and Disseminated False and Misleading Marketing Materials.

94. Certain Manufacturer Defendants sponsored purportedly neutral medical boards and foundations that educated doctors and set guidelines for the use of opioids in medical treatment to promote the liberal prescribing of opioids for chronic pain for benefit of all the Manufacturer Defendants. These organizations, funded by certain Manufacturer Defendants, advised doctors that liberal prescribing of opioids was both safe and effective. In truth, it was neither.

95. **Federation of State Medical Boards**: The Federation of State Medical Boards ("FSMB") is a national organization that functions as a trade group representing the 70 medical and osteopathic boards in the United States. The FSMB often develops guidelines that serve as the basis for model policies with the stated goal of improving medical practice. The Sacklers, through Purdue, as well as Defendant Cephalon and Defendant Endo have provided substantial funding to the FSMB.

96. In 2007, the FSMB printed and distributed a physician's guide on the use of opioids to treat chronic pain titled, "Responsible Opioid Prescribing" by Dr. Scott M. Fishman

("Fishman"). After the guide (in the form of a book, still available for sale on Amazon) was adopted as a model policy, the FSMB reportedly asked Purdue for $100,000 to help pay for printing and distribution. Ultimately, the guide was disseminated by the FSMB to 700,000 practicing doctors.

97. The guide's clear purpose is to focus prescribers on the purported under-treatment of pain and falsely assure them that opioid therapy is an appropriate treatment for chronic, non-cancer pain. It contains lies such as *"Opioid therapy to relieve pain and improve function is a legitimate medical practice for* acute and *chronic pain of* both cancer and *non-cancer origins*."[48]

98. While it acknowledges the risk of "abuse and diversion" (with little attention to addiction), the guide purports to offer "professional guidelines" that will "easily and efficiently" allow physicians to manage that risk and "minimize the potential for [such] abuse."[49]

99. The guide further warns physicians to "[b]e aware of the distinction between pseudoaddiction and addiction" and teaches that behaviors such as "[r]equesting [drugs] by name," "[d]emanding or manipulative behavior," "[o]btaining opioid drugs from more than one physician" and "[h]oarding opioids," which are, in fact, signs of genuine addiction, are all really just signs of "pseudoaddiction."[50] It defines "Physical Dependence" as an acceptable result of opioid therapy not to be equated with addiction, and it states that while "[i]t may be tempting to assume that patients with chronic pain and a history of recreational drug use who are not adherent to a treatment regimen are abusing medications," there could be other acceptable reasons for non-adherence.[51] The guide, sponsored by the Manufacturer Defendants, non-joined

[48] Scott M. Fishman, *Responsible Opioid Prescribing: A Physician's Guide* 8-9 (Waterford Life Sciences 2007).
[49] *Id.* at 9.
[50] *Id*. at 62.
[51] *Id*.

manufacturers, and their pain foundations, became the seminal authority on opioid prescribing for the medical profession and dramatically overstated the safety and efficacy of opioids and understated the risk of opioid addiction.

100. In 2012, Fishman updated the guide and continued emphasizing the "catastrophic" "under-treatment" of pain and the "crisis" such under-treatment created:

> Given the magnitude of the problems related to opioid analgesics, it can be tempting to resort to draconian solutions: clinicians may simply stop prescribing opioids, or legislation intended to improve pharmacovigilance may inadvertently curtail patient access to care. As we work to reduce diversion and misuse of prescription opioids, *it's critical to remember that the problem of unrelieved pain remains as urgent as ever*.[52]

101. In another guide by Fishman, he continues to downplay the risk of addiction: "I believe clinicians must be very careful with the label 'addict.' I draw a distinction between a 'chemical coper' and an addict."[53] The guide also continues to present symptoms of addiction as symptoms of "pseudoaddiction."

102. The heightened focus on the under-treatment of pain was a concept designed by Manufacturer Defendants and non-joined manufacturers to sell opioids. *The FSMB actually issued a report calling on medical boards to punish doctors for inadequately treating pain*.[54] Among the drafters of this policy was Dr. J. David Haddox ("Haddox"), who coined the term "pseudoaddiction," a term which lacked any scientific basis but quickly became a common way for the Manufacturer Defendants, and non-joined manufacturers and their allies to promote the use of opioids even to patients displaying addiction symptoms. Haddox became a Purdue vice

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[52] Scott M. Fishman, *Responsible Opioid Prescribing: A Clinician's Guide* 10-11 (Waterford Life Sciences 2012).
[53] Scott M. Fishman, Listening to Pain: A Physician's Guide to Improving Pain Management Through Better Communication 45 (Oxford Univ. Press 2012).
[54] Thomas Catan & Evan Perez, *A Pain-Drug Champion Has Second Thoughts*, Wall St. J., Dec. 17, 2012, at A1.

president who likened OxyContin to a vegetable, stating at a 2003 conference at Columbia University,[55] "If I gave you a stalk of celery and you ate that, it would be healthy. But if you put it in a blender and tried to shoot it into your veins, it would not be good."[56]

103. In 2012 and again in 2017, the guides and the sources of their funding became the subject of a Senate investigation.

104. On June 8, 2012, the FSMB submitted a letter to the U.S. Senate Committee on Finance ("Senate Finance Committee") concerning its investigation into the abuse and misuse of opioids.[57] While the letter acknowledged the escalation of both drug abuse and deaths resulting from prescription painkillers, the FSMB continued to focus on the "serious and related problem" that "[m]illions of Americans suffer from debilitating pain – a condition that, for some, can be relieved through the use of opioids." Among other things, the letter stated that "[s]tudies have concluded that both acute pain and chronic pain are often under-treated in the United States, creating serious repercussions that include the loss of productivity and quality of life." The letter cited no such studies. The letter also confirmed that the FSMB's "Responsible Opioid Prescribing: A Physician's Guide" had been distributed in all 50 states and the District of Columbia.

105. In addition, the FSMB letter disclosed payments the FSMB had received from organizations that develop, manufacture, produce, market, or promote the use of opioid-based drugs for decades from 1997. In the payments received were those from Defendant Endo and Defendant Cephalon.

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[55] Gounder, *Who Is Responsible*, *supra* n.42.
[56] Patrick Radden Keefe, *The Family that Built an Empire of Pain*, The New Yorker (Oct. 30, 2017).
[57] June 8, 2012 Letter from Federation of State Medical Boards to U.S. Senators Max Baucus and Charles Grassley, https://assets.documentcloud.org/documents/3109089/FSMB-Response-Letter-to-US-Senate.pdf.

106. The letter also disclosed payments of $40,000 by Defendant Endo to directly fund the production of "Responsible Opioid Prescribing" and revealed that sales of "Responsible Opioid Prescribing" had generated more than $2.75 million in revenues in California alone.[58]

107. **The Joint Commission**: The Joint Commission is an organization that establishes standards for treatment and accredits healthcare organizations in the United States. Manufacturer Defendants and the Sacklers through Purdue, contributed misleading and groundless teaching materials and videos to the Joint Commission, which emphasized what Big Pharma coined the "under-treatment of pain," referenced pain as the "fifth vital sign" (the first and only unmeasurable/subjective "vital sign") that must be monitored and treated, and encouraged the use of prescription opioids for chronic pain while minimizing the dangers of addiction. It also called doctors' concerns about addiction "inaccurate and exaggerated."

108. In 2000, the Joint Commission printed a book for purchase by doctors as part of required continuing education seminars that cited studies, claiming "*there is no evidence that addiction is a significant issue when persons are given opioids for pain control*." The book was sponsored by Purdue.

109. In 2001, the Joint Commission and the National Pharmaceutical Council (founded in 1953 and supported by the nation's major research-based biopharmaceutical companies[59]) collaborated to issue a 101-page monograph titled, "Pain: Current understanding of assessment, management, and treatments." The monograph states falsely that beliefs about opioids being addictive are "erroneous."[60]

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[58] *Id*. at 15.
[59] Funded by Johnson & Johnson, Purdue, and Teva, among others.
[60] National Pharmaceutical Council, Inc., *Pain: Current Understanding of Assessment, Management, and Treatments* at 16-17 (Dec. 2001), http://www.npcnow.org/system/files/research/download/Pain-Current-Understanding-of-Assessment-Management-and-Treatments.pdf (footnotes and citations omitted).

110. The Manufacturer Defendants' and non-joined manufacturers' infiltration and influence over the Joint Commission's standards and literature exerted overwhelming pressure on doctors to treat and eliminate pain. As more and more doctors migrated from private practice to integrated healthcare systems in the 2000s, treatment options were dictated by, among other things, the Joint Commission's guidelines.[61] Consistent with the Joint Commission's guidelines, doctors who left pain untreated were viewed as demonstrating poor clinical skills and/or being morally compromised.[62]

111. **The American Pain Foundation**: The American Pain Foundation ("APF"), described itself as the nation's largest organization for pain patients.[63] While APF held itself out as an independent patient advocacy organization, in reality it received 90% of its funding in 2010 from the drug and medical-device industry, including from Defendant Endo, Defendant Janssen, and Defendant Cephalon. It received more than $10 million in funding from opioid manufacturers from 2007 to 2012, when it shut down days after the Senate Finance Committee launched an investigation of the APF's promotion of prescription opioids.

112. The APF's guides for patients, journalists, and policymakers trivialized the risk of addiction and greatly exaggerated the benefits associated with opioid painkillers.[64]

113. For example, in 2001, the APF published "Treatment Options: A Guide for People Living with Pain."[65] The guide, which was produced with support from companies

[61] *Id*. at 119.
[62] *Id*. at 42.
[63] The APF was the focus of a December investigation by ProPublica in the *Washington Post* that detailed its close ties to drugmakers.
[64] Charles Ornstein & Tracy Weber, *American Pain Foundation Shuts Down as Senators Launch Investigation of Prescription Narcotics*, ProPublica (May 8, 2012, 8:57 PM), https://www.propublica.org/article/senate-panel-investigates-drug-company-ties-to-pain-groups/ (hereinafter, "Ornstein, *American Pain Foundation*").
[65] *Treatment Options: A Guide for People Living with Pain*, American Pain Foundation, https://assets.documentcloud.org/documents/277605/apf-treatmentoptions.pdf (last visited May 5, 2022).

including Defendant Cephalon and Purdue, misrepresented the risks associated with opioid use. Among other things, the guide:

- lamented that opioids were sometimes called narcotics because "*[c]alling opioid analgesics 'narcotics' reinforces myths and misunderstandings* as it places emphasis on their potential abuse rather than on the importance of their use as pain medicines";[66]
- stated that "[o]pioids are an essential option for treating *moderate* to severe pain associated with surgery or trauma";[67] and
- opined that "[r]estricting access to the most effective medications for treating pain [opioids] is not the solution to drug abuse or addiction."[68]

The guide included blurbs from Portenoy, who is quoted as saying, "[t]his is a very good resource for the pain patient," and Fishman, who is quoted as saying, "[w]hat a great job! Finally, a pill consumer resource created for patients with pain. A 'must have' for every physician's waiting room."[69]

114. In 2009, Defendant Endo sponsored the APF's publication and distribution of "Exit Wounds: A Survival Guide to Pain Management for Returning Veterans & Their Families" ("Exit Wounds"). Among other false statements, Exit Wounds reported: "Long experience with opioids shows that *people who are not predisposed to addiction are very unlikely to become addicted to opioid pain medications*."[70] Defendant Endo, through the APF, thus distributed false information to provide veterans false information they could use to self-advocate for opioids while omitting a discussion of the risks associated with opioid use.

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[66] *Id*. at 11.
[67] *Id*.
[68] *Id*. at 15.
[69] *Id.* at 76.
[70] Derek McGinnis, *Exit Wounds: A Survival Guide to Pain Management for Returning Veterans and Their Families*, American Pain Foundation (2009), p. 107.

115. In 2009, the APF played a central role in a first-of-its-kind, web-based series called, "Let's Talk Pain," hosted by veteran television journalist Carol Martin. The series brought together healthcare providers and "people with pain to discuss a host of issues from managing health care for pain to exploring integrative treatment approaches to addressing the psychological aspects associated with pain." The "Let's Talk Pain" talk show is still available online. In the very first episode of this talk show, the following exchange took place:

> [**Teresa Shaffer (APF Action Network Leader)**:] As a person who has been living with pain for over 20 years, opioids are a big part of my pain treatment. And I have been hearing such negative things about opioids and the risk factors of opioids. Could you talk with me a little bit about that?
>
> [**Dr. Al Anderson (AAPM Board of Directors)**:] The general belief system in the public is that the opioids are a bad thing to be giving a patient. Unfortunately, it's also prevalent in the medical profession, so patients have difficulty finding a doctor *when they are suffering from pain for a long period of time*, especially *moderate* to severe pain. And *that's the patients that we really need to use the opioids* methods of treatment, because they are the ones who need to have some help with the function and they're the ones that need to have their pain controlled enough so that they can increase their quality of life.[71]

116. In reality, there is little scientific evidence to support the contention that opioids taken long-term improve function or quality of life for chronic pain patients.[72] To the contrary, the evidence shows that opioids impose significant risks and adverse outcomes on long-term users and that they may actually reduce function.[73] As a recent article in the *New England*

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[71] *Episode 1: Safe Use of Opioids (PainSAFE)*, Let's Talk Pain (Sept. 28, 2010), https://www.youtube.com/watch?v=zeAlVAMRgsk.

[72] Lembke (2016), supra n.16 at 59.

[73] Discussing the CDC's "March 2016 Guidelines for Prescribing Opioids for Chronic Pain," doctors wrote:

> Most placebo-controlled, randomized trials of opioids have lasted 6 weeks or less, and we are aware of no study that has compared opioid therapy with other treatments in terms of long-term (more than 1 year) outcomes related to pain, function, or qualify of life. The few randomized trials to evaluate opioid efficacy for longer than 6 weeks had consistently poor results. In fact, several studies have showed that use of opioids for chronic pain may actually worsen pain and functioning, possibly by potentiating pain perception.

Journal of Medicine concluded: "Although opioid analgesics rapidly relieve many types of acute pain and improve function, the benefits of opioids when prescribed for chronic pain are much more questionable." The article continues, "opioid analgesics are widely diverted and improperly used, and the widespread use of the drugs has resulted in a national epidemic of opioid overdose deaths and addictions."[74] More recently still, a study published in *JAMA* concluded that "[t]reatment with opioids was not superior to treatment with nonopioid medications for improving pain-related function over 12 months."[75]

117. The APF also developed the National Initiative on Pain Control ("NIPC"), which ran a facially unaffiliated website, www.painknowledge.org. NIPC promoted itself as an education initiative and promoted its expert leadership team, including purported experts in the pain management field. The website www.painknowledge.org promised that, on opioids "your level of function should improve; you may find you are now able to participate in activities of daily living, such as work and hobbies, that you were not able to enjoy when your pain was worse." Elsewhere, the website touted improved quality of life as a benefit of opioid therapy. In a brochure available on www.painknowledge.org titled, "Pain: Opioid Facts," the NIPC misleadingly stated that "people who have no history of drug abuse, including tobacco, and use their opioid medication as directed will probably not become addicted" and even refused to rule out the use of opioid pain relievers for patients who have a history of addiction to opioids.[76]

Thomas R. Frieden & Debra Houry, *Reducing the Risks of Relief – The CDC Opioid-Prescribing Guidelines*, 374 New Eng. J. Med. 1501-04 (Apr. 21, 2016), https://www.nejm.org/doi/full/10.1056/NEJMp1515917.

[74] Nora D. Volkow & A. Thomas McLellan, Opioid Abuse in Chronic Pain – Misconceptions and Mitigation Strategies, 374 New Eng. J. Med. 1253-63 (Mar. 31, 2016).

[75] Krebs, *Effect of Opioid vs. Nonopioid Medications*, supra n. 20.

[76] *Pain: Opioid Facts*, Pain Knowledge (2007) https://web.archive.org/web/20101007102042/http://painknowledge.org/patiented/pdf/Patient%20Education%20b380_b385%20%20pf%20opiod.pdf (last visited Oct. 1, 2019).

118. In or around 2011, the APF published the "Policymaker's Guide," sponsored by Purdue, which dispelled the notion that "strong pain medication leads to addiction" by characterizing it as a "*common misconception*[]":

> *Many people living with pain, and even some health care practitioners, falsely believe that opioid pain medicines are universally addictive*. As with any medication, there are risks, but these risks can be managed when these medicines are properly prescribed and taken as directed. For more information about safety issues related to opioids and other pain therapies, visit http://www.painsafe.org.[77]

119. The guide further falsely asserts that "multiple clinical studies" have shown that opioids are effective in improving daily function, psychological health, and health-related quality of life for chronic-pain patients.[78]

120. In December 2011, the *Washington Post* reported on ProPublica's investigation of the APF, which detailed the APF's close ties to drugmakers:

> *The foundation collected nearly 90 percent of its $5 million in funding last year from the drug and medical-device industry – and closely mirrors its positions*, an examination by ProPublica found.[79]

121. **American Academy of Pain Medicine ("AAPM") and American Pain Society ("APS")**: The Manufacturer Defendants, including at least Defendant Endo and Defendant Janssen, have contributed funding to the AAPM and the APS for decades.

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[77] *A Policymaker's Guide to Understanding Pain & Its Management*, American Pain Foundation at 5 (Oct. 2011), https://assets.documentcloud.org/documents/277603/apf-policymakers-guide.pdf.

[78] The "Policymaker's Guide" cites for support "Opioids for chronic noncancer pain: a meta-analysis of effectiveness and side effects," a review published in 2006 in the *Canadian Medical Association Journal*. *Id*. at 34. However, the review concludes: "For functional outcomes, *the other analgesics were significantly more effective than were opioids*." Andrea D. Furlan et al., *Opioids for chronic noncancer pain: a meta-analysis of effectiveness and side effects*, 174(11) Canadian Med. Assoc. J. 1589-94 (May 23, 2006), https://www.ncbi.nlm.nih.gov/pmc/articles/PMC1459894/. The Purdue-sponsored guide failed to disclose both this conclusion and the fact that the review analyzed studies that lasted, on average, five weeks and therefore could not support the long-term use of opioids.

[79] Charles Ornstein & Tracy Weber, *Patient advocacy group funded by success of painkiller drugs, probe finds*, Wash. Post (Dec. 23, 2011), https://www.washingtonpost.com/national/health-science/patient-advocacy-group-funded-by-successof-painkiller-drugs-probe-finds/2011/12/20/gIQAgvczDP_story.html?utm_term=. 22049984c606.

122. In 1997, the AAPM issued a "consensus" statement that endorsed opioids to treat chronic pain and claimed that the risk that patients would become addicted to opioids was low. At the time, the chairman of the committee that issued the statement, Dr. J. David Haddox, was a paid speaker for Purdue. Haddox was later hired as Purdue's vice president for health policy. The consensus statement, which also formed the foundation of the AAPM's 1998 guidelines, was published on the AAPM's website. AAPM's corporate council included Depomed, Defendant Teva, and other pharmaceutical companies. AAPM's past presidents include Haddox (1998), Fishman (2005), Dr. Perry G. Fine ("Fine") (2011) and Lynn R. Webster ("Webster") (2013), all of whose connections to the opioid manufacturers are well documented.

123. At or about the same time, the APS introduced the "pain as the 5th vital sign" campaign, followed soon thereafter by the U.S. Department of Veterans Affairs incorporating that message as part of its national pain management strategy.

124. The AAPM and APS issued guidelines in 2009 ("2009 Guidelines") that continued to recommend the use of opioids to treat chronic pain. Fourteen of the twenty-one panel members who drafted the 2009 Guidelines received funding from Defendant Janssen, Defendant Cephalon, or Defendant Endo.

125. The 2009 Guidelines falsely promoted opioids as safe and effective for treating chronic pain and concluded that the risk of addiction was manageable for patients regardless of past abuse histories.[80] The 2009 Guidelines have been a particularly effective channel of deception and have influenced not only treating physicians but also the body of scientific evidence on opioids; they were reprinted in the journal *Pain*, have been cited hundreds of times

[80] Roger Chou et al., *Clinical Guidelines for the Use of Chronic Opioid Therapy in Chronic Noncancer Pain*, 10(2) J. Pain 113-30 (Feb. 2009), http://www.jpain.org/article/S1526-5900(08)00831-6/pdf (hereinafter, "Chou, *Clinical Guidelines*").

in the academic literature, and remain available online. The Manufacturer Defendants and non-joined manufacturers widely cited and promoted the 2009 Guidelines without disclosing the lack of evidence to support their conclusions.

126. **The Alliance for Patient Access**: Founded in 2006, the Alliance for Patient Access ("APA") is a self-described patient advocacy and health professional organization, which styles itself as "a national network of physicians dedicated to ensuring patient access to approved therapies and appropriate clinical care."[81] It is run by Woodberry Associates LLC, a lobbying firm also established in 2006.[82] As of June 2017, the APA listed 30 "Associate Members and Financial Supporters." The list included Defendant Johnson & Johnson, Defendant Endo, Defendant Cephalon, and Defendant Allergan.

127. APA's board members have also directly received substantial funding from pharmaceutical companies.[83] For instance, board vice president Dr. Srinivas Nalamachu ("Nalamachu"), who practices in Kansas, received more than $800,000 from 2013 through 2015 from pharmaceutical companies – nearly all of it from manufacturers of opioids or drugs that treat opioids' side-effects, including from Defendant Endo, Insys, Purdue and Defendant Cephalon. Nalamachu's clinic was raided by Federal Bureau of Investigation ("FBI") agents in connection with an investigation of Insys and its payment of kickbacks to physicians who

[81] *About AfPA*, The Alliance for Patient Access, http:// allianceforpatientaccess.org (last visited Dec. 14, 2018). References herein to APA include two affiliated groups: The Global Alliance for Patient Access and the Institute for Patient Access.
[82] Mary Chris Jaklevic, *Non-profit Alliance for Patient Access uses journalists and politicians to push Big Pharma's agenda*, Health News Review (Oct. 2, 2017), https://www.healthnewsreview.org/2017/10/non-profit-alliance-patient-access-uses-journalists-politicians-push-big-pharmas-agenda/ (hereinafter, "Jaklevic, *Non-profit Alliance for Patient Access*").
[83] All information concerning pharmaceutical company payments to doctors in this paragraph is from ProPublica's Dollars for Docs database, available at https://projects.propublica.org/docdollars/.

prescribed Subsys.[84] Other past and present board members have included Dr. Robert A. Yapundich from North Carolina, who received $215,000 from 2013 through 2015 from pharmaceutical companies, including payments by Defendant Cephalon and Mallinckrodt; Dr. Jack D. Schim from California, who received more than $240,000 between 2013 and 2015 from pharmaceutical companies, including Defendant Endo and Defendant Cephalon; Dr. Howard Hoffberg from Maryland, who received $153,000 between 2013 and 2015 from pharmaceutical companies, including Defendant Endo and Defendant Cephalon; and Dr. Robin K. Dore from California, who received $700,000 between 2013 and 2015 from pharmaceutical companies.

128. Among its activities, the APA issued a white paper titled, "Prescription Pain Medication: Preserving Patient Access While Curbing Abuse."[85] Among other things, the white paper criticizes prescription monitoring programs, purporting to express concern that they are burdensome, not user-friendly, unfair to physicians, and of questionable efficacy.[86]

129. The white paper also purports to express concern about policies that have been enacted in response to the prevalence of pill mills:

> Although well intentioned, many of the policies designed to address this problem have made it difficult for legitimate pain management centers to operate. For instance, in some states, [pain management centers] must be owned by physicians or professional corporations, must have a Board certified medical director, may need to pay for annual inspections, and are subject to increased record keeping and reporting requirements. . . .
>
> [I]t is not even certain that the regulations are helping prevent abuses.[87]

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[84] Andy Marso, *FBI seizes records of Overland Park pain doctor tied to Insys*, Kansas City Star (July 20, 2017), https://www.kansascity.com/news/business/health-care/article162569383.html.
[85] *Prescription Pain Medication: Preserving Patient Access While Curbing Abuse*, Institute for Patient Access (Oct. 2013), https://1yh21u3cjptv3xjder1dco9mx5s-wpengine.netdna-ssl.com/wp-content/uploads/2013/12/PT_White-Paper_Finala.pdf.
[86] *Id*. at 4-5 (footnote omitted).
[87] *Id*. at 5-6.

130. In addition, in an echo of earlier industry efforts to push back against what they termed "opiophobia," the white paper laments the stigma associated with prescribing and taking pain medication:

> Both pain patients and physicians can face negative perceptions and outright stigma. When patients with chronic pain can't get their prescriptions for pain medication filled at a pharmacy, they may feel like they are doing something wrong – or even criminal. . . . Physicians can face similar stigma from peers.[88]

131. In conclusion, the white paper states that "[p]rescription pain medications, and specifically the opioids, can provide substantial relief for people who are recovering from surgery, afflicted by chronic painful diseases, or experiencing pain associated with other conditions that does not adequately respond to over-the-counter drugs."[89]

132. ***Exposing the Financial Ties Between Opioid Manufacturers and Third-Party Groups***: A February 12, 2018, report, titled "Fueling an Epidemic Report Two: Exposing the Financial Ties Between Opioid Manufacturers and Third Party Advocacy Groups," issued by the U.S. Senate Homeland Security & Government Affairs Committee, Ranking Member Claire McCaskill's Office, helps clarify the financial connections between opioid manufacturers and purportedly neutral patient advocacy organizations and medical professional societies that, unsurprisingly, have "echoed and amplified messages favorable to increased opioid use – and ultimately the financial interests of opioid manufacturers."[90]

[88] *Id*. at 6.
[89] *Id*. at 7.
[90] *February 2018 McCaskill Report*, *supra* n.14.

133. According to the report, the five manufacturers whose information was subpoenaed by Senator McCaskill alone contributed almost $9 million combined to patient advocacy organizations and professional societies operating in the opioids policy area:

FIGURE 1: Manufacturer Payments to Selected Groups, 2012-2017

	Purdue[22]	Janssen[23]	Depomed	Insys	Mylan	Total
Academy of Integrative Pain Management	$1,091,024.86	$128,000.00	$43,491.95	$3,050.00[24]	$0.00	$1,265,566.81
American Academy of Pain Medicine	$725,584.95	$83,975.00	$332,100.00	$57,750.00	$0.00	$1,199,409.95
AAPM Foundation	$0.00	$0.00	$304,605.00	$0.00	$0.00	$304,605.00
ACS Cancer Action Network	$168,500.00[25]	$0.00	$0.00	$0.00	$0.00	$168,500.00
American Chronic Pain Association	$312,470.00	$50,000.00	$54,670.00	$0.00	$0.00	$417,140.00
American Geriatrics Society	$11,785.00[26]	$0.00	$0.00	$0.00	$0.00	$11,785.00
American Pain Foundation	$25,000.00	$0.00	$0.00	$0.00	$0.00	$25,000.00
American Pain Society	$542,259.52	$88,500.00	$288,750.00	$22,965.00	$20,250.00	$962,724.52
American Society of Pain Educators	$30,000.00	$0.00	$0.00	$0.00	$0.00	$30,000.00
American Society of Pain Management Nursing	$242,535.00	$55,177.85[27]	$25,500.00[28]	$0.00	$0.00	$323,212.85
The Center for Practical Bioethics	$145,095.00	$18,000.00	$0.00	$0.00	$0.00	$163,095.00
The National Pain Foundation[29]	$0.00	$0.00	$0.00	$562,500.00	$0.00	$562,500.00
U.S. Pain Foundation	$359,300.00	$41,500.00	$22,000.00	$2,500,000.00[30]	$0.00	$2,922,800.00
Washington Legal Foundation	$500,000.00	$0.00	$0.00	$0.00	$0.00	$500,000.00
	$4,153,554.33	$465,152.85	$1,071,116.95	$3,146,265.00	$20,250.00	$8,856,339.13

134. Breaking down by year the payments made by these five manufacturers is also revealing:

FIGURE 3: Manufacturer Yearly Payment Totals, 2012-2017

	2012	2013	2014	2015	2016	2017	Total
Purdue	$824,227.86	$973,328.00	$812,451.95	$935,344.00	$558,067.52	$50,135.00	$4,153,554.33
Janssen	$239,902.85[36]	$99,250.00	$126,000.00				$465,152.85
Depomed	$73,080.00	$135,300.00	$113,600.00	$350,000.00	$318,257.47	$80,879.48	$1,071,116.95
Insys	$14,040.00	$68,000.00	$34,200.00	$530,025.00		$2,500,000.00	$3,146,265.00
Mylan				$15,000.00	$2,500.00	$2,750.00	$20,250.00
Total	$1,151,250.71	$1,275,878.00	$1,086,251.95	$1,830,369.00	$878,824.99	$2,633,764.48	$8,856,339.13

135. Along with the nearly $9 million in payments to purportedly neutral patient advocacy organizations and medical professional societies, the five subpoenaed opioid manufacturers made an additional $1.6 million in payments to the organizations' and societies' group executives, staff members, board members, and advisory board members. When payments from all opioid manufacturers are tabulated, more than $10.6 million was paid to individuals affiliated with such organizations and societies from 2013 through the date of the report:

FIGURE 8: Payments from All Opioid Manufacturers to Group-Affiliated Individuals, 2013-Present[52]

	Manufacturer Payments to Affiliated Individuals
The National Pain Foundation	$8,307,243.47
AAPM Foundation	$798,051.22
American Society of Pain Educators	$749,564.78
American Academy of Pain Medicine	$204,631.53
American Pain Society	$187,699.34
ACS Cancer Action Network	$154,578.09
American Chronic Pain Association	$145,861.30
Academy of Integrative Pain Management	$82,596.98
The Center for Practical Bioethics	$16,945.88
American Geriatrics Society	$7,548.35
U.S. Pain Foundation	$138.91
American Pain Foundation	N/A
American Society of Pain Management Nursing	N/A
Washington Legal Foundation	N/A
Total	$10,654,859.85

136. Included in the above-listed payments were payments of more than $140,000 from opioid manufacturers, including Defendant Endo, to ten members of the American Chronic Pain Association Advisory Board; and more than $950,000 to members of the NPF board of directors from various opioid manufacturers.

137. Worse still, the organizations provided limited disclosures of these sources of funding – when they provided any information at all. The American Society of Pain Educators, the NPF, and the Academy of Integrative Pain Management provided no information concerning their policies for disclosing donors or donations, while several others stated explicitly that they did not disclose any information about donor relationships. When the groups investigated did disclose their sources of funding, they did so without providing specifics such as donation amounts.

138. Most importantly, many groups investigated "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." Several of the groups "also lobbied to change laws directed at curbing opioid use, strongly criticized landmark CDC guidelines on opioid prescribing, and challenged legal efforts to hold physicians and industry executives responsible for overprescription and misbranding."[91] The report provided details regarding four ways the groups investigated set about these tasks.

139. The report states that "[m]any of the groups have issued guidelines to physicians and other health practitioners that minimize the risk of opioid addiction or emphasize the long-term use of opioids to treat chronic pain."[92] The report provides examples, including the

[91] *Id*. at 12.
[92] *Id*.

AAPM's and APS's 1997 consensus statement endorsing opioids for chronic pain and stating that the risk of addiction was low, and the 2009 guidelines by the AAPM and the APS allegedly promoting opioids as safe and effective for chronic pain and concluding the risk of addiction was manageable regardless of past abuse history.

140. In conclusion, the report found that, while health advocacy organizations are "among the most influential and trusted stakeholders in U.S. health policy," the reality is that their "positions closely correspond to the marketing aims of pharmaceutical and device companies," including in the area of opioids policy. "The findings in this report indicate that this tension exists in the area of opioids policy – that organizations receiving substantial funding from manufacturers have, in fact, amplified and reinforced messages favoring increased opioid use." This amplification "may have played a significant role in creating the necessary conditions for the U.S. opioids epidemic."[93]

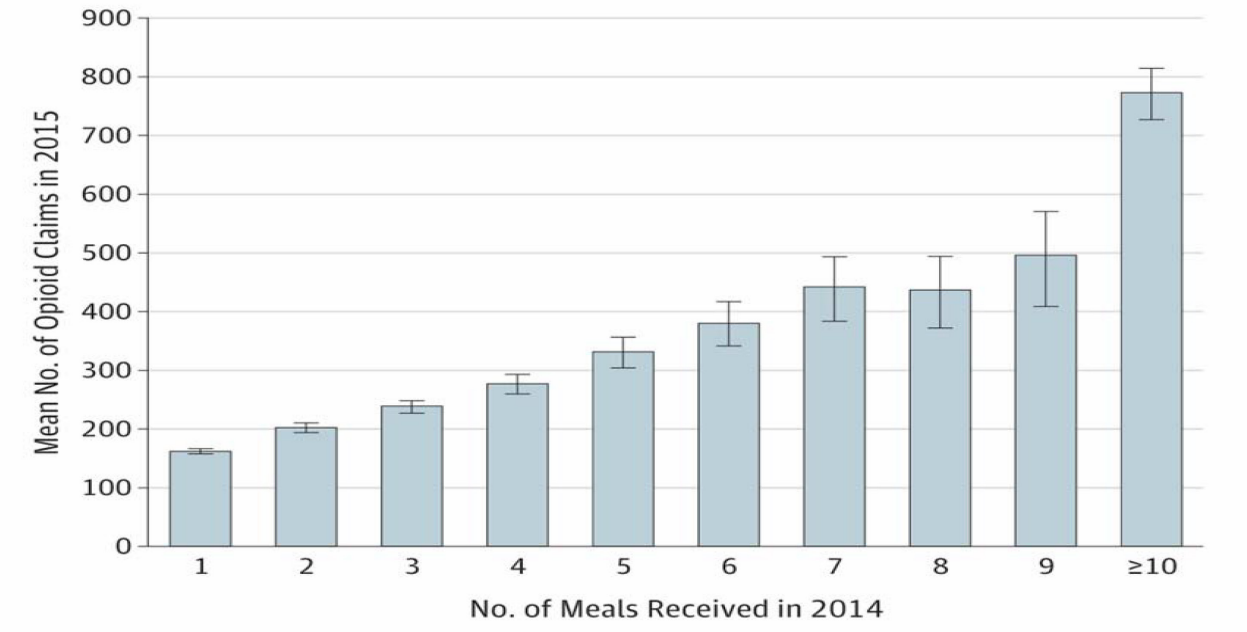
4. The Manufacturer Defendants and Non-Joined Manufacturers Paid Key Opinion Leaders and Sponsored Speakers' Bureaus to Disseminate False and Misleading Messaging.

141. The Manufacturer Defendants and non-joined manufacturers have paid millions of dollars to physicians to promote aggressive prescribing of opioids for chronic pain. Released federal data show that they increased such payments to physicians who treat chronic pain even while the opioid crisis accelerated and overdose deaths from prescription opioids and related illicit drugs, such as heroin, soared to record rates.[94] These payments come in the form of consulting and speaking fees, free food and beverages, discount coupons for drugs, and other freebies. The total payments from the Manufacturer Defendants and non-joined manufacturers to

[93] *Id*. at 17.
[94] Joe Lawlor, *Even amid crisis, opioid makers plied doctors with perks*, Portland PressHerald (Dec. 25, 2016), http://www.pressherald.com/2016/12/25/even-amid-crisis-opioid-makers-plied-doctors-with-perks/.

doctors related to opioids doubled from 2014 to 2015. Moreover, according to experts, research shows even small amounts of money can have large effects on doctors' prescribing practices.[95] Physicians who are high prescribers of opioids are more likely to be invited to participate in Manufacturer Defendants' and non-joined manufacturers' speakers' bureaus. According to a study published by the U.S. National Institutes of Health, "[s]peakers' bureau activities fall squarely within this definition of peer selling and hence product endorsement."[96]

142. According to a research letter published in *JAMA Internal Medicine* on May 14, 2018, doctors' mean number of opioid prescriptions increased with the number of free meals they received from an opioid company.[97]



[95] *Id.*

[96] Lynette Reid & Matthew Herder, *The speakers' bureau system: a form of peer selling*, 7(2) Open Med. e31-e39 (Apr. 2, 2013), https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3863750/.

[97] Scott E. Hadland et al., *Association of Pharmaceutical Industry Marketing of Opioid Products to Physicians With Subsequent Opioid Prescribing*, JAMA Intern. Med. (May 14, 2018), https://jamanetwork.com/journals/jamainternalmedicine/fullarticle/2681059. The study looked at the Open Payments database, which was used to pull out non-research payments to doctors in 2014. It then compared that data to claims in the Medicare Part D Opioid Prescriber Summary File from doctors who wrote opioid prescriptions in 2015, leaving in "all physicians with complete, nonduplicate information who had at least 10 opioid claims during 2015."

143. The use of speakers' bureaus has led to substantial ethical concerns within the medical field. A 2013 publication by the Institute on Medicine as a Profession summarized that the bureaus "leverage the credibility of physicians in order to promote the use of pharmaceutical products" and "[e]xposure to industry-sponsored speaking events is associated with decreased quality of prescribing."[98]

144. For example, Fishman is a physician whose ties to the opioid drug industry are clear. He has served as an APF board member and as president of the AAPM and has participated yearly in many CME activities for which he received "market rate honoraria." As discussed above, he has authored publications, including the seminal guides on opioid prescribing, which were funded by the Manufacturer Defendants and non-joined manufacturers. He has also worked to oppose legislation requiring doctors and others to consult pain specialists before prescribing high doses of opioids to non-cancer patients. He has himself acknowledged his failure to disclose all potential conflicts of interest in a letter in *JAMA* titled, "Incomplete Financial Disclosures in a Letter on Reducing Opioid Abuse and Diversion."[99]

145. Similarly, Fine's ties to the Manufacturer Defendants and non-joined manufacturers have been well documented.[100] He has authored articles and testified in court cases and before state and federal committees, and he, too, has served as president of the AAPM and argued against legislation restricting high-dose opioid prescription for non-cancer patients.

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[98] *Speakers' Bureaus: Best Practices for Academic Medical Centers*, IMAP (Oct. 10, 2013), http://imapny.org/wp-content/themes/imapny/File%20Library/Best%20Practice%20toolkits/Best-Practices_Speakers--bureaus.pdf (citing research in *JAMA*, *The Journal of Law, Medicine & Ethics* and *Academic Psychiatry*).

[99] Scott M. Fishman, *Incomplete Financial Disclosures in a Letter on Reducing Opioid Abuse and Diversion*, 306(13), JAMA 1445 (2011), https://jamanetwork.com/journals/jama/article-abstract/1104464.

[100] Tracy Weber & Charles Ornstein, *Two Leaders in Pain Treatment Have Long Ties to Drug Industry*, ProPublica (Dec. 23, 2011, 2:14 PM), https://www.propublica.org/article/two-leaders-in-pain-treatment-have-long-ties-to-drug-industry (hereinafter, "Weber, *Two Leaders in Pain*").

Multiple videos feature Fine delivering educational talks about prescription opioids. He even testified at trial that the 1,500 pills a month prescribed to celebrity Anna Nicole Smith for pain did not make her an addict before her death.[101] He has also acknowledged having failed to disclose many conflicts of interest.

146. Fishman and Fine are only two of the many physicians whom the Manufacturer Defendants and non-joined manufacturers paid to promote false or biased information on the use of opioids for chronic pain.

5. Senate Investigations of the Manufacturer Defendants and Non-Joined Manufacturers.

147. In May 2012, the Chair and Ranking Member of the Senate Finance Committee, Max Baucus (D-MT) and Chuck E. Grassley (R-IA), launched an investigation into makers of narcotic painkillers and groups that champion them. The investigation was triggered by "an epidemic of accidental deaths and addiction resulting from the increased sale and use of powerful narcotic painkillers," including popular brand names like OxyContin, Vicodin, and Opana.

148. The Senate Finance Committee sent letters to Defendant Endo and Defendant Johnson & Johnson, as well as five groups that support pain patients, physicians, or research, including the APF, AAPM, APS, University of Wisconsin Pain & Policy Studies Group, and the Center for Practical Bioethics. Letters also went to the Federation of State Medical Boards ("FSMB") and the Joint Commission. The letters addressed the magnitude of the epidemic and asserted that mounting evidence supports that the pharmaceutical companies may be responsible.[102]

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[101] Linda Deutsch, *Doctor: 1,500 pills don't prove Smith was addicted*, Seattle Times (Sept. 22, 2010, 5:16pm), https://www.seattletimes.com/entertainment/doctor-1500-pills-dont-prove-smith-was-addicted/.
[102] May 8, 2012 Letter from U.S. Senators Charles E. Grassley and Max Baucus to Catherine Underwood, Executive Director, American Pain Society,

149. The Senators demanded substantial discovery, including payment information from the companies to various groups, including the front organizations identified above, and to physicians, including Portenoy, Fishman, and Fine, among others. They asked about any influence the companies had on a 2004 pain guide for physicians that was distributed by the FSMB, on the APS' guidelines, and on the APF's Military/Veterans Pain Initiative. Almost immediately upon the launch of the Senate investigation, the APF shut down "due to irreparable economic circumstances." In 2018, the Senate Finance Committee demanded discovery detailing payments from the Manufacturer Defendants and non-joined manufacturers to nonprofit front groups, including those described above and the U.S. Pain Foundation,[103] American Academy of Pain Medicine, American Pain Society, and Center for Practical Bioethics, dating back to 1997.[104] The opioid report resulting from this investigation has not been released publicly.[105]

150. On March 29, 2017, it was widely reported[106] that yet another Senate investigation had been launched by Missouri Senator Claire McCaskill, targeting the heads of Defendant Janssen, Defendant Johnson & Johnson, Insys, Mylan, and Depomed.

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https://www.finance.senate.gov/imo/media/doc/05092012%20Baucus%20Grassley%20Opioid%20Investigation%20Letter%20to%20American%20Pain%20Society.pdf

[103] Letter from Senator Ron Wyden to Nicole Hemmenway, Interim CEO, U.S. Pain Foundation (Dec. 18, 2018), https://www.finance.senate.gov/imo/media/doc/121818%20Senator%20Wyden%20to%20the%20U.S.%20Pain%20Foundation.pdf.

[104] Thomas Sullivan, Senate Finance Committee Reacts to Reports of Opioid Abuse and Conflict of Interests: Letters to Manufacturers and Organizations (May 6, 2018), https://www.policymed.com/2012/05/senate-finance-committee-reacts-to-reports-of-opioid-abuse-and-conflict-of-interests-letters-to-manufactures-and-organizatio.html.

[105] Paul D. Thacker, *Senators Hatch and Wyden: Do your jobs and release the sealed opioids report*, Stat News (June 27, 2016), https://www.statnews.com/2016/06/27/opioid-addiction-orrin-hatch-ron-wyden/; *see also* Ornstein, *American Pain Foundation*, *supra* n.72.

[106] Nadia Kounang, *Senator McCaskill opens investigation into opioid manufacturers*, CNN (Mar. 29, 2017, 11:06 AM), https://www.cnn.com/2017/03/28/health/senate-opioid-manufacturer-investigation/index.html.

151. On September 12, 2017, Senator McCaskill convened a Roundtable Discussion on Opioid Marketing. During the hearing, Senator McCaskill stated, "Our national opioid epidemic is complex, but one explanation for this crisis is simple, pure greed."

152. Professor Adriane Fugh-Berman ("Fugh-Berman"), Associate Professor at Georgetown University Medical Center and director of a program at Georgetown called Pharmed Out, which conducts research on and educates the public about inappropriate pharmaceutical company marketing, also testified during the hearing.

153. Fugh-Berman answered why doctors were able to be convinced by pharmaceutical companies' marketing efforts:

> Why do physicians fall for this? Well, physicians are overworked, overwhelmed, buried in paperwork and they feel unappreciated. Drug reps are cheerful. They're charming. They provide both appreciation and information. Unfortunately, the information they provide is innately unreliable.
>
> Pharmaceutical companies influence healthcare providers' attitudes and their therapeutic choices through financial incentives that include research grants, educational grants, consulting fees, speaking fees, gifts and meals.

154. Fugh-Berman further described the false information provided by pharmaceutical companies and the industry creation of front organizations, including the APF, to pass industry influenced regulations and policies:

> Pharmaceutical companies convinced healthcare providers that they were opiophobic and that they were causing suffering to their patients by denying opioids to patients with back pain or arthritis.

155. In addition, Fugh-Berman pointed out that promotion of opioids remains ongoing despite increasing public concern about their use:

> Promotion of opioids is not in the past. Between 2013 and 2015, one in 12 physicians took out money from opioid manufacturers, a total of more than $46 million. Industry-friendly messages that pharmaceutical companies are currently perpetuating reassure physicians that prescribing opioids is safe as long as patients do not have a history of substance abuse or mental illness.

6. The Devastating Impact of the Manufacturer Defendants' and Non-Joined Manufacturers' Propaganda Campaign.

156. As stated, the impact of the Manufacturer Defendants' and non-joined manufacturers' false messaging has been profound. The drug companies profited handsomely as more and more people became addicted to opioids and died of overdoses.[107]

157. The nation is experiencing an unprecedented opioid addiction and overdose epidemic, costing millions in health insurance and public safety spending, as well as lost productivity in the workforce.

158. In 2012 alone, an estimated 259 million opioid prescriptions were filled, enough to medicate every adult in the United States for a month on around-the-clock basis.[108] The use of prescription painkillers cost health insurers up to $72.5 billion annually in direct healthcare costs.[109]

C. The Manufacturer Defendants' Specific Unlawful Practices that Targeted Prescribers Nationwide.

1. Defendants Johnson & Johnson and Janssen

159. Defendant Johnson & Johnson is the only company that owns more than 10% of Defendant Janssen Pharmaceuticals, Inc.'s stock and corresponds with the FDA regarding Defendant Janssen's products. Upon information and belief, Defendant Johnson & Johnson controls the sale and development of Defendant Janssen's drugs including opioids, and Defendant Janssen's profits inure to Defendant Johnson & Johnson's benefit. Together,

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[107] German Lopez, *How big pharma got people hooked on dangerous opioids – and made tons of money off it*, Vox (Sept. 22, 2016, 3:00 PM), http://www.vox.com/2016/2/5/10919360/opioidepidemic-chart.
[108] *Opioid Painkiller Prescribing*, Centers for Disease Control and Prevention: Vital Signs (July 2014), https://www.cdc.gov/vitalsigns/opioid-prescribing/.
[109] Katherine Eban, *OxyContin: Purdue Pharma's painful medicine*, Fortune Magazine (Nov. 9, 2011), http://fortune.com/2011/11/09/oxycontin-purdue-pharmas-painful-medicine/ (hereinafter, "Eban, *Painful Medicine*").

Defendants Johnson & Johnson and Janssen: (1) funded the production and dissemination of and disseminated false, misleading, and deceptive information about the efficacy and addictive properties of prescription opioids; and (2) failed to monitor and report suspicious sales as required by federal law.

a) Defendant Janssen

160. Defendant Janssen manufactured, marketed, sold, and distributed opioids, nationwide, including Florida that includes the following:

Duragesic (fentanyl)	Opioid analgesic delivered via skin patch; contains gel form of fentanyl, a synthetic opioid that is up to 100 times more potent than morphine; delivers fentanyl at regulated rate for up to 72 hours; first approved by the FDA in August 1990.	Schedule II
Nucynta ER (tapentadol hydrochloride)	Opioid agonist; extended-release formulation indicated for severe pain.	Schedule II
Nucynta (tapentadol hydrochloride)	Immediate-release version of tapentadol hydrochloride for the management of moderate to severe acute pain.	Schedule II

161. Defendant Janssen introduced Duragesic in 1990. It is indicated for the "management of pain in opioid-tolerant patients, severe enough to require daily, around-the-clock, long-term opioid treatment and for which alternative treatment options are inadequate." Janssen also marketed Nucynta, which was first approved by the FDA in 2008, formulated in tablet form and in an oral solution and indicated for the "relief of moderate to severe acute pain in patients 18 years of age or older." Janssen also marketed Nucynta ER, which was first approved by the FDA in 2011 in tablet form. Initially, it was indicated for the "management of . . . pain severe enough to require daily, around-the-clock, long-term opioid treatment and for which alternative treatment options are inadequate." This pain indication was later altered to "management of moderate to severe chronic pain in adults" and "neuropathic pain associated

with diabetic peripheral neuropathy (DPN) in adults." Janssen sold Nucynta and Nucynta ER to Depomed. in 2015 for $1.05 billion.

162. In 1997, after seeing OxyContin successfully marketed for chronic non-cancer pain, Johnson & Johnson/Janssen re-launched fentanyl-based Duragesic patch for the chronic, non-cancer market as well.

(1) The FDA Warned Defendant Janssen Regarding Its False Messaging.

163. On February 15, 2000, the FDA sent Janssen a letter concerning the alleged dissemination of "homemade" promotional pieces that promoted Duragesic in violation of the Federal Food, Drug, and Cosmetic Act ("FDCA"), 21 U.S.C. §301, *et seq.* In a subsequent letter, dated March 30, 2000, the FDA explained that the "homemade" promotional pieces were "false or misleading because they contain misrepresentations of safety information, broaden Duragesic's indication, contain unsubstantiated claims, and lack fair balance."

164. The March 30, 2000, letter identified specific violations, including misrepresentations that Duragesic had a low potential for abuse.[110]

165. The March 30, 2000, letter also stated that the promotional materials represented that Duragesic was "more useful in a broader range of conditions or patients than has been demonstrated by substantial evidence." Specifically, the FDA stated that Janssen was marketing Duragesic for indications other than the treatment of chronic pain that cannot otherwise be managed, for which it was approved.[111]

[110] NDA 19-813 Letter from Spencer Salis, U.S. Food & Drug Administration, to Cynthia Chianese, Janssen Pharmaceutical at 2 (Mar. 30, 2000), available at *Cnty. of Wayne and County of Oakland v. Purdue Pharma, et al*., No. 2:17-cv-13334-JCO-EAS, Dkt. 2-10 (E.D. Mich. Oct. 12, 2017).
[111] *Id*. at 2-3.

166. The March 30, 2000, letter also stated Janssen failed to adequately present "contraindications, warnings, precautions, and side effects with a prominence and readability reasonably comparable to the presentation of information relating to the effectiveness of the product."[112]

167. On September 2, 2004, the U.S. Department of Health and Human Services ("HHS") sent Janssen a warning letter concerning Duragesic due to "false or misleading claims about the abuse potential and other risks of the drug, and . . . unsubstantiated effectiveness claims for Duragesic," including, specifically, "suggesting that Duragesic has a lower potential for abuse compared to other opioid products."

168. The September 2, 2004, letter warned Janssen about its claims that Duragesic had a low reported rate of mentions in the Drug Abuse Warning Network ("DAWN") as compared to other opioids. The letter stated that the claim was false or misleading because the claim was not based on substantial data and because the lower rate of mentions was likely attributable to Duragesic's lower frequency of use compared to other opioids listed in DAWN.[113]

169. The September 2, 2004, letter also detailed a series of unsubstantiated, false, or misleading claims of Duragesic's effectiveness. The letter concluded that various claims made by Janssen were insufficiently supported, including:

- "Demonstrated effectiveness in chronic back pain with additional patient benefits, . . . 86% of patients experienced overall benefit in a clinical study based on: pain control, disability in ADLs, quality of sleep."
- "All patients who experienced overall benefit from DURAGESIC would recommend it to others with chronic low back pain."

[112] *Id*. at 3 (emphasis in original).
[113] Warning Letter from Thomas W. Abrams, U.S. Department of Health and Human Services, to Ajit Shetty, Janssen Pharmaceutica, Inc., at 2 (Sept. 2, 2004), http://www.johnsonandtoxin.com/ 040920_duragesic_letter.pdf.

- "Significantly reduced nighttime awakenings."
- "Significant improvement in disability scores as measured by the Oswestry Disability Questionnaire and Pain Disability Index."
- "Significant improvement in physical functioning summary score."
- "Significant improvement in social functioning."[114]

170. In addition, the September 2, 2004, letter identified "outcome claims [that] are misleading because they imply that patients will experience improved social or physical functioning or improved work productivity when using Duragesic." The claims include "'1,360 [lives] . . . and counting,' '[w]ork, uninterrupted,' '[l]ife, uninterrupted,' '[g]ame, uninterrupted,' '[c]hronic pain relief that supports functionality,' '[h]elps patients think less about their pain,' and '[i]mprove[s] . . . physical and social functioning.'" The September 2, 2004, letter stated: "Janssen has not provided references to support these outcome claims. We are not aware of substantial evidence or substantial clinical experience to support these claims."[115]

171. On July 15, 2005, the FDA issued a public health advisory warning doctors of deaths resulting from the use of Duragesic and a generic manufactured by Mylan n/k/a Defendant Viatris, Inc. The advisory noted that the FDA had been "examining the circumstances of product use to determine if the reported adverse events may be related to inappropriate use of the patch" and noted the possibility "that patients and physicians might be unaware of the risks" of using the fentanyl transdermal patch, a potent opioid analgesic meant to treat chronic pain that does not respond to other painkillers.

172. Regardless, even after receiving these letters, Janssen instructed sales representatives nationwide to market Duragesic as having better efficacy, better tolerability, and

[114] *Id*. at 2-3.
[115] *Id.* at 3.

better patient compliance because it was a patch instead of a pill. These sales representatives were instructed to tell doctors that the patch provided better control in the event of patient opioid abuse because patients could not increase the patch dosage. However, sales representatives were aware of patients who increased the dosage by applying more than one patch at a time and also knew that some patients abused the patch by freezing, then chewing on it.

(2) Defendant Janssen Funded False Publications and Presentations.

173. Defendant Janssen disseminated false information about opioids on the website "Prescribe Responsibly." According to the website's legal notice, all content on the site "is owned or controlled by Janssen."[116] The website included numerous false or misleading representations concerning the relative safety of opioids and omissions of the risks associated with taking them. For example, it stated that while practitioners are often concerned about prescribing opioids due to "questions of addiction," such concerns "are often overestimated. According to clinical opinion polls, true addiction occurs only in a small percentage of patients with chronic pain who receive chronic opioid . . . analgesic therapy."[117]

174. Prescribe Responsibly also compared the risks of opioid use favorably to those associated with nonsteroidal anti-inflammatory drugs ("NSAIDs"), such as aspirin and ibuprofen, and stated that many patients develop a tolerance for opioids' side effects: Opioid analgesics are often the first line of treatment for many painful conditions and may offer advantages over NSAIDs.

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[116] *Legal Notice*, Prescribe Responsibly, https://web.archive.org/web/20171003192940/http://www.prescriberesponsibly.com/legal-notice (last visited Sept. 19, 2019).

[117] *Use of Opioid Analgesics in Pain Management*, Prescribe Responsibly, https://web.archive.org/web/20180714193514/http://www.prescriberesponsibly.com/articles/opioid-pain-management (last visited May 5, 2022).

> Opioid analgesics, for example, have no true "ceiling dose" for analgesia and do not cause direct organ damage; however, they do have several possible side effects, including constipation, nausea, vomiting, a decrease in sexual interest, drowsiness, and respiratory depression. With the exception of constipation, many patients often develop tolerance to most of the opioid analgesic-related side effects.[118]

175. Further, Prescribe Responsibly repeated the scientifically unsupported discussion of "pseudoaddiction" as "a syndrome that causes patients to seek additional medications due to inadequate pharmacotherapy being prescribed. Typically when the pain is treated appropriately, the inappropriate behavior ceases."[119] Thus, "pseudoaddiction" was defined as a condition requiring the prescription of more or stronger opioids.

176. Another unbranded marketing initiative that Defendant Janssen employed was the dissemination of a brochure, titled "Finding Relief," which AAPM sponsored by AAPM.[120] The Finding Relief brochure, which was widely disseminated, did not differentiate between different kinds of opioids and discussed them as a class of drugs without reference to any of the differences between them. The Finding Relief brochure actively promoted the concept that pain was undertreated. The brochure downplayed any risks associated with opioids.

177. Defendant Janssen also made thousands of payments to physicians nationwide for activities including participating on speakers' bureaus, providing consulting services, assisting in post-marketing safety surveillance and other services.

178. Defendant Janssen used a sales force to promote, market, and sell various opioids, including branded opioid drugs that they manufactured: Duragesic, Ultram, and Nucynta.

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[118] *Id.*

[119] *What a Prescriber Should Know Before Writing the First Prescription*, Prescribe Responsibly, https://web.archive.org/web/20180720092635/http://www.prescriberesponsibly.com/articles/before-prescribing-opioids (last visited May 5, 2022).

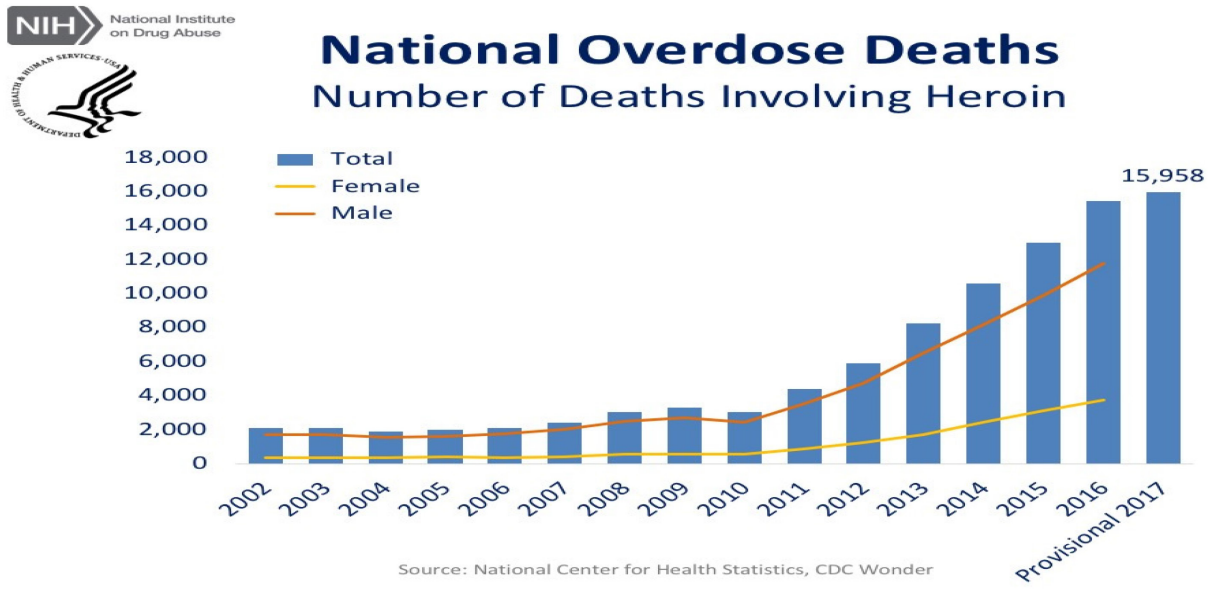
[120] Finding Relief: Pain Management for Older Adults (2009), available at https://docplayer.net/28610911- Finding-relief-pain-management-for-older-adults.html (last visited May 5, 2022).

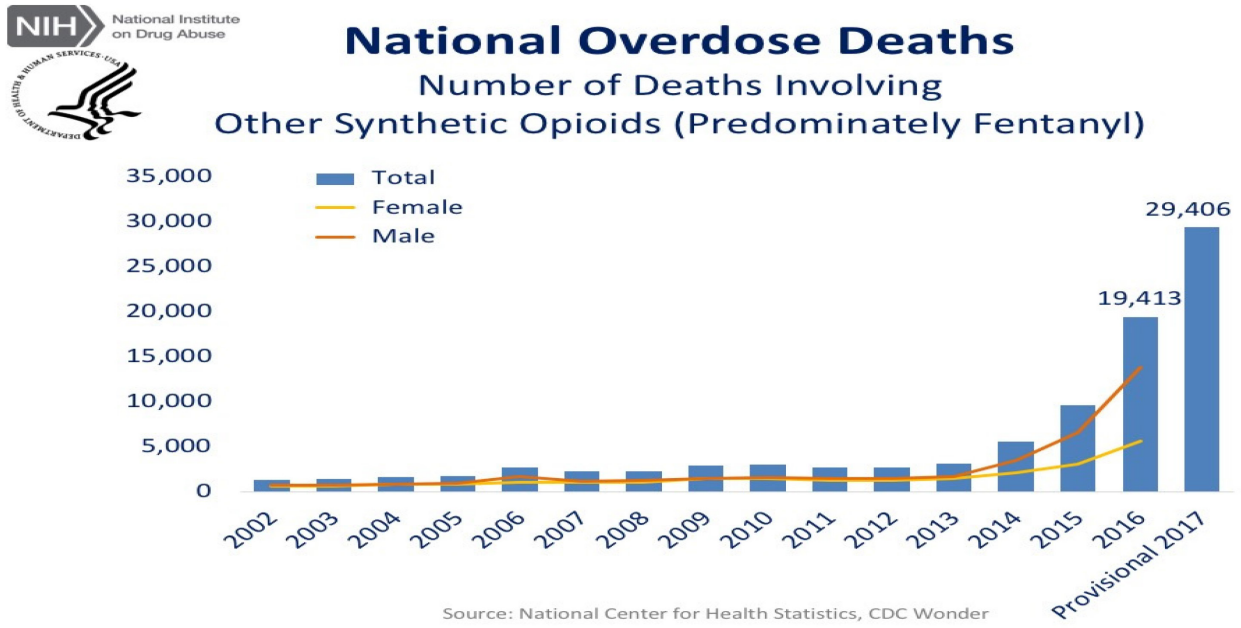
179. Defendant Janssen's training of its sales representatives included teaching sales representatives to avoid the so-called "addiction ditch"—*i.e.*, to avoid the negatives (addiction) and emphasize the positives (supposed efficacy) in sales calls—and to use a study from Dr. Portenoy "to create dialogue about Opiophobia as a barrier."

180. As part of this training, Defendant Janssen trained their sales representatives that there was a 2.6% or lower risk of addiction when using opioids prescribed by a doctor. As part of this same training, Defendant Janssen trained sales representatives to "establish that moderate to severe acute pain continues to be undertreated."

181. Defendant Janssen did not provide its sales force with any training on opioid addiction.

182. As people became more and more hooked on prescription painkillers, many moved to heroin, and increasingly to fentanyl, which is even more potent and cheaper than heroin, and is increasingly mixed with or sold as heroin and, as set forth above, was also being deceptively marketed by Janssen. This transition to heroin and fentanyl caused a dramatic spike in heroin overdose deaths after 2011 and in fentanyl overdose deaths in 2014:





b) Defendant Johnson & Johnson

183. Along with marketing Janssen opioids, Johnson & Johnson owned two companies that grew, imported, and processed the raw materials to make opioids and sold them to many of the other Manufacturer Defendants and Purdue.

184. From the 1990s through at least 2016, Johnson & Johnson wholly owned Tasmania Alkaloids Limited ("Tasmanian Alkaloids"), which was based in Tasmania and cultivated and processed opium poppy plants to manufacture narcotic raw materials to be imported into the U.S. to be processed and made into active pharmaceutical ingredients ("APIs") necessary to manufacture opioid drugs. It also wholly owned Noramco, Inc. which is based in Athens, Georgia, and imported the raw narcotic materials produced by Tasmania Alkaloids, processed the materials into APIs, and then sold the APIs to other opioid manufacturers in the U.S.

185. Johnson & Johnson had acquired and formed Tasmanian Alkaloids and Noramco, in the 1980s to ensure a "reliable source of [narcotic] raw materials" and "security of supply" for its Tylenol with codeine range of pain medications.

186. Until 2016, when Johnson & Johnson sold its Noramco/Tasmanian Alkaloids business, Tasmanian Alkaloids and Noramco were "sister companies," as both were members of Johnson & Johnson's "family of companies." Noramco employees did not believe Noramco maintained its own bank accounts, separate from Defendant Johnson & Johnson's treasury. Johnson & Johnson, Noramco, and Tasmanian Alkaloids shared employees and resources that were required to operate the business. Noramco employees physically worked at Johnson & Johnson's facilities in New Jersey at various times. Further, employees simultaneously held positions at multiple companies within Johnson & Johnson companies at times. During this time, Noramco and Tasmanian Alkaloids were key parts of Johnson & Johnson's "pain management franchise" or "pain franchise."

187. Johnson & Johnson, through these subsidiaries, supplied the following opioid API to other drug manufacturers in the U.S., including Purdue and Defendant Teva: oxycodone, hydrocodone, morphine, codeine, fentanyl, sufentanil, buprenorphine, hydromorphone, and naloxone.

188. Noramco, located in the U.S., imports the narcotic raw materials produced by Tasmanian Alkaloids, like morphine or thebaine,[121] into the U.S., processes them into APIs, then sells them to drug manufacturers in the U.S. Noramco was an important part of Johnson & Johnson's business from the mid-1990s until at least 2010. Johnson & Johnson's ownership of these subsidiaries uniquely positioned its pain management franchise to provide U.S. drug

[121] Thebaine is an opiate alkaloid, chemically similar to morphine and codeine, used as an intermediate in the biosynthesis of other opioids.

manufacturers, including Defendant Johnson & Johnson itself, with "Security of Supply-Direct Access to Narcotic Raw Material - From Our Fields to Your Formulations."

189. In 1994, Johnson & Johnson, in concert with its subsidiary, Tasmanian Alkaloids, anticipated demand for API oxycodone. Specifically, Johnson & Johnson scientists at Tasmanian Alkaloids began a project "in 1994 in order to develop a high thebaine poppy variety to meet the anticipated demand." The result of the research project was the creation of a "high thebaine" poppy called the "Norman Poppy," which Johnson & Johnson internally described as "a transformational technology that enabled the growth of oxycodone."

190. Through Noramco, Defendant Johnson & Johnson met the anticipated opioid demand by selling API and supplied other U.S. opioid manufacturers, including the Manufacturer Defendants, with opioid APIs, including oxycodone, hydrocodone, morphine, codeine, buprenorphine, hydromorphone, and naloxone.

191. Through Noramco, Defendant Johnson & Johnson supplied API via long-term agreements and had such agreements with all 7 of the top U.S. generic companies.

192. Noramco grew to become the number one narcotic API supplier of oxycodone, hydrocodone, codeine, and morphine in the United States.

c) Defendant Johnson & Johnson and Defendant Janssen Failed to Monitor and Report Suspicious Sales as Required by Federal Law.

193. The CSA imposes on all "registrants" the obligation to design and operate a system to monitor suspicious orders of controlled substances and requires the registrant to notify the DEA field division office in its area of any suspicious orders. "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).

194. Both Defendant Johnson & Johnson and Defendant Janssen are "registrants" under the CSA. 21 C.F.R. §1300.02(b) defines a registrant as any person who is registered with the DEA under 21 U.S.C. §823. Section 823, in turn, requires manufacturers of Schedule II controlled substances to register with the DEA.

195. Both Defendant Johnson & Johnson and Defendant Janssen failed to design and operate a system to monitor suspicious orders of controlled substances and/or failed to notify the appropriate DEA field division of suspicious orders. They also failed to report sales of dangerous drugs subject to abuse. Their failure to timely report these and other suspicious sales violated the CSA.

2. Defendant Endo

196. Defendant Endo manufactured, marketed, sold, and distributed opioids, nationwide, include the following:

Opana ER (oxymorphone hydrochloride)	Opioid agonist; extended-release tablet formulation; first drug in which oxymorphone was available in an oral, extended-release formulation; first approved in 2006	Schedule II
Opana (oxymorphone hydrochloride)	Opioid agonist; first approved in 2006.	Schedule II
Percodan (oxymorphone hydrochloride and aspirin)	Branded tablet combining oxymorphone hydrochloride and aspirin; first approved in 1950; first marketed by Endo in 2004.	Schedule II
Percocet (oxymorphone hydrochloride & acetaminophen)	Branded tablet that combines oxymorphone hydrochloride and acetaminophen; first approved in 1999; first marketed by Endo in 2006.	Schedule II
Oxycodone	Generic product.	Schedule II
Oxymorphone	Generic product.	Schedule II
Hydromorphone	Generic product.	Schedule II
Hydrocodone	Generic product.	Schedule II

197. The FDA first approved an injectable form of Opana in 1959. The injectable form of Opana was indicated "for the relief of moderate to severe pain" and "for preoperative

medication, for support of anesthesia, for obstetrical analgesia, and for relief of anxiety in patients with dyspnea associated with pulmonary edema secondary to acute left ventricular dysfunction." However, oxymorphone drugs were removed from the market in the 1970s due to widespread abuse.[122]

198. In 2006, the FDA approved a tablet form of Opana in 5 mg and 10 mg strengths. The tablet form was "indicated for the relief of moderate to severe acute pain where the use of an opioid is appropriate." Also in 2006, the FDA approved Opana ER, an extended-release tablet version of Opana available in 5 mg, 10 mg, 20 mg, and 40 mg tablet strengths. Opana ER was indicated "for the relief of moderate to severe pain in patients requiring continuous, around-the-clock opioid treatment for an extended period of time." Endo's goal was to use Opana ER to take market share away from OxyContin; thus, it was marketed as being safer, with less abuse potential than OxyContin because it is supposed to be crush-resistant.

199. According to Endo's annual reports, sales of Opana and Opana ER regularly generate several hundred million dollars in annual revenue for the company, growing from $107 million in 2007 to as high as $384 million in 2011. From 2010 to 2020, Percocet has generated an average of well over $100 million in annual revenue for the company.

a) Endo Falsely Marketed Opana ER as Crush Resistant.

200. In December 2011, the FDA approved a reformulated version of Opana ER, which Endo claimed offered "safety advantages" over the original formulation because the new version "is resistant to crushing by common methods and tools employed by abusers of prescription opioids . . . [and] is less likely to be chewed or crushed even in situations where

[122] John Fauber & Kristina Fiore, *Opana gets FDA approval despite history of abuse, limited effectiveness in trials*, Milwaukee Journal Sentinel (May 9, 2015), http://archive.jsonline.com/watchdog/watchdogreports/opana-gets-fda-approval-despite-history-of-abuse-limited-effectiveness-intrials-b99494132z1-303198321.html/.

there is no intent for abuse, such as where patients inadvertently chew the tablets, or where caregivers attempt to crush the tablets for easier administration with food or by gastric tubes, or where children accidentally gain access to the tablets."

201. Endo publicized the reformulated version of Opana ER as "crush-resistant." To combat the fear of opioids, sales representatives touted it to doctors as a safer option due to its crush-resistance and extended release.

202. However, in October 2012, the CDC issued a health alert noting that 15 people in Tennessee had contracted thrombotic thrombocytopenic purpura, a rare blood-clotting disorder, after injecting reformulated Opana ER. In response, Endo's chief scientific officer stated that, while Endo was looking into the data, he was not too concerned because "it's in a very, very distinct area of the country."[123]

203. Shortly thereafter, the FDA determined that Endo's conclusions about the purported safety advantages of the reformulated Opana ER were unfounded. In a May 10, 2013, letter to Endo, the FDA found that the tablet was still vulnerable to "cutting, grinding, or chewing," "can be prepared for insufflation (snorting) using commonly available tools and methods" and "can [be readily] prepared for injection." It also warned that preliminary data suggested "the troubling possibility that a higher percentage of reformulated Opana ER abuse is via injection than was the case with the original formulation."

204. A 2014 study co-authored by an Endo medical director corroborated the FDA's warning. This 2014 study found that while overall abuse of Opana had fallen following Opana

[123] Tom Dreisbach et al., *How A Painkiller Designed To Deter Abuse Helped Spark An HIV Outbreak*, National Public Radio (Apr. 1, 2016), http://www.npr.org/sections/healthshots/2016/04/01/472538272/how-a-painkiller-designed-to-deter-abuse-helped-spark-an-hiv-outbreak.

ER's reformulation, injection had become the preferred way of abusing the drug.[124] However, and incredibly, the study reassured that it was not possible to draw a causal link between the reformulation and injection abuse.

205. The study's failure to adequately warn healthcare providers and the public was catastrophic. On April 24, 2015, the CDC issued a health advisory concerning its investigation of "a large outbreak of recent human immunodeficiency virus (HIV) infections among persons who inject drugs."[125] The CDC specifically attributed the outbreak to the injection of Opana ER.[126]

b) New York's Investigation Found Endo Falsely Marketed Opana ER.

206. On February 18, 2017, the State of New York announced a settlement with Endo requiring it "to cease all misrepresentations regarding the properties of Opana ER [and] to describe accurately the risk of addiction to Opana ER."[127] In the Assurance of Discontinuance that effectuated the settlement, the State of New York revealed evidence showing that Endo had known about the risks arising from the reformulated Opana ER even before it received FDA approval.

207. In October 2011, one month before the FDA's approval of reformulated Opana ER, Endo's director of project management e-mailed the company that developed the formulation technology for the drug to say there was little or no difference between the new

[124] *Id.*
[125] *Outbreak of Recent HIV and HCV Infections Among Persons Who Inject Drugs*, Centers for Disease Control and Prevention, https://emergency.cdc.gov/han/han00377.asp (last visited Sept. 26, 2019).
[126] *Id.*
[127] Press Release, Attorney General Eric T. Schneiderman, A.G. Schneiderman Announces Settlement With Endo Health Solutions Inc. & Endo Pharmaceuticals Inc. Over Marketing Of Prescription Opioid Drugs (Mar. 3, 2016), https://ag.ny.gov/press-release/ag-schneidermanannounces-settlement-endo-health-solutions-inc-endo-pharmaceuticals.

formulation and the earlier formulation, which Endo withdrew due to risks associated with grinding and chewing:

> "*We already demonstrated that there was little difference between [the original and new formulations of Opana] in Study 108 when both products were ground. FDA deemed that there was no difference* and this contributed to their statement that we had not shown an incremental benefit. *The chewing study (109) showed the same thing no real difference* which the FDA used to claim no incremental benefit."[128]

208. Endo conducted two more studies to test the reformulated Opana ER's crush resistance. Study 901 tested whether it was harder to extract opioid from reformulated Opana ER than from the original version, and whether it would take longer to extract opioid from reformulated Opana ER than from the original version. The test revealed that both formulations behaved similarly with respect to manipulation time and produced equivalent opioid yields.

209. The settlement also identified and discussed a February 2013 communication from a consultant hired by Endo to the company, in which the consultant concluded that "[t]he initial data presented do not necessarily establish that the reformulated Opana ER is tamper resistant." The same consultant also reported that the distribution of the reformulated Opana ER had led to higher levels of abuse of the drug via injection.[129]

210. Despite the results of Endo's own studies and the conclusions of both Endo's director of project management and consultant, pamphlets produced by Endo and distributed to physicians misleadingly marketed the reformulated Opana ER as "'designed to be' crush

[128] *In the Matter of Endo Health Solutions Inc. and Endo Pharmaceuticals Inc.*, Assurance No. 15-228, Assurance of Discontinuance Under Executive Law Section 63, Subdivision 15 at 5 (Mar. 1, 2016), (hereinafter "NYAG Endo Discontinuance") https://ag.ny.gov/pdfs/Endo_AOD_030116-Fully_Executed.pdf.
[129] *Id.*

resistant," and Endo's sales representative training identified Opana ER as "CR," short for crush resistant.[130]

211. The Office of the Attorney General of New York also revealed that the "managed care dossier" Endo provided to formulary[131] committees of healthcare plans and PBMs misrepresented the Opana ER studies. The dossier was distributed in order to assure the inclusion of reformulated Opana ER in their formularies.

212. According to Endo's Vice President for Pharmacovigilance and Risk Management, the dossier was presented as a complete compendium of all research on the drug. However, it omitted certain studies: Study 108 (completed in 2009) and Study 109 (completed in 2010), which showed that reformulated Opana ER could be ground and chewed.

213. The settlement also detailed Endo's false and misleading representations about the non-addictiveness of opioids and Opana. Until April 2012, Endo's website for the drug, www.opana.com, contained the following representation: "Most healthcare providers who treat patients with pain agree that patients treated with prolonged opioid medicines usually do not become addicted."[132] However, Endo neither conducted nor possessed a survey demonstrating that most healthcare providers who treat patients with pain agree with that representation.

214. The Office of the Attorney General of New York also disclosed that training materials provided by Endo to sales representatives stated: "Symptoms of withdrawal do not indicate addiction."[133] This representation conflicts with the diagnosis of opioid-use disorder as provided in the *Diagnostic and Statistical Manual of Mental Disorders by the American Psychiatric Association (Fifth Edition)*.

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[130] *Id.*
[131] A formulary is the official list of medicines that may be prescribed in a particular health care plan.
[132] NYAG Endo Discontinuance, *supra* n. 127.
[133] *Id*. at 7.

215. The Office of the Attorney General of New York also found that Endo trained its sales representatives to falsely distinguish addiction from "pseudoaddiction," which it defined as a condition in which patients exhibit drug-seeking behavior that resembles, but is different from, addiction. However, Endo's Vice President for Pharmacovigilance and Risk Management testified that he was unaware of any research validating the concept of pseudoaddiction.

c) Endo Funded False Publications and Presentations.

216. Like other opioid manufacturers, Endo provided substantial funding to purportedly neutral medical organizations, including the APF.

217. For example, in April 2007, Endo sponsored an article aimed at prescribers, written by Dr. Charles E. Argoff in *Pain Medicine News*, titled, "Case Challenges in Pain Management: Opioid Therapy for Chronic Pain."[134]

218. The article started with the observation that "[a]n estimated 50 to 60 million people . . . suffer from chronic pain." It continued:

> Opioids represent a highly effective but controversial and often misunderstood class of analgesic medications for controlling both chronic and acute pain. The phenomenon of tolerance to opioids – the gradual waning of relief at a given dose – and fears of abuse, diversion, and misuse of these medications by patients have led many clinicians to be wary of prescribing these drugs, and/or to restrict dosages to levels that may be insufficient to provide meaningful relief.[135]

219. The article included a case study that focused on the danger of extended use of NSAIDs, including that the subject was hospitalized with a massive upper gastrointestinal bleed believed to have resulted from his protracted NSAID use. In contrast, the article did not provide the same detail concerning the serious side effects associated with opioids. It concluded by saying that "use of opioids may be effective in the management of chronic pain."

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[134] Charles E. Argoff, *Case Challenges in Pain Management: Opioid Therapy for Chronic Pain*, Pain Med. News, http://www.painmedicinenews.com/download/BtoB_Opana_WM.pdf.
[135] *Id*.

220. Later, in 2014, Endo issued a patient brochure titled, "Understanding Your Pain: Taking Oral Opioid Analgesics." It was written by nurses Margo McCaffery and Chris Pasero and edited by APF board member Portenoy.

221. The brochure included many false and misleading statements minimizing the dangers associated with prescription opioid use. Among other things, the brochure falsely and misleadingly represented that:

> Addiction **IS NOT** when a person develops "withdrawal" (such as abdominal cramping or sweating) after the medicine is stopped quickly or the dose is reduced by a large amount. Your doctor will avoid stopping your medication suddenly by slowly reducing the amount of opioid you take before the medicine is completely stopped. Addiction also **IS NOT** what happens when some people taking opioids need to take a higher dose after a period of time in order for it to continue to relieve their pain. This normal "tolerance" to opioid medications doesn't affect everyone who takes them and does not, by itself, imply addiction. If tolerance does occur, it does not mean you will "run out" of pain relief. Your dose can be adjusted or another medicine can be prescribed.
>
> * * *
> *How can I be sure I'm not addicted?*
>
> - Addiction to an opioid would mean that your pain has gone away but you still take the medicine regularly when you don't need it for pain, maybe just to escape from your problems.
>
> - Ask yourself: Would I want to take this medicine if my pain went away? If you answer no, you are taking opioids for the right reasons – to relieve your pain and improve your function. You are not addicted.[136]

222. In 2008, Endo also provided an "educational grant" to PainEDU.org, which produced a document titled, "Screener and Opioid Assessment for Patients with Pain (SOAPP) Version 1.0-14Q." Endo and King Pharmaceuticals sponsor PainEDU.org.[137] SOAPP describes itself "as a tool for clinicians to help determine how much monitoring a patient on long-term

[136] Margo McCaffrey et al., *Understanding Your Pain: Taking Oral Opioid Analgesics*, Endo Pharmaceuticals (2004), http://www.thblack.com/links/RSD/Understand_Pain_Opioid_Analgesics.pdf.
[137] B. Eliot Cole, *Resources for Education on Pain and Its Management: A Practitioner's Compendium* 2 (Am. Society of Pain Educators 2009), https://www.nhms.org/sites/default/files/Pdfs/SOAPP-5.pdf.

opioid therapy might require." It falsely highlights purportedly "recent findings suggesting that most patients are able to successfully remain on long-term opioid therapy without significant problems."

223. Endo also sponsored the now-defunct website painknowledge.com, which was created by the APF and stated it was "a one-stop repository for print materials, educational resources, and physician tools across the broad spectrum of pain assessment, treatment, and management approaches."[138] Among other featured content, painknowledge.com included a flyer titled, "Pain: Opioid Therapy," which failed to warn of significant adverse effects that could arise from opioid use, including hyperalgesia, immune and hormone dysfunction, cognitive impairment, decreased tolerance, dependence and addiction.

224. Endo, along with Defendant Janssen and Purdue, also provided grants to the APF to distribute Exit Wounds, discussed above.

225. Endo also made thousands of payments to physicians nationwide for activities including participating on speakers' bureaus, providing consulting services, assisting in post-marketing safety surveillance, and other services.

d) The FDA Requested Endo to Withdraw Opana ER Due to the Public Health Consequences of Abuse.

226. On June 8, 2017, the FDA requested that Endo remove reformulated Opana ER from the market "based on its concern that the benefits of the drug may no longer outweigh its risks." According to the FDA's press release, it sought removal "due to the public health consequences of abuse." The decision to seek Opana ER's removal from sale followed a March 2017 FDA advisory committee meeting, during which a group of independent experts voted 18-8

[138] *AboutPainKnowledge.org*, PainKnowledge, http://web.archive.org/web/20120119124921/http://www.painknowledge.org/aboutpaink.aspx (last visited May 5, 2022).

that the drug's benefits no longer outweigh the risks associated with its use. According to Dr. Janet Woodcock, director of the FDA's Center for Drug Evaluation and Research, the risks include "several serious problems," including "outbreaks of HIV and Hepatitis C from sharing the drug after it was extracted by abusers" and "a[n] outbreak of serious blood disorder." Dr. Woodcock stated that if Endo did not comply with the request, the FDA would issue a notice of a hearing and begin proceedings to compel its removal from the market.

227. On July 6, 2017, Endo pulled Opana ER from the U.S. market.

e) Endo Failed to Monitor and Report Suspicious Sales as Required.

228. The CSA imposes on all "registrants" the obligation to design and operate a system to monitor suspicious orders of controlled substances and requires the registrant to notify the DEA field division office in its area of any suspicious orders. "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).

229. Endo is a "registrant" under the CSA. 21 C.F.R. §1300.02(b) defines a registrant as any person who is registered with the DEA under 21 U.S.C. §823. Section 823, in turn, requires manufacturers of Schedule II controlled substances to register with the DEA.

230. Endo failed to design and operate a system to monitor suspicious orders of controlled substances and/or failed to notify the appropriate DEA field division of suspicious orders. Endo also failed to report sales of suspicious drugs subject to abuse. Endo's failure to timely report these and other suspicious sales violated the CSA.

3. Defendant Cephalon

231. Defendant Cephalon manufactured, marketed, sold, and distributed opioids, nationwide, include the following:

Actiq (fentanyl citrate)	Opioid analgesic; oral transmucosal lozenge; indicated only for the management of breakthrough pain ("BTP") in cancer patients – pain that for a short time "breaks through" medication that otherwise effectively controls a patient's persistent pain – in patients 16 and older with malignancies; commonly referred to as a lollipop because designed to look and perform like one; approved in 1998 with restricted distribution program.	Schedule II
Fentora (fentanyl buccal)	Rapid-release tablet for BTP in cancer patients who are already receiving and tolerant of around-the-clock opioid therapy; approved in 2006.	Schedule II
Generic of OxyContin (oxycodone hydrochloride)	Opiate agonist.	Schedule II

232. Actiq is designed to resemble a lollipop and is meant to be sucked on at the onset of intense breakthrough pain ("BTP")[139] in cancer patients. It delivers fentanyl citrate, a powerful opioid agonist that is 80 times stronger than morphine,[140] rapidly into a patient's bloodstream through the oral membranes.[141] Because it is absorbed through those membranes, it passes directly into circulation without having to go through the liver or stomach, thereby providing faster relief.[142]

[139] Breakthrough pain, or BTP, is an intense spike of pain experienced by some cancer patients when the pain exceeds the level which is controlled by chronic pain medications.
[140] *See* John Carreyrou, *Narcotic "Lollipop" Becomes Big Seller Despite FDA Curbs*, Wall St. J. (Nov. 3, 2006), https://www.wsj.com/articles/SB116252463810112292 (hereinafter, "Carreyrou, *Narcotic Lollipop*").
[141] Actiq would later become part of a category of opioids now known as transmucosal immediate-release fentanyl ("TIRF") products. "Transmucosal" refers to how the opioid is delivered into a patient's bloodstream, across mucous membranes, such as inside the cheek, under the tongue, or in the nose.
[142] *Cephalon, Inc.*, Company-Histories.com, http://www.companyhistories.com/Cephalon-Inc-Company-History.html (last visited May 5, 2022).

233. In November 1998, the FDA approved Actiq for only a very narrow group of people – cancer patients "with malignancies who are already receiving and who are tolerant to opioid therapy for their underlying persistent cancer pain."[143]

234. Understanding the risks of introducing such an intense opioid analgesic to the market, the FDA provided approval of Actiq "*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."[144] Further, the FDA explicitly stated that Actiq "*must not* be used in opioid non-tolerant patients," was contraindicated for the management of acute or postoperative pain, could be deadly to children and was "intended to be used only in the care of opioid-tolerant cancer patients and only by oncologists and pain specialists who are knowledgeable of and skilled in the use of Schedule II opioids to treat cancer pain."

235. The FDA also required that Actiq be provided only in compliance with a strict risk management program that explicitly limited the drug's direct marketing to the approved target audiences, defined as oncologists, pain specialists, their nurses and office staff.[145]

236. In October 2000, Cephalon acquired the worldwide product rights to Actiq and began marketing and selling Actiq in the United States.

237. Cephalon also purchased the rights to Fentora, an even faster-acting tablet formulation of fentanyl, from Cima Labs, and submitted a new drug application to the FDA in August 2005. In September 2006, Cephalon received FDA approval to sell Fentora as a faster-

[143] 1998 FDA Label, https://www.accessdata.fda.gov/drugsatfda_docs/nda/98/20747_Actiq_appltr.pdf.
[144] NDA 20-747 Letter from Cynthia McCormick, Center for Drug Evaluation and Research, to Patricia J. Richards, Anesta Corporation, http://www.accessdata.fda.gov/drugsatfda_docs/appletter/1998/20747ltr.pdf.
[145] Carreyrou, *Narcotic Lollipop*, *supra* n.139.

acting version of Actiq; but once again concerned about the power and risks inherent to fentanyl, the FDA limited Fentora's approval to the treatment of BTP in cancer patients who were already tolerant to around-the-clock opioid therapy for their underlying persistent cancer pain. Cephalon began marketing and selling Fentora in October 2006.

a) Cephalon Falsely and Aggressively Marketed Cancer Drug Actiq to Non-Cancer Treating Physicians.

238. Due to the FDA's restrictions, Actiq's consumer base was limited, as was its potential for revenue growth. In order to increase its revenue and market share, Cephalon needed to find a broader audience for the drug, and thus began marketing its opioid lollipop to treat headaches, back pain, sports injuries, and other chronic non-cancer pain. Cephalon targeted non-oncology practices, including, but not limited to, pain doctors, general practitioners, migraine clinics, anesthesiologists, and sports clinics. It did so in violation of applicable regulations prohibiting the marketing of medications for off-label use and in direct contravention of the FDA's strict instructions that Actiq be prescribed only to terminal cancer patients and by oncologists and pain management doctors experienced in treating cancer pain.

239. According to "[d]ata gathered from a network of doctors by research firm ImpactRx between June 2005 and October 2006" ("ImpactRx Survey"), Cephalon sales representatives' visits to non-oncologists to market Actiq increased six-fold between 2002 and 2005. Cephalon representatives would reportedly visit non-oncologists monthly, providing up to 60 or 70 coupons (each coupon was good for six free Actiq lozenges) and encouraging prescribers to try Actiq on their non-cancer patients.[146]

[146] *Id.*

240. Cephalon's efforts paid off. In 2000, Actiq generated $15 million in sales.[147] By 2002, it attributed a 92% increase in Actiq sales 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."[148] By 2005, Actiq's sales total had jumped to $412 million, making it Cephalon's second-best-selling drug. By the end of 2006, Actiq's sales had exceeded $500 million.

241. Although Actiq is a drug approved for only a very narrow customer base, during the first six months of 2006, only 1% of the 187,076 prescriptions for Actiq filled at retail pharmacies were prescribed by oncologists. Results of the ImpactRx Survey suggested that "more than 80 percent of patients who use[d] the drug don't have cancer."[149]

b) Government Investigations Found Cephalon Inappropriately Marketed Actiq for Off-Label Uses.

242. Beginning in or about 2003, former Cephalon employees filed four whistleblower lawsuits claiming the company had wrongfully marketed Actiq for unapproved, off-label uses. On September 29, 2008, Cephalon finalized and entered into a corporate integrity agreement with the Office of the Inspector General of HHS and agreed to pay $425 million in civil and criminal penalties for its off-label marketing of Actiq and two other drugs (Gabitril and Provigil). According to a U.S. Department of Justice ("DOJ") press release, Cephalon trained sales representatives to disregard restrictions of the FDA-approved label, employed sales

[147] *Id.*
[148] Cephalon, Inc. Annual Report (Form 10-K) at 28 (Mar. 31, 2003), http://getfilings.com/o0001047469-03-011137.html.
[149] Carreyrou, *Narcotic Lollipop*, *supra* n.139.

representatives and healthcare professionals to speak to physicians about off-label uses of the three drugs, and funded CME to promote off-label uses.[150]

243. Upon information and belief, documents uncovered in the government's investigations confirm that Cephalon directly targeted non-oncology practices and pushed its sales representatives to market Actiq for off-label use. For instance, the government's investigations confirmed:

- Cephalon instructed its sales representatives to ask non-cancer doctors whether they have the potential to treat cancer pain. Even if the doctor answered "no," a decision tree provided by Cephalon instructed the sales representatives to give these physicians free Actiq coupons.

- Cephalon targeted neurologists to encourage them to prescribe Actiq to patients with migraine headaches.

- Cephalon sales representatives used the assistance of outside pain management specialists when visiting non-cancer physicians to pitch Actiq. The pain management specialist would falsely inform the physician that Actiq does not cause patients to experience a "high" and carries a low risk of diversion toward recreational use.

- Cephalon set sales quotas for its sales and marketing representatives that could not possibly have been met solely by promoting Actiq for its FDA-approved indication.

- Cephalon promoted the use of higher doses of Actiq than patients required by encouraging prescriptions of the drug to include larger-than-necessary numbers of lozenges with unnecessarily high doses of fentanyl.

- Cephalon promoted Actiq for off-label use by funding and controlling CME seminars that promoted and misrepresented the efficacy of the drug for off-label uses such as treating migraine headaches and for patients not already opioid tolerant.[151]

[150] Press Release, U.S. Department of Justice, Pharmaceutical Company Cephalon To Pay $425 Million For Off-Label Drug Marketing (Sept. 29, 2008), https://www.justice.gov/archive/usao/pae/News/2008/sep/cephalonrelease.pdf.
[151] John Carreyrou, *Cephalon Used Improper Tactics to Sell Drug, Probe Finds*, Wall St. J. Nov. 21, 2006, at B1 (hereinafter, "Carreyrou, *Cephalon Used Improper Tactics*").

244. Still, the letters, the FDA's safety alert, the government's investigations, and the massive settlement seemed to have had little effect on Cephalon as it continued its deceptive marketing strategy for both Actiq and Fentora.

c) Cephalon Falsely and Aggressively Marketed Cancer Drug Fentora to Non-Cancer Treating Physicians.

245. From the time it introduced Fentora to the market in October 2006, Cephalon targeted non-cancer doctors; falsely represented Fentora as a safe, effective off-label treatment for noncancer pain; and continued its disinformation campaign about the safety and non-addictiveness of Fentora specifically and opioids generally. In fact, Cephalon targeted the same pain specialists and non-oncologists that it had targeted with its off-label marketing of Actiq, simply substituting Fentora.

246. During an investor earnings call shortly after Fentora's launch, Cephalon's CEO described the "opportunity" presented by the use of Fentora for non-cancer pain:

> *The other opportunity of course is the prospect for FENTORA outside of cancer pain, in indications such as breakthrough lower back pain and breakthrough neuropathic pain*.
>
> * * *
>
> Of all the patients taking chronic opioids, 32% of them take that medication to treat back pain, and 30% of them are taking their opioids to treat neuropathic pain. In contrast only 12% are taking them to treat cancer pain, 12%.
>
> We know from our own studies that breakthrough pain episodes experienced by these non-cancer sufferers respond very well to FENTORA. And for all these reasons, we are tremendously excited about the significant impact FENTORA can have on patient health and well-being and the exciting growth potential that it has for Cephalon.
>
> In summary, we have had a strong launch of FENTORA and continue to grow the product aggressively. Today, that growth is coming from the physicians and patient types that we have identified through our efforts in the field over the last

> seven years. In the future, with new and broader indications and a much bigger field force presence, the opportunity that FENTORA represents is enormous.[152]

d) The FDA Warned Cephalon Regarding its False and Off-Label Marketing of Fentora.

247. 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 warned of death or life-threatening side effects. The FDA warned: Fentora should not be used to treat any type of short-term pain such as headaches or migraines, and that it should be used only under the close supervision of a doctor.[153]

248. Nevertheless, in 2008, Cephalon pushed forward to expand the target base for Fentora and filed a supplemental drug application requesting FDA approval of Fentora for the treatment of non-cancer BTP. In the application and supporting presentations to the FDA, Cephalon admitted both that it knew the drug was heavily prescribed for off-label use and that the drug's safety for such use had never been clinically evaluated.[154] An FDA advisory committee lamented that Fentora's existing risk management program was ineffective and stated that Cephalon would have to institute a risk evaluation and mitigation strategy for the drug before the FDA would consider broader label indications. In response, Cephalon revised Fentora's label and medication guide to add strengthened warnings.

249. But in 2009, the FDA once again informed Cephalon that the risk management program was not sufficient to ensure the safe use of Fentora for already approved indications.

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[152] Seeking Alpha, Transcript of Q1 2007 Cephalon, Inc. Earnings Conference Call (May 1, 2007), http://seekingalpha.com/article/34163-cephalon-q1-2007-earnings-call-transcript.
[153] FDA safety page: How to use Fentora safely, Drug Topics, https://www.drugtopics.com/fda/fda-safety-page-how-use-fentora-safely (last accessed May 6, 2022).
[154] *FENTORA (fentanyl buccal tablet) CII, Joint Meeting of Anesthetic and Life Support Drugs and Drug Safety and Risk Management Advisory Committee*, U.S. Food & Drug Administration (May 6, 2008).

250. 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." Rather, Fentora was indicated only for those who were already opioid tolerant. It also criticized Cephalon's other direct Fentora advertisements because they did not disclose the risks associated with the drug.

251. Flagrantly disregarding the FDA's refusal to approve Fentora for non-cancer BTP and its warning against marketing the drug for the same, Cephalon continued to use the same sales tactics to push Fentora as it did with Actiq.

252. For example, on January 13, 2012, Cephalon published 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 stated: "It is well recognized that the judicious use of opioids can facilitate effective and safe management of chronic pain."[155]

e) Cephalon Funded False Publications and Presentations.

253. Along with its direct marketing, Cephalon indirectly marketed through third parties to change the way doctors viewed and prescribed opioids – disseminating the unproven and deceptive messages that opioids were safe for the treatment of chronic, long-term pain; that they were non-addictive; and that they were woefully under-prescribed to the detriment of

[155] *An Integrated Risk Evaluation and Mitigation Strategy (REMS) for FENTORA (Fentanyl Buccal Tablet) and ACTIQ (Oral Transmucosal Fentanyl Citrate)*, Pharmacy Times (Jan. 13, 2012), http://www.pharmacytimes.com/publications/issue/2012/january2012/r514-jan-12-rems.

patients who were needlessly suffering. It did so by sponsoring pro-opioid front groups, misleading prescription guidelines, articles, and CME programs, as well as by paying physicians thousands of dollars every year to publicly opine that opioids were safe, effective, and non-addictive for many uses.

254. Cephalon sponsored numerous CME programs, which were made widely available through organizations like Medscape, LLC ("Medscape") and which disseminated false and misleading information to physicians across the country.

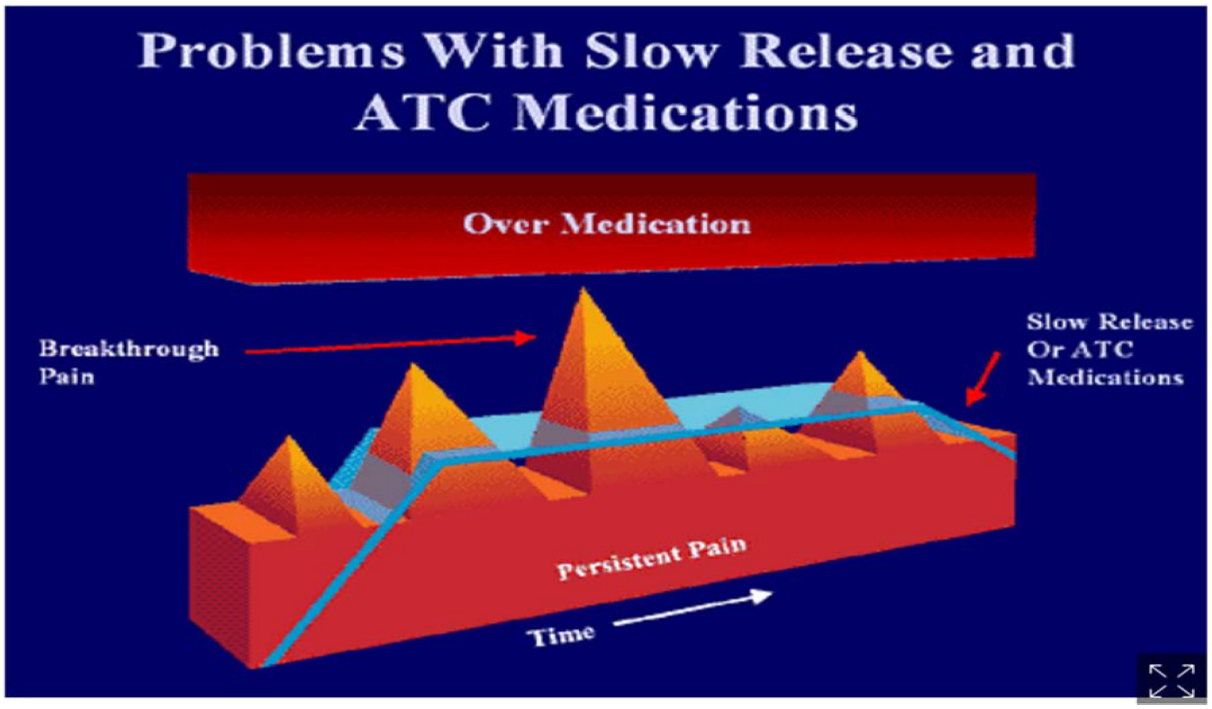
255. For example, a 2003 Cephalon-sponsored CME presentation titled, "Pharmacologic Management of Breakthrough or Incident Pain," posted on Medscape in February 2003, stated:

> [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.[156]

256. 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 "previously operated back, complex regional pain syndromes, the neuropathies, and interstitial cystitis." (One slide from that CME presentation is set forth below.) The presentation describes the pain process as a non-time-

[156] Michael J. Brennan et al., *Pharmacologic Management of Breakthrough or Incident Pain*, Medscape, https://www.medscape.org/viewarticle/449803 (last visited May 5, 2022).

dependent continuum that requires a balanced analgesia approach using "targeted pharmacotherapeutics to affect multiple points in the pain-signaling pathway."[157] The doctor lists fentanyl as one of the most effective opioids available for treating BTP, 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.



257. Dr. Stephen H. Landy ("Landy") authored a 2004 CME manuscript available on Medscape titled, "Oral Transmucosal Fentanyl Citrate for the Treatment of Migraine Headache Pain In Outpatients: A Case Series." The manuscript preparation was supported by Cephalon. Landy describes the findings of a study of fentanyl citrate to treat migraine headache pain and concluded that "OTFC rapidly and significantly relieved acute, refractory migraine pain in

[157] Daniel S. Bennett, *Breakthrough Pain: Treatment Rationale With Opioids*, Medscape, https://www.medscape.org/viewarticle/461612 (last visited May 5, 2022).

outpatients . . . and was associated with high patient satisfaction ratings."[158] Based on an analysis of publicly available data, Cephalon paid Landy approximately $190,000 in 2009-2010 alone, and in 2015-2016, Cephalon paid Landy another $75,000.

258. In 2006, Cephalon sponsored a review of scientific literature to create additional fentanyl-specific dosing guidelines titled, *Evidence-Based Oral Transmucosal Fentanyl Citrate (OTFC®) Dosing Guidelines*.[159] The article purports to review the evidence for dosing and efficacy of oral transmucosal fentanyl citrate in the management of pain and produce dosing guidelines in both cancer and non-cancer patients. It states:

> Oral transmucosal fentanyl citrate has a proven benefit in treating cancer associated breakthrough pain in opioid-tolerant patients with cancer, which is the Food and Drug Administration (FDA)-approved indication for Actiq. *Pain medicine physicians have also used OTFC successfully to provide rapid pain relief in moderate to severe noncancer pain in both opioid-tolerant and opioid-nontolerant patients*.[160]

259. Later in the article, the authors attempt to assuage doctors' concerns regarding possible overdose and respiratory distress in non-cancer patients by arguing "*[t]here is no evidence that opioid safety and efficacy differs in opioid-tolerant patients with chronic noncancer pain*." Regarding the use of fentanyl to treat non-opioid-tolerant patients, the article's authors stated:

> Alternatively, *OTFC might also be used cautiously and safely for* acute pain experienced by *patients who are not opioid tolerant*. *Parenteral opioids are routinely used for acute pain in patients who are not opioid tolerant*. Examples include episodic pain (*i.e.*, refractory migraine pain, recurrent renal calculi, etc.) and acute pain that follows surgery, trauma, or painful procedures (burn dressing change, bone marrow aspiration, lumbar puncture). Assuming that clinical

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[158] Stephen H. Landy, *Oral Transmucosal Fentanyl Citrate for the Treatment of Migraine Headache Pain In Outpatients: A Case Series*, 44(8) Headache (2004), https://www.medscape.com/viewarticle/488337_2 (last visited May 6, 2022).
[159] Gerald M. Aronoff et al., *Evidence-Based Oral Transmucosal Fentanyl Citrate (OTFC) Dosing Guidelines*, 6(4) Pain Med. 305-14 (Aug. 2005).
[160] *Id*.

> experience with IV morphine in patients who are not opioid tolerant can be extrapolated, OTFC should be safe and efficacious in such settings as well.[161]

260. Through its sponsorship of FSMB, Cephalon continued to encourage the prescribing of opioid medication to "reverse . . . and improve" patient function, attributing patients' displays of traditional drug-seeking behaviors as merely "pseudoaddiction."

261. Cephalon also disseminated its false messaging through speakers' bureaus and publications. For example, at an AAPM annual meeting held February 22 through 25, 2006, Cephalon sponsored a presentation by Webster and others titled, "Open-label study of fentanyl effervescent buccal tablets in patients with chronic pain and breakthrough pain: Interim safety results." The presentation's agenda description states: "Most patients with chronic pain experience episodes of breakthrough pain (BTP), yet no currently available pharmacologic agent is ideal for its treatment." The presentation purports to cover a study analyzing the safety of a new form of fentanyl buccal tablets in the chronic pain setting and promises to show the "[i]nterim results of this study suggest that FEBT is safe and well-tolerated in patients with chronic pain and BTP."

262. Cephalon sponsored another CME presentation written by Webster and M. Beth Dove titled, "Optimizing Opioid Treatment for Breakthrough Pain" and offered on Medscape from September 28, 2007, through December 15, 2008. The presentation stated that non-opioid analgesics and combination opioids containing non-opioids such as aspirin and acetaminophen are less effective at treating BTP than pure opioid analgesics because of dose limitations on the non-opioid component.

263. Fine authored a Cephalon-sponsored CME presentation titled, "Opioid-Based Management of Persistent and Breakthrough Pain," with Drs. Christine A. Miaskowski and

[161] *Id.*

Michael J. Brennan. Cephalon paid to have this CME presentation published as a "Special Report" supplement of the journal *Pain Medicine News* in 2009.[162] The CME presentation targeted various non-oncologist healthcare providers who treat patients with chronic pain to educate "health care professionals about a semi-structured approach to the opioid-based management of persistent and breakthrough pain," including the use of fentanyl. The CME presentation purported to analyze the "combination of evidence- and case-based discussions" and ultimately concluded:

> *All individuals with chronic, moderate to severe pain associated with functional impairment should be considered for a trial or opioid therapy, although not all of them will be selected.*[163]

264. Along with co-conspirator Purdue, Cephalon sponsored the APF's guide, which warned against the purported *under*-prescribing of opioids, taught that addiction is ***rare***, and suggested that opioids have "*no ceiling dose*" and are therefore the most appropriate treatment for severe pain. A summary of the February 12-16, 2008, AAPM annual meeting reinforced the message, promoted both by the AAPM and the APS, that "the undertreatment of pain is unjustified." It continued, *"Pain management is a fundamental human right* in all patients not only with acute postoperative pain but also *in patients suffering from chronic pain*."[164]

265. Cephalon was one of several opioid manufacturers who collectively paid 14 of the 21 panel members who drafted the 2009 APS-AAPM opioid treatment guidelines.[165]

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[162] Perry G. Fine et al., *Opioid-Based Management of Persistent and Breakthrough Pain*, Special Report (2009), https://www.yumpu.com/en/document/view/11409251/opioid-basedmanagement-of-persistent-and-breakthrough-pain/9.
[163] *Id*.
[164] Mohamed A. Elkersh & Zahid H. Bajwa, *Highlights From the American Academy of Pain Medicine 24th Annual Meeting*, 2(1) Advances in Pain Management 50-52 (2008).
[165] *See* Chou, *Clinical Guidelines*, *supra* n. 79.

266. In the March 2007 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,"[166] published in the nationally circulated journal *Pain Medicine*, physicians paid by Cephalon (including Webster) described the results of a Cephalon-sponsored study seeking to expand the definition of BTP to the chronic, non-cancer setting. The authors stated that the "OTFC 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."[167] 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 cited Portenoy and recommended 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.[168]

267. Cephalon also sponsored, through an educational grant, the regularly published journal *Advances in Pain Management*. A single 2008 issue of the journal contained numerous articles from Portenoy, Dr. Steven Passik ("Passik"), Dr. Kenneth L. Kirsh ("Kirsh"), and Webster, all advancing the safety and efficacy of opioids. In an article titled, "Screening and Stratification Methods to Minimize Opioid Abuse in Cancer Patients," Webster expressed disdain for the prior 20 years of opioid phobia.

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[166] Donald R. Taylor et al., *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 (OTFC, ACTIQ)*, 8(3) Pain Med. 281-88 (Mar. 2007).
[167] *Id.*
[168] *Id.*

268. In another article from the same issue, "Appropriate Prescribing of Opioids and Associated Risk Minimization," Passik and Kirsh stated: "[c]hronic pain, currently experienced by approximately 75 million Americans, is becoming one of the biggest public health problems in the US." They assert that addiction is rare, that "[m]ost pain specialists have prescribed opioids for long periods of time with success demonstrated by an improvement in function" and that then-recent work had shown "that opioids do have efficacy for subsets of patients who can remain on them long term and have very little risk of addiction."[169]

269. In November 2010, Fine and others published an article presenting the results of another Cephalon-sponsored study titled, "Long-Term Safety and Tolerability of Fentanyl Buccal Tablet for the Treatment of Breakthrough Pain in Opioid-Tolerant Patients with Chronic Pain: An 18-Month Study."[170] In that article, Fine explained that the 18-month "open-label" study "assessed the safety and tolerability of FBT [Fentora] for the [long-term] treatment of BTP in a large cohort . . . of opioid-tolerant patients receiving around-the-clock . . . opioids for noncancer pain." The article acknowledged that: (a) "[t]here has been a steady increase in the use of opioids for the management of chronic noncancer pain over the past two decades"; (b) the "widespread acceptance" had led to the publishing of practice guidelines "to provide evidence- and consensus-based recommendations for the optimal use of opioids in the management of chronic pain"; and (c) those guidelines lacked "data assessing the long-term benefits and harms of opioid therapy for chronic pain."[171]

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[169] Steven D. Passik & Kenneth L. Kirsh, *Appropriate Prescribing of Opioids and Associated Risk Minimization*, 2(1) Advances in Pain Management 9-16 (2008).
[170] Perry G. Fine et al., *Long-Term Safety and Tolerability of Fentanyl Buccal Tablet for the Treatment of Breakthrough Pain in Opioid-Tolerant Patients with Chronic Pain: An 18-Month Study*, 40(5) J. Pain & Symptom Management 747-60 (Nov. 2010).
[171] *Id*.

270. The article concluded: "[T]he safety and tolerability profile of FBT in this study was generally typical of a potent opioid. The [adverse events] observed were, in most cases, predictable, manageable, and tolerable." That article concluded that the number of abuse-related events was "small."[172]

271. From 2000 forward, Cephalon has paid doctors nationwide millions of dollars for programs relating to its opioids, many of whom were not oncologists and did not treat cancer pain. These doctors included Portenoy, Webster, Fine, Passik, Kirsh, Landy, and others.

272. Cephalon's payments to doctors have resulted in studies that support its sales but are biased or irreparably flawed. For instance, and upon information and belief, the governmental whistleblower investigation into Actiq revealed that two studies touted by Cephalon had tested fewer than 28 patients and had no control group.[173] A 2012 article evaluating the then status of transmucosal fentanyl tablet formulations for the treatment of BTP in cancer patients noted that clinical trials to date used varying criteria, that "the approaches taken . . . [did] not uniformly reflect clinical practice," and that "the studies ha[d] been sponsored by the manufacturer and so ha[d] potential for bias."[174]

273. Defendant Teva, which acquired Cephalon, repeatedly refused to produce information requested as part of a Senate investigation into opioid manufacturers and distributors. Senator McCaskill issued requests on July 26, 2017, and September 28, 2017. In a letter to Teva sent September 28, 2017, Senator McCaskill explained that "the company's decision to obstruct basic oversight on the opioid epidemic should deeply concern shareholders." On March 6, 2018, Senator McCaskill issued a press release castigating Teva for its continued

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[172] *Id*.
[173] Carreyrou, *Cephalon Used Improper Tactics*, *supra* n. 150.
[174] Eric Prommer & Brandy Fleck, *Fentanyl transmucosal tablets: current status in the management of cancer-related breakthrough pain*, 2012(6) Patient Preference and Adherence 465-75 (June 25, 2012).

refusal to comply with her requests: "Teva's refusal to cooperate with Congressional requests strongly suggests they have something to hide."[175] As of July 12, 2018, the date Senator McCaskill's third report titled, *Fueling an Epidemic: A Flood of 1.6 Billion Doses of Opioids into Missouri and the Need for Stronger DEA Enforcement*, was published, Teva remained uncooperative.[176]

f) Cephalon Failed to Monitor and Report Suspicious Sales as Required.

274. The CSA imposes on all "registrants" the obligation to design and operate a system to monitor suspicious orders of controlled substances and requires the registrant to notify the DEA field division office in its area of any suspicious orders. "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).

275. Cephalon is a "registrant" under the federal CSA. 21 C.F.R. §1300.02(b) defines a registrant as any person who is registered with the DEA under 21 U.S.C. §823. Section 823, in turn, requires manufacturers of Schedule II controlled substances to register with the DEA.

276. Cephalon failed to design and operate a system to monitor suspicious orders of controlled substances and/or failed to notify the appropriate DEA field division of suspicious orders. Cephalon's failure to timely report these and other suspicious sales violated the CSA.

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[175] Press Release, U.S. Senate Committee on Homeland Security & Governmental Affairs, McCaskill: Teva Is Stonewalling a Senate Investigation (Mar. 6, 2018), https://www.hsgac.senate.gov/media/minority-media/mccaskill-teva-is-stonewalling-a-senate-investigation.

[176] *Fueling an Epidemic, Report Three: A Flood of 1.6 Billion Doses of Opioids into Missouri and the Need for Stronger DEA Enforcement*, U.S. Senate Homeland Security & Governmental Affairs Committee, Ranking Member's Office at 1 (July 12, 2018), https://www.hsgac.senate.gov/imo/media/doc/REPORT-Fueling%20an%20Epidemic-A%20Flood%20of%201.6%20Billion%20Doses%20of%20Opioids%20into%20Missouri%20and%20the%20Need%20for%20Stronger%20DEA%20Enforcement.pdf (hereinafter, "*July 2018 McCaskill Report*").

4. Defendant Actavis

277. Defendant Actavis has manufactured, marketed, sold, and distributed pharmaceutical drugs nationwide. Until it sold its portfolio of generic opioids to Defendant Teva, Actavis was among the largest U.S. suppliers of opioid pain medications.

278. Among the drugs Actavis distributes or distributed during the times relevant to the allegations herein are the following:

Kadian (morphine sulfate, extended release)	Opioid agonist indicated for the management of pain severe enough to require daily, around-the-clock, long-term opioid treatment and for which alternative treatments are inadequate. 20 mg, 50 mg, and 100 mg strengths approved by the FDA in 1996. 30 mg and 60 mg strengths approved by the FDA in 2001. 80 mg strength approved by the FDA in 2006. 10 mg and 200 mg strengths approved by the FDA in 2007. 40 mg, 70 mg, 130 mg, and 150 mg strengths approved by the FDA in 2012.	Schedule II
Norco (hydrocodone bitartate and Acetaminophen	Opioid agonist initially indicated for the relief of moderate to moderately severe pain. Later, indication amended to treat acute pain sever enough to require opioid analgesic and for which alternative treatments are inadequate. Norco was initially approved by the FDA in 1997.	Schedule III (1997-2014) Schedule II (2014-present)
Oxymorphone hydrochloride	Generic equivalent of Opana ER. Launched in 2013.	Schedule II
Morphine sulfate	Generic equivalent of Kadian. Launched in 2013.	Schedule II
Fentanyl citrate transdermal	Generic equivalent of Duragesic. Launched in 2007.	Schedule II

279. Actavis acquired Kadian from King Pharmaceuticals in 2008 for an amount up to $127.5 million, depending on quarterly sales-related milestones.

280. Actavis marketed and sold generic opioids until it sold its generic opioid portfolio for $40.5 billion to Defendant Teva in 2016.

a) The FDA Issued a Warning Letter to Actavis Concerning Extensive False and Misleading Claims in Kadian Marketing Materials.

281. On February 18, 2010, the FDA's Division of Drug Marketing, Advertising, and Communications issued a warning letter ("2010 Warning Letter") to Actavis concerning the marketing of Kadian. The letter warned that certain marketing materials for Kadian "are false or misleading because they omit and minimize the serious risks associated with the drug, broaden and fail to present the limitations to the approved indication of the drug, and present unsubstantiated superiority and effectiveness claims" in violation of the FDCA and regulations promulgated thereunder. The 2010 Warning Letter addressed two marketing materials: a Comparison Detailer and a Co-Pay Assistance Program brochure.

282. According to the 2010 Warning Letter, the marketing materials "present several effectiveness claims for Kadian but fail to present any contraindications, and also omit several warnings, precautions, drug interactions and adverse events" including by failing to include "warnings regarding potentially fatal abuse of opioids [and] use by individuals other than the patient for whom the drug was prescribed."

283. The 2010 Warning Letter also states that the Comparison Detailer "fails to present risk information with a prominence and readability that is reasonably comparable to the presentation of benefit information." Whereas "the first five of the six pages of the Comparison Detailer prominently present efficacy claims about Kadian using large, bolded headers and claims surrounded by a significant amount of white space . . . using colorful charts and graphs," "the only specific risk information presented is relegated to the back cover . . . in a small font . . . beneath a large, bolded headline claim that presents a benefit claim."

284. The 2010 Warning Letter provides that the effect of these presentations "minimizes the risks associated with Kadian and misleadingly suggests that Kadian is safer than has been demonstrated."

285. Further, the 2010 Warning Letter states that Kadian promotional materials were misleading because they "present broad claims about the drug's use in treating pain, therefore implying that Kadian is appropriate for use in a broader range than it is approved to treat." The 2010 Warning Letter cites these examples from the Comparison Detailer:

- "Allow for less breakthrough pain and more consistent pain relief for patients."
- "Better pain control . . . ."
- "Improved pain control . . . ."
- "Allow patients to live with less pain . . . ."
- "Less Pain. More options."

286. According to the 2010 Warning Letter, "[t]hese presentations in the Comparison Detailer suggest that Kadian is appropriate for patients with broader types of pain than the drug is indicated for."

287. The 2010 Warning Letter found similar problems in the Co-Pay Assistance Program brochure, which included these statements (emphases in original):

- "**Why is pain management important?** Pain management is a large part of your overall health care plan. Many Americans suffer from chronic or ongoing pain . . . Managing your pain the right way begins by talking to your healthcare provider. Discover the cause of your pain by taking note of what makes your pain start and what makes it worse."
- "**What is chronic pain?** Chronic pain is ongoing and can last longer than 6 months. Chronic pain can be mild or severe. . . ."
- "**How can I treat my chronic pain?** To help manage your pain, your healthcare provider will determine what level of pain control you need.

> Depending on what kind of pain you have and how it affects your life, your healthcare provider will choose a drug that works just for you."

288. The 2010 Warning Letter states that these statements "suggest[] that patients with broader types of chronic pain than the drug is indicated for are appropriate candidates for Kadian therapy, when this is not the case. . . . Kadian is *only* appropriate for a very limited patient population who experience pain." (Emphasis in original.) It continues, "[i]n addition, the partial indication included on the back cover of the Co-Pay Assistance Program brochure, unlike the chronic pain information, is written in technical medical language that is not likely to be easily understood by consumers."

289. Next, the 2010 Warning Letter identifies unsubstantiated superiority claims, including that Kadian "[a]llow[s] for less breakthrough pain and more consistent pain relief for patients" and asks, "Why settle for generic MS Contin tablets . . . When you can prescribe the benefits of KADIAN capsules?" According to the Letter, these "claims and presentations misleadingly imply that Kadian has been shown to be superior to MS Contin or generic controlled-release morphine" but the "FDA is not aware of ***any*** substantial evidence or substantial clinical expertise that supports these claims and presentations." (Emphasis in original.)

290. The 2010 Warning Letter also identifies the following claims "supported by a historically controlled study of inadequate design, completely lacking any concurrent control"; "[b]etter pain control and improved sleep scores"; "[i]mproved pain control and sleep scores in patients treated with KADIAN who were previously on CR morphine tablets"; and "[a]llow patients to live with less pain and get adequate rest with less medication." The 2010 Warning Letter states that the trial identified in support of these claims "clearly do[es] not support any conclusion that Kadian is superior to alternative treatments in pain or sleep measures."

291. Further, the 2010 Warning Letter focuses on the Comparison Detailer's inclusion of dosing claims comparing Kadian with MS Contin and Avinza. The Detailer claims that Kadian presents "[f]ewer barriers to prescribing" because "[t]he unique dosing flexibility of KADIAN gives you more options with morphine" than does MS Contin or Avinza. However, "the FDA is unaware of any substantial evidence or substantial clinical experience to support the claim that the above dosing characteristics allow Kadian to have 'fewer barriers to prescribing' (the meaning of which is not clear) as compared to other extended-release morphine products."

292. In conclusion, the 2010 Warning Letter found that the Comparison Detailer and Co-Pay Assistance Program brochure "misbrand Kadian in violation of the [FDCA]."

b) Actavis Failed to Monitor and Report Suspicious Sales as Required.

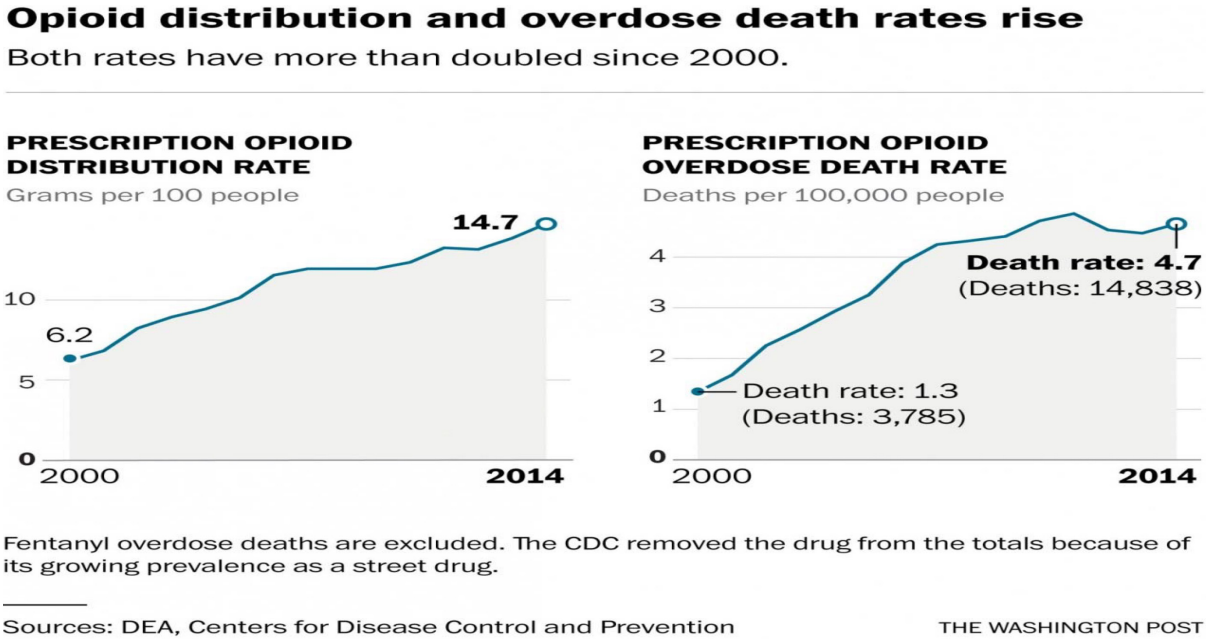
293. The CSA imposes on all "registrants" the obligation to design and operate a system to monitor suspicious orders of controlled substances and requires the registrant to notify the DEA field division office in its area of any suspicious orders. "Suspicious orders include orders of unusual size, orders deviating substantially from a normal pattern, and orders of unusual frequency." 21 C.F.R. §1301.74(b).

294. Actavis is a "registrant" under the CSA. 21 C.F.R. §1300.02(b) defines a registrant as any person who is registered with the DEA under 21 U.S.C. §823. Section 823, in turn, requires manufacturers of Schedule II controlled substances to register with the DEA.

295. Actavis failed to design and operate a system to monitor suspicious orders of controlled substances and/or failed to notify the appropriate DEA field division of suspicious orders. Actavis's failure to timely report these and other suspicious sales violated the CSA.

D. The Distributor Defendants Failed to Track and Report Suspicious Sales as Required by Federal Law.

296. Manufacturers rely on wholesale distributors to distribute their drugs. Distributor Defendants McKesson, Defendant Cardinal Health, and Defendant Amerisource Bergen are hereinafter collectively referred to as the "Distributor Defendants." They serve as middlemen, sending billions of doses of opioid pain pills to pharmacists, hospitals, nursing homes, and pain clinics. According to the CDC, the increased distribution of opioids directly correlates to increased overdose death rates:



297. On October 23, 2017, CBS aired an episode of *60 Minutes* featuring former DEA agent Joe Rannazzisi ("Rannazzisi"), who blamed opioid distributors for killing people by violating the CSA requirement to report suspicious orders:

> **RANNAZZISI**: This is an industry that's out of control. What they wanna do, is do what they wanna do, and not worry about what the law is. And if they don't follow the law in drug supply, people die. That's just it. People die.
>
> * * *

> This is an industry that allowed millions and millions of drugs to go into bad pharmacies and doctors' offices, that distributed them out to people who had no legitimate need for those drugs.
>
> **[INTERVIEWER]**: Who are these distributors?
>
> **RANNAZZISI**: The three largest distributors are Cardinal Health, McKesson, and AmerisourceBergen. They control probably 85 or 90 percent of the drugs going downstream.
>
> **[INTERVIEWER]**: You know the implication of what you're saying, that these big companies knew that they were pumping drugs into American communities that were killing people.
>
> **RANNAZZISI**: That's not an implication, that's a fact. That's exactly what they did.[177]

298. Jim Geldhof ("Geldhof"), a 40-year veteran of the DEA who ran investigations in the Detroit field office, corroborated Rannazzisi's account, saying that the distributors are "absolutely" responsible for the opioid epidemic:

> **[INTERVIEWER]**: These companies are a big reason for this epidemic?
>
> **GELDHOF**: Yeah, absolutely they are. And I can tell you with 100 percent accuracy that we were in there on multiple occasions trying to get them to change their behavior. And they just flat out ignored us.[178]

1. Defendant McKesson

299. Defendant McKesson, headquartered in San Francisco, is a wholesale pharmaceutical distributor of controlled and uncontrolled prescription medications, including opioids. It is the largest pharmaceutical drug distributor in the United States. It distributes pharmaceuticals through a network of distribution centers across the country. McKesson ranked fifth on the 2017 Fortune 500 list, with over $192 billion in revenues.

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[177] Bill Whitaker, *Ex-DEA Agent: Opioid Crisis Fueled by Drug Industry and Congress*, CBS News (Jun. 17, 2018), https://www.cbsnews.com/news/60-minutes-ex-dea-agent-opioid-crisis-fueled-by-drug-industry-and-congress/.
[178] *Id*.

300. McKesson has supplied various pharmacies in the United States, including Florida, an increasing amount of prescription opioids, products frequently misused that are at the heart of the current opioid epidemic.

301. McKesson distribution centers are required to operate in accordance with the statutory provisions of the CSA. The regulations promulgated under the CSA include a requirement to design and operate a system to detect and report "suspicious orders" for controlled substances, as that term is defined in the regulation. *See* 21 C.F.R. §1301.74(b). The CSA authorizes imposing a civil penalty of up to $10,000 for each violation of 21 C.F.R. §1301.74(b). *See* 21 U.S.C. §842(a)(5) & (c)(1)(B).

302. In or about 2007, the DEA accused McKesson of failing to report suspicious orders and launched an investigation. In 2008, McKesson entered into a settlement agreement with the DOJ and a memorandum of agreement, agreeing to pay a $13.25 million fine for failure to report suspicious orders of pharmaceutical drugs and promising to set up a monitoring system.

303. As a result, McKesson developed a Controlled Substance Monitoring Program ("CSMP") but still failed to design and implement an effective system to detect and report "suspicious orders" for controlled substances distributed to its independent and small chain pharmacy customers—*i.e.*, orders unusual in their frequency, size, or in some other way. McKesson continued to fail to detect and disclose suspicious orders of controlled substances. It failed to conduct adequate due diligence on its new or existing customers, failed to keep complete and accurate records in the CSMP files maintained for many of its customers, and bypassed suspicious order reporting procedures set forth in the CSMP.

304. In 2011, McKesson's then-director of regulatory affairs, David B. Gustin, told his colleagues that he was concerned about the "number of accounts we have that have large gaps

between the amount of Oxy or Hydro they are allowed to buy … and the amount they really need … This increases the 'opportunity' for diversion by exposing more product for introduction into the pipeline than may be used for legitimate purposes."[179]

305. In 2013, the DEA again began investigating reports that McKesson was failing to maintain proper controls to prevent the diversion of opioids and accused McKesson of failing to design and use an effective system to detect "suspicious orders" from pharmacies for powerful painkillers such as oxycodone, as required by the CSA. Nine DEA field divisions and 12 U.S. Attorneys General built a case against McKesson for the company's role in the opioid crisis, which David Schiller ("Schiller"), then Assistant Special Agent in Charge for the Denver Field Division and leader of the DEA team investigating McKesson, called "the best case we've ever had against a major distributor in the history of the Drug Enforcement Administration."[180]

306. On December 17, 2017, CBS aired an episode of *60 Minutes* featuring Assistant Special Agent Schiller, who described McKesson as a company that killed people for its own financial gain and blatantly ignored the CSA requirement to report suspicious orders:

> **SCHILLER**: If they would [have] stayed in compliance with their authority and held those that they're supplying the pills to, the epidemic would be nowhere near where it is right now. Nowhere near.
>
> * * *
>
> They had hundreds of thousands of suspicious orders they should have reported, and they didn't report any. There's not a day that goes by in the pharmaceutical world, in the McKesson world, in the distribution world, where there's not something suspicious. It happens every day.

[179] Scott Higham, Sari Horwitz, and Steven Rich, Internal drug company emails show indifference to opioid epidemic, Washington Post (July 19, 2019), https://www.washingtonpost.com/investigations/internal-drug-company[1]emails-show-indifference-to-opioid-epidemic-ship-ship-ship/2019/07/19/003d58f6-a993-11e9- a3a6-ab670962db05_story.html?utm_term=.a3f264b7138e.

[180] Bill Whitaker, *Whistleblowers: DEA Attorneys Went Easy on McKesson, the Country's Largest Drug Distributor*, CBS News (Dec. 17, 2017), https://www.cbsnews.com/news/whistleblowers-dea-attorneys-went-easy-on-mckesson-the-countrys-largest-drug-distributor/.

> **[INTERVIEWER]**: And they had none.
>
> **SCHILLER**: They weren't reporting any. I mean, you have to understand that, nothing was suspicious?[181]

307. Indeed, according to the DOJ, McKesson continued to fail to report suspicious orders between 2008 and 2012, in violation of the company's settlement with the DOJ, and never fully implemented or followed the monitoring program required under the settlement to which it agreed.

308. On January 17, 2017, in one of the most severe sanctions ever agreed to by a distributor, McKesson agreed to pay a record $150 million in fines and suspend sales of controlled substances from distribution centers in four states (Colorado, Ohio, Michigan, and Florida) to settle allegations that the company violated federal law. As part of the 2017 agreement, McKesson acknowledged:

> at various times during the Covered Time Period, 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.[182]

2. Defendant Cardinal Health

309. Defendant Cardinal Health describes itself as a global integrated healthcare services and products company. It generated $121.5 billion in total revenue during fiscal year 2016 (ended June 30, 2016). It is ranked 15th on the 2017 Fortune 500 list of top United States companies with revenues of over $121 billion.

310. Cardinal Health has two operating segments: pharmaceutical and medical. Its pharmaceutical segment, has distributed branded and generic pharmaceutical, special

[181] *Id*.
[182] McKesson Settlement Agreement and Release, 5 (Jan. 5, 2017), available at https://www.justice.gov/opa/press-release/file/928471/download.

pharmaceutical, over-the-counter, and consumer products, including opioids, in the United States, including Florida. Of Cardinal Health's $121.5 billion in revenue during fiscal year 2016, $109.1 billion was derived from the pharmaceutical operating segment.

311. Cardinal Health distributes pharmaceuticals through a network of distribution centers across the country. Cardinal Health's largest customer is CVS Health, which accounted for 25% of Cardinal Health's fiscal year 2016 revenue.

312. Cardinal Health distribution centers are required to operate in accordance with the statutory provisions of the CSA and the regulations promulgated thereunder, 21 C.F.R. §1300, *et seq.* The regulations promulgated under the CSA include a requirement to design and operate a system to detect and report "suspicious orders" for controlled substances as that term is defined in the regulation. *See* 21 C.F.R. §1301.74(b). The CSA authorizes imposing a civil penalty of up to $10,000 for each violation of 21 C.F.R. §1301.74(b). *See* 21 U.S.C. §842(a)(5) & (c)(1)(B).

313. On December 23, 2016, Cardinal Health agreed to pay the United States $44 million to resolve allegations that it violated the CSA in Maryland, Florida, and New York by failing to report suspicious orders of controlled substances, including oxycodone, to the DEA.[183]

314. In the settlement agreement, Cardinal Health admitted, accepted, and acknowledged that it had violated the CSA between January 1, 2009, and May 14, 2012, by failing to:

- "timely identify suspicious orders of controlled substances and inform the DEA of those orders, as required by 21 C.F.R. §1301.74(b)";

[183] Earlier in 2016, CVS also agreed to pay the United States $8 million to resolve violations of the CSA by its Maryland pharmacies. According to the settlement agreement, CVS admitted that between 2008 and 2012, certain of its Maryland pharmacies dispensed oxycodone, fentanyl, hydrocodone, and other pharmaceuticals in violation of the CSA because the drugs were dispensed without ensuring that the prescriptions were issued for legitimate medical purposes. Press Release, Cardinal Health Agrees to $44 Million Settlement for Alleged Violations of Controlled Substances Act, https://www.justice.gov/usao-md/pr/cardinal-health-agrees-44-million-settlement-alleged-violations-controlled-substances-act.

- "maintain effective controls against diversion of particular controlled substances into other than legitimate medical, scientific, and industrial channels, as required by 21 C.F.R. §1301.74, including the failure to make records and reports required by the CSA or DEA's regulations for which a penalty may be imposed under 21 U.S.C. §842(a)(5)"; and

- "execute, fill, cancel, correct, file with the DEA, and otherwise handle DEA 'Form 222' order forms and their electronic equivalent for Schedule II controlled substances, as required by 21 U.S.C. §828 and 21 C.F.R. Part 1305."

315. The settlement agreement was announced by the U.S. Attorney for the District of Maryland, Rod J. Rosenstein ("Rosenstein"), and the DEA Special Agent in Charge – Washington Field Division, Karl C. Colder ("Colder"). In the press release, Colder confirmed that the settlement primarily concerned the opioid oxycodone:

> DEA is responsible for ensuring that all controlled substance transactions take place within DEA's regulatory closed system. All legitimate handlers of controlled substances must maintain strict accounting for all distributions and Cardinal failed to adhere to this policy . . . . Oxycodone is a very addictive drug and failure to report suspicious orders of oxycodone is a serious matter. The civil penalty levied against Ga should send a strong message that all handlers of controlled substances must perform due diligence to ensure the public safety . . .[184]

3. Defendant AmerisourceBergen

316. Defendant AmerisourceBergen is a wholesale distributor of pharmaceuticals, including controlled substances and non-controlled prescription medications. It has handled the distribution of approximately 20% of all pharmaceuticals sold and distributed in the United States, including Florida, through a network of 26 pharmaceutical distribution centers. It ranked 11th on the Fortune 500 list in 2017, with over $146 billion in annual revenue.

317. AmerisourceBergen distribution centers are required to operate in accordance with the statutory provisions of the CSA and the regulations promulgated thereunder, 21 C.F.R. §1300, *et seq.* The regulations promulgated under the CSA include a requirement to design and

[184] *Id.*

operate a system to detect and report "suspicious orders" for controlled substances as that term is defined in the regulation. *See* 21 C.F.R. §1301.74(b). The CSA authorizes imposing a civil penalty of up to $10,000 for each violation of 21 C.F.R. §1301.74(b). *See* 21 U.S.C. §842(a)(5) & (c)(1)(B).

318. In 2012, West Virginia sued Defendant AmerisourceBergen and Defendant Cardinal Health, as well as several smaller wholesalers, for numerous causes of action, including violations of the CSA, consumer credit and protection, and antitrust laws, as well as the creation of a public nuisance. Unsealed court records from that case show that Defendant AmerisourceBergen, along with Defendant McKesson and Defendant Cardinal Health, together shipped 423 million pain pills to West Virginia between 2007 and 2012.[185] Defendant AmerisourceBergen itself shipped 80.3 million hydrocodone pills and 38.4 million oxycodone pills at the time. Public documents also demonstrate that the average dose of each tablet distributed grew substantially during that time period. The Distributor Defendants shipped large quantities of oxycodone and hydrocodone tablets to the state. In 2016, Defendant AmerisourceBergen agreed to settle the West Virginia lawsuit by paying $16 million to the state, with the funds set aside to fund drug treatment programs to respond to the opioid addiction crisis.

E. The National Retail Pharmacy Defendants Were on Notice of and Contributed to Illegal Diversion of Prescription Opioids.

319. National retail pharmacy chains earned enormous profits by flooding the country, including Florida, with prescription opioids. They were keenly aware of the oversupply of prescription opioids through the extensive data and information they developed and maintained as both distributors and dispensaries. Yet, they continued to participate in the

[185] Eric Eyre, *Drug firms poured 780M painkillers into WV amid rise of overdoses*, Charleston Gazette-Mail (Dec. 17, 2016), https://www.wvgazettemail.com/news/legal_affairs/drug-firms-poured-m-painkillers-into-wv-amid-rise-of/article_99026dad-8ed5-5075-90fa-adb906a36214.html.

oversupply and profit from it instead of taking any meaningful action to stem the flow of opioids into communities.

320. Each of the National Retail Pharmacy Defendants, CVS, Walgreens, and Walmart, does substantial business throughout the United States and Florida. This business includes the distribution and dispensing of prescription opioids. The National Retail Pharmacy Defendants failed to take meaningful action to stop this diversion despite their knowledge of it and contributed substantially to the diversion problem.

321. The National Retail Pharmacy Defendants developed and maintained extensive data on opioids they distributed and dispensed. Through this data, the National Retail Pharmacy Defendants had direct knowledge of patterns and instances of improper distribution, prescribing, and use of prescription opioids in communities throughout the country, including Florida. They used the data to evaluate their own sales activities and workforce. On information and belief, the National Retail Pharmacy Defendants also provided other Defendants with data regarding, *inter alia*, individual doctors in exchange for rebates or other forms of consideration. The National Retail Pharmacy Defendants' data is a valuable resource that they could have used to help stop diversion but they failed to do so. In 2010, for example, Walgreens' fiscal year 2010 SEC Form 10-K disclosed that it recognizes "purchased prescription files" as "intangible assets" valued at $749,000,000.[186] In addition, Walgreens' own advertising has acknowledged that Walgreens has centralized data such that customers' "complete prescription records" from Walgreens' "thousands of locations nationwide" are "*instantly available*."

[186] Walgreen Co. and Subsidiaries Annual Report for the Year Ended August, 31, 2010, SEC.gov, available at https://www.sec.gov/Archives/edgar/data/104207/000010420710000098/exhibit_13.htm (last visited Oct. 22, 2020).

322. Similarly, CVS's Director of Managed Care Operations, Scott Tierney, testified that CVS's data vendors included IMS Health, Verispan, and Walters Kluwers and that CVS used the vendors for "analysis and aggregation of data" and "some consulting services." He also testified that CVS would provide the vendors with "prescriber level data, drug level data, plan level data, [and] de-identified patient data."[187]

323. Each of the National Retail Pharmacy Defendants had complete access to all prescription opioid dispensing data related to its pharmacies across the United States, and to the Florida Prescription Drug Monitoring Program, also known as E-FORCSE (Electronic-Florida Online Reporting of Controlled Substance Evaluation Program), created by the 2009 Florida Legislature in an initiative to encourage safer prescribing of controlled substances and to reduce drug abuse and diversion within the state of Florida[188] providing complete access to information revealing the doctors who prescribed the opioids dispensed in Florida pharmacies and the size and frequency of their prescriptions, and complete access to information revealing the customers who filled or sought to fill prescriptions for opioids in the almost 5,000 Florida pharmacies.

1. The National Retail Pharmacy Defendants Have a Duty to Prevent Diversion.

324. Each participant in the supply chain of opioid distribution, including the National Retail Pharmacy Defendants, is responsible for preventing the diversion of prescription opioids into the illegal market by, among other things, monitoring and reporting suspicious activity.

[187] Joint Appendix in *Sorrell v. IMS Health Inc.*, No. 10-779, 2011 WL 687134 (U.S.) *245-46 (Feb. 22, 2011).
[188] Section 893.055, F.S.

325. The National Retail Pharmacy Defendants, like opioid manufacturers and other distributors, are registrants under the CSA. 21 C.F.R. §1301.11. Under the CSA, pharmacy registrants are required to "provide effective controls and procedures to guard against theft and diversion of controlled substances." See 21 C.F.R. §1301.71(a). In addition, 21 C.F.R. §1306.04(a) states, "[t]he responsibility for the proper prescribing and dispensing of controlled substances is upon the prescribing practitioner, but a corresponding responsibility rests with the pharmacist who fills the prescription." Because pharmacies themselves are registrants under the CSA, the duty to prevent diversion lies with the pharmacy entity, not only the individual pharmacists.

326. The DEA, among others, has provided extensive guidance to pharmacies concerning their duties to the public. The guidance advises pharmacies on how to identify suspicious orders and other evidence of diversion.

327. Suspicious pharmacy orders include orders of unusually large size, orders that are disproportionately large in comparison to the population of a community served by the pharmacy, orders that deviate from a normal pattern, and/or orders of unusual frequency and duration, among others.

328. Additional types of suspicious orders include: (1) prescriptions written by a doctor who writes significantly more prescriptions (or in larger quantities or higher doses) for controlled substances compared to other practitioners in the area; (2) prescriptions which should last for a month in legitimate use, but are being refilled on a shorter basis; (3) prescriptions for antagonistic drugs, such as depressants and stimulants, at the same time; (4) prescriptions that look "too good" or where the prescriber's handwriting is too legible; (5) prescriptions with quantities or doses that differ from usual medical usage; (6) prescriptions that do not comply

with standard abbreviations and/or contain no abbreviations; (7) photocopied prescriptions; or (8) prescriptions containing different handwriting. Most of the time, these attributes are not difficult to detect and should be easily recognizable by pharmacies and their pharmacists.

329. Suspicious pharmacy orders are red flags for, if not direct evidence of, diversion.

330. Other signs of diversion can be observed through data gathered, consolidated, and analyzed by the National Retail Pharmacy Defendants themselves. That data allows them to observe patterns or instances of dispensing that are potentially suspicious, of oversupply in particular stores or geographic areas, or of prescribers or facilities that seem to engage in improper prescribing. According to industry standards, if a pharmacy finds evidence of prescription diversion, the local Board of Pharmacy and DEA must be contacted.

331. Further, after using the statewide Florida electronic database, E-FORCSE, prior to dispensing any Schedule II controlled substances, including opioids, Florida pharmacists must comply with the requirements of Section 893.055(3)(a), F.S., which requires reporting of specific information to the electronic "system as soon thereafter as possible but no later than the close of next business day after the controlled substance is dispersed."

332. Despite their legal obligations as registrants under the CSA, the National Retail Pharmacy Defendants allowed widespread diversion to occur—and they did so knowingly.

333. Performance metrics and prescription quotas adopted by the National Retail Pharmacy Defendants for their retail stores contributed to their failure. By example, under CVS's Metrics System, its pharmacists are directed to meet high goals that make it difficult, if not impossible, to comply with applicable laws and regulations. There is no measurement for pharmacy accuracy or customer safety. Moreover, the bonuses for pharmacists are calculated, in part, on how many prescriptions that pharmacist fills within a year. The result is both deeply

troubling and entirely predictable: opioids flowed out of National Retail Pharmacy Defendants' pharmacies and into communities throughout the country, including Florida. The policies remained in place even as the epidemic raged.

334. Upon information and belief, this problem was compounded by the National Retail Pharmacy Defendants' failure to adequately train their pharmacists and pharmacy technicians on how to properly and adequately handle prescriptions for opioid painkillers, including what constitutes a proper inquiry into whether a prescription is legitimate, whether a prescription is likely for a condition for which the FDA has approved treatments with opioids, and what measures and/or actions to take when a prescription is identified as phony, false, forged, or otherwise illegal, or when suspicious circumstances are present, including when prescriptions are procured and pills supplied for the purpose of illegal diversion and drug trafficking.

335. Upon information and belief, the National Retail Pharmacy Defendants also failed to adequately use data available to them to identify doctors, including those in Florida, who were writing suspicious numbers of prescriptions and/or prescriptions of suspicious amounts of opioids, or to adequately use data available to them to do statistical analyses to prevent the filling of prescriptions that were illegally diverted or otherwise contributed to the opioid crisis.

336. Upon information and belief, the National Retail Pharmacy Defendants failed to analyze, nationally and in Florida: (a) the number of opioid prescriptions filled by individual pharmacies relative to the population of the pharmacy's community; (b) the increase in opioid sales relative to past years; (c) the number of opioid prescriptions filled relative to other drugs; and (d) the increase in annual opioid sales relative to the increase in annual sales of other drugs.

337. Upon information and belief, the National Retail Pharmacy Defendants also failed to conduct adequate internal or external audits of their opioid sales to identify patterns regarding prescriptions that should not have been filled and to create policies accordingly, or if they conducted such audits, they took no meaningful action as a result.

338. Upon information and belief, the National Retail Pharmacy Defendants also failed to effectively respond to concerns raised by their own employees regarding inadequate policies and procedures regarding the filling of opioid prescriptions.

339. The National Retail Pharmacy Defendants were, or should have been, fully aware that the quantity of opioids being distributed and dispensed by them was untenable, and in many areas patently absurd; yet, they did not take meaningful action to investigate or to ensure that they were complying with their duties and obligations under the laws on controlled substances.

2. National Retail Pharmacy Defendants Failed to Maintain Effective Controls Against Diversion.

340. As described further below, the National Retail Pharmacy Defendants failed to fulfill their legal duties and instead, routinely distributed and/or dispensed controlled substances while ignoring red flags of diversion and abuse.

a) CVS

341. CVS is one of the largest companies in the world, with annual revenue of more than $150 billion. According to news reports and its website, it manages medications for nearly 90 million customers at 9,900 retail locations, 883 of which had pharmacies in Florida. CVS could be a force for good in connection with the opioid crisis, but like the other Defendants, CVS sought profits over people.

(1) CVS Lacked a Genuine Suspicious Order Monitoring System For Much of the Relevant Time.

342. CVS distribution centers, in tandem with outside wholesalers, such as Defendant Cardinal Health, supplied opioids to CVS pharmacy stores until October 2014. CVS self-distributed hydrocodone and hydrocodone combination products to its own stores, of which CVS had approximately 6,000 by 2006 and 9,700 by 2014. Hydrocodone ("HCP") was rescheduled to FDA Schedule II status on October 6, 2014, and CVS ceased self-distributing HCP the same day.

343. CVS pharmacies nationwide placed orders with CVS distribution centers through CVS's central mainframe computer ordering system.

344. Before 2009, CVS lacked any meaningful suspicious order monitoring ("SOM") system. Instead, CVS relied on the gut instincts of the pickers and packers of the drugs in the distribution center – workers responsible for pulling items off distribution shelves for delivery to pharmacy stores – to identify "really big" orders that they believed were too large to be legitimate.

345. CVS also lacked a training program to train its pickers and packers on how to identify orders unusual in size, frequency, or pattern. CVS also lacked any written policies, procedures, or protocols on the pickers' and packers' obligations until August 2013. There were no formal job requirements to be employed as a picker and packer.

346. In 2007, with help from an outside consultant, CVS began work on a Standard Operating Procedure ("SOP") Manual intended to cover all facets of DEA controlled substances compliance, including suspicious order monitoring. However, as of the summer of 2010, neither the final manual nor the SOM section was complete. Internal documents from that time acknowledge that CVS was "still in the process of writing the suspicious order monitoring

section of this standard operating procedure." In fact, the section of the Standard Operating Procedures for SOM states, "BEING DEVELOPED AND WRITTEN."

347. Drafts of the SOP Manual, meanwhile, show CVS understood or should have understood that the status quo was unacceptable. The draft manual provides that: "CVS is responsible for ensuring compliance with DEA regulatory requirements, and that responsibility cannot be abdicated or transferred to anyone else." Despite this acknowledgment, when the first version of the SOP Manual was issued in December 2007 and for multiple revisions thereafter, the SOM section remained incomplete. As John Mortelliti, ("Mortelliti"), CVS's Director of Loss Prevention, wrote in November 2009, this had become "a big issue with CVS and the DEA," and he was "trying to get a rough draft SOM SOP" before a DEA meeting.

348. On August 24, 2010, the DEA initiated an audit and investigation of CVS Indiana for its distribution practices. The next day, CVS Pharmacy, Inc. sent a new SOP manual, which included for the very first time, a policy on SOM.

349. It was only in 2009 that CVS began using a computer algorithm that flagged potentially suspicious orders needing additional investigation. CVS called the output of the flagged orders an Item Review Report ("IRR"). An outside vendor developed the program for CVS.

350. Originally, the vendor designed the algorithm to identify orders with a score of 0.15 or higher as potentially suspicious. (The higher the score, the more suspicious the order.) In the summer of 2010, Mortelliti adjusted the score threshold from 0.15 to 0.65, which caused fewer suspicious orders to be flagged for investigation. On February 8, 2011, the algorithm designer delivered to CVS a completely retuned SOM algorithm, which reverted the score threshold to 0.15. Afterward, CVS again raised the score to 0.65.

351. The IRRs were CVS's primary SOM process. As a CVS corporate representative explained on behalf of the company, for the most part, if an order was not flagged as suspicious under the IRR system, there would be no due diligence of that order.

352. CVS's SOM algorithm failed to factor in outside vendor orders. In other words, CVS's SOM system would not track how many opioids CVS was ordering from third-party distributors such as Defendant Cardinal Health when evaluating whether to distribute opioids to one of its pharmacies. CVS knew this was a problem, as a "[s]tore may order a little from both the OV [outside vendor] and DC [CVS distribution center] to stay under the radar." It also knew that excluding outside vendor data meant CVS "may ship a potentially reportable suspicious order from [its] DC." Stores, including one that had a "68,000 hydrocodone pill loss," could also place telephone orders to outside vendors, into which there was "no visibility . . . until a later time." This deficiency is particularly glaring because, at a corporate level, CVS had full access to the orders its pharmacies placed to outside vendors.

353. Acknowledging the ineffectiveness and deficiencies within its SOM system, CVS hired new consultants in 2012 to troubleshoot its existing SOM systems for the purpose of either fixing the deficient system or developing a new SOM system to attempt to become compliant with the law.

354. Still, as late as July 2013, an internal email reflects that CVS's primary tool for investigating suspicious orders relied on data that was months or even years old, making any analysis "for the most part, irrelevant and pointless."

355. Not until mid to late 2014 did CVS fully implement a new SOM system, but even then, CVS encountered problems in evaluating suspicious orders for opioids. CVS implemented a new SOM system in the Indianapolis distribution system in March 2014. The

deployment was delayed due to system data feed issues that created inaccuracies in the SOM historical data. A risk analysis of the new system was conducted in June 2014, and the SOM system's risk level was determined to be high in these categories: (1) inconsistent due diligence in SOM analysts reaching out to stores to investigate suspicious orders; (2) inconsistency in documenting due diligence investigations of suspicious orders; (3) lack of engagement by the Management Team; (4) lack of communication between the SOM Management Team and SOM analysts; (5) lack of resources to handle the rollout of the new SOM system to all distribution centers; and (6) lack of clarity in how the new SOM system is identifying suspicious orders. That year, CVS stopped distributing opioids at the wholesale level.

356. Meanwhile, by August 5, 2013, the DEA had begun an audit and investigation of the CVS distribution center in Indiana, focused on CVS's failure to maintain a SOM program for controlled substances. In response to queries from the DEA, CVS wrote a letter to the DEA revealing it had only stopped seven suspicious orders across the entire country as of November 21, 2013. Right before sending the letter, its author, Mark Nicastro, head of the CVS distribution center in Indiana, conceded internally that "I wish I had more stopped orders that went back further." While Mr. Nicastro was drafting the letter, he could not locate the SOP for SOM, writing to his colleague, Pam Hinkle, Senior Manager for Logistics, Quality, and Compliance for CVS, "For the life of me I can't find the SOP for SOM. Can you send me an electronic copy please? I have been on the logistics website, looked through hundreds of e-mails, nothing. I'm surprised it is not on the website." Mr. Hinkle responded that she too was unsure of the final version of the SOP SOM. CVS ultimately sent the wrong version of the SOP SOM to the DEA.

357. In May 2014, CVS had a closing meeting with the DEA related to the distribution center audit. According to handwritten notes from a CVS employee who attended the meeting, the "most serious" violation is "failure to design" a SOM system. An internal CVS email summarizing the meeting made a similar statement: DEA determined that CVS "faile[d] to maintain an SOM program."

358. The DEA issued its closing letter concluding that CVS failed to design and maintain a system to detect and report suspicious orders for Schedule III-V Controlled Substances as required by 21 U.S.C. §§821, 823(e)(1), and 21 C.F.R. §1301.73(b), in violation of 2 U.S.C. §842(a)(5).

(2) CVS failed to perform due diligence.

359. All orders that appeared on the IRR required a thorough due diligence investigation, but CVS only performed appropriate due diligence on a fraction of them. From early/mid-2009 through early 2011, one employee, Mortelliti, "was taking the first pass through the IRR himself." According to CVS's corporate witness, "Mr. Mortelliti's practice would have been to review the report on a daily basis and determine whether items on the report warranted further review and due diligence and conduct review and due diligence as he deemed appropriate." At certain times in 2013, CVS had only one full-time employee in the position of "SOM analyst" reviewing all potentially suspicious orders for every pharmacy in the country. The SOM system would identify orders as potentially suspicious based on a number of factors, but the CVS SOM analyst would conduct an "in depth" dive on only a small subset of those orders. In fact, the SOM program could identify up to 1,000 suspicious orders a day, and the CVS employee would do a "deep dive" on only one to six orders per day.

360. CVS's SOM policy specified that if multiple orders for the same store are flagged during the same month, all orders after the first order will not be investigated and will be automatically released based on the release of the first order.

(3) CVS failed to implement effective policies and procedures to guard against diversion from its retail stores.

361. By 2009, CVS Pharmacy, Inc. owned and/or operated more than 9,000 pharmacies in the United States, including in Florida. At all relevant times, CVS pharmacies sold controlled substances, including FDA Schedule II and FDA Schedule III controlled substances — opiate narcotics or opioids.

362. "CVS Corporation," not any individual CVS store, is the DEA registrant for each of CVS's pharmacies across the country. CVS renews the DEA licenses for its pharmacies through a "Registration Chain Renewal." From October 2013 through December 2016, CVS headquarters paid more than $5 million to renew the licenses for 7,597 CVS locations, including in Florida.

363. As described above, until October 6, 2014, CVS pharmacies ordered and were supplied FDA Schedule III hydrocodone combination products ("HCPs") from a combination of outside vendors and CVS distribution centers. CVS pharmacies also received Schedule II opioids from outside vendors, with Defendant Cardinal Health acting as its exclusive outside supplier for the entire period for which data is available. Upon information and belief, Defendant McKesson also acts or has acted as an outside vendor for CVS.

364. CVS Pharmacy, Inc. instituted, ran, directed and staffed with its own employees most SOM functions for its pharmacy stores.

365. CVS lacked meaningful policies and procedures to guide its pharmacy staff in maintaining effective controls against diversion, even as they evolved. It was not until 2012 that CVS created guidelines explaining in more detail the "red flags" or cautionary signals that CVS pharmacists should know about to prevent diversion and to uphold their corresponding responsibilities to ensure that all dispensed controlled substances are issued for a legitimate medical purpose.

366. CVS failed to use data held at the corporate level to assist pharmacists in evaluating red flags of diversion. CVS's later dispensing policies and procedures make clear that for the majority of the time CVS has been engaged in the sale and dispensing of opioids, there was no meaningful integration of data and information within the possession and control of CVS corporate personnel.

367. With respect to CVS's suspicious order monitoring system for its wholesale distribution, the MDL 2804 Court has denied a motion for summary judgment contesting the evidence regarding the inadequacy of its SOM system in that litigation. *See* Opinion and Order [Denying CVS's Motion for Summary Judgment], MDL No. 2804, Doc. 3099 (N.D. Ohio Jan. 27, 2020).

b) Walgreens

368. Walgreens is the second-largest pharmacy store chain in the United States behind CVS, with annual revenue of more than $118 billion. According to its website, Walgreens operates more than 8,100 retail locations, 816 pharmacies in Florida, and filled 990 million prescriptions on a 30-day adjusted basis in fiscal 2017.

369. Acting as both a distributor and a retail pharmacy chain, Walgreens also self-distributed opioids to its own individual Walgreens pharmacies. Although Walgreens had

visibility into red flags of diversion due to its vertically integrated distribution and dispensing practices, it failed to consider these factors in its SOM program during most of the time it was distributing prescription opioids. Moreover, its program was wholly inadequate and did not fulfill its duties to prevent diversion. Likewise, Walgreens also failed to maintain effective controls against diversion from its pharmacy stores.

(1) Walgreens Delayed Developing a Suspicious Ordering System.

370. Though Walgreens had access to significant information about red flags due to its vertical integration with its stores, Walgreens failed to use available information to monitor and effectively prevent diversion.

371. At least as early as 1998, and perhaps as early as 1988, Walgreens began to use a series of formulas to identify orders that Walgreens considered suspicious based on the orders' extraordinary size. These orders were listed on a report called the Suspicious Control Drug Order report.

372. Walgreens used two formulas: one formula from (at least) 1998-2007 and one formula from March 2007 through 2012. These formulas were alike in that they each used an average number based on historical orders, applied a three times multiplier to that base number, and then considered certain orders greater than that number to be suspicious. Under the later formula, orders were only listed on the report as being suspicious if the orders exceeded the three times multiplier for two consecutive months in a given time period. Walgreens based this second formula on the DEA's Chemical Handler's Manual's order monitoring system for listed chemicals.

373. The first variation on this formula was in place until March 2007, even though the DEA warned Walgreens that the "formulation utilized by the firm for reporting suspicious

ordering of controlled substances was insufficient," via a May 2006 Letter of Admonition. The Letter cited Walgreens for controlled substances violations at its Perrysburg Distribution Center, but highlighted problems that went far beyond that particular facility.

374. The DEA also reminded Walgreens that its suspicious ordering "formula should be based on (size, pattern, frequency)," though Walgreens failed to even examine anything other than the size of an order. When Walgreens did update its program some ten months later, however, it still did not perform the size, pattern, and frequency analysis prescribed by the DEA, continuing to use another "three times" formula.

375. Walgreens did not perform any due diligence on the thousands of orders identified as "suspicious" on the Suspicious Control Drug Order reports but instead shipped the orders without review.

376. Walgreens did not report the suspicious orders listed on the Suspicious Control Drug Order report until after the orders were already filled and shipped. The report was generated on a monthly, nationwide basis, directly contravening the regulatory requirement that suspicious orders be reported when discovered. 21 C.F.R. §1301.74(b). In some instances, months may have elapsed between an order's shipment and its subsequent reporting to the DEA, given the requirement, described above, of two consecutive months of exceeding the three times multiplier to trigger reporting.

377. In September 2012, the DEA issued an immediate suspension order ("ISO") for one of Walgreens' 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 DEA further found that Walgreens' Jupiter, Florida Distribution Center violated DEA regulations that required it to report to the DEA suspicious

drug orders that Walgreens received from its retail pharmacies, resulting in at least tens of thousands of violations, particularly concerning massive volumes of prescription opiates.

(2) Walgreens Knew its After-the-Fact Excessive Purchase Reports Failed to Satisfy Its Obligations to Identify, Report, and Halt Suspicious Orders.

378. Walgreens knew its procedures were inadequate well before the 2012 ISO issued. In addition to the guidance described above, in 1988, the DEA specifically advised Walgreens that "[t]he submission of a monthly printout of after-the-fact sales does not relieve the registrant of the responsibility of reporting excessive or suspicious orders." The DEA further advised Walgreens that, while "[a]n electronic data system may provide the means and mechanism for complying with the regulations . . . the system is not complete until the data is carefully reviewed and monitored by the registrant."

379. Despite this instruction, there is no evidence that Walgreens ever took any action related to the Suspicious Control Drug Order report besides generating it and mailing it out. Walgreens has admitted that there is no evidence that Walgreens ever performed a due diligence review on any of the orders listed on the Suspicious Control Drug Order report before shipment.

380. As described above, in May 2006, the DEA told Walgreens again that the formula Walgreens was using to identify suspicious orders for the Suspicious Control Drug Order reports was "insufficient" and "inadequate."

381. Moreover, in September 2007, three Walgreens' senior employees (Dwayne Pinon, Senior Attorney; James Van Overbake, Auditor; and Irene Lerin, Audit Manager) attended the DEA Office of Diversion Control's 13th Pharmaceutical Industry Conference in Houston, Texas. Michael Mapes, Chief, DEA, Regulatory Section, gave a presentation at this

Conference relating to suspicious orders, which included the reminder that the CSA "requirement is to report suspicious orders, not suspicious sales after the fact." Participant notes from this meeting indicate that Mr. Mapes advised the audience not to "confuse suspicious order report with an excessive purchase report. They are two different things."

382. Similarly, handwritten notes on an internal document from July 2008 state that "DEA really wants us to validate orders and only report true suspicious orders or what was done to approve orders" and that "[j]ust reporting these orders is not good enough – need to document what happened."

383. Additionally, in November 2012, the Walgreens' Divisional Vice President of Pharmacy Services reported to Kermit Crawford, Walgreens' President of Pharmacy, Health and Wellness, his notes from meeting with the DEA about reporting suspicious orders, which included the note, "[i]f suspicious - you don't ship."

384. In a December 2008 Internal Audit of its Perrysburg Distribution Center, Walgreens admitted to systemic and longstanding failures in the systems surrounding DEA compliance, stating, "In our opinion internal controls that ensure compliance with DEA regulations at the Perrysburg DC require improvement. In addition, some of these issues pertain to all company DCs and should be addressed to avoid potential DEA sanctions."

385. The team that performed the Internal Audit recommended discussion continue across multiple departments company wide. In that respect, it makes clear that the failures described are systemic. Yet the report states that the next meeting to address the problem would not occur for five months.

(3) Walgreens Lacked Meaningful Additional Systems to Address the Failures in Its System of After-the-Fact Reporting of Certain Orders.

386. Walgreens nominally employed additional procedures within its Distribution Centers ("DC"), but these systems did not address the failings of the Suspicious Control Drug Order reports. These DC systems were not designed to detect suspicious orders of controlled substances, but rather were designed to detect typos or errors in order entry by the stores. Walgreens admits that its DCs are "more akin to supply warehouses," are "not designed to be a backstop to pharmacists," and that they are not well "equipped to ensure compliance" or to "assist in combatting controlled substance abuse," and "do not have the ability to detect trends in local markets."

387. Walgreens' "DC" level procedures are documented in a 2006 Questionable Order Quantity policy, which had two facets: first, it instructed DC personnel to review orders and contact the pharmacy with questions regarding quantities. The policy did not mention reporting suspicious orders until 2010, when it was updated to state that the Corporate Office Internal Audit Department would handle suspicious store orders and inquiries. There is no evidence that the Internal Audit department had any involvement in reporting suspicious orders.

388. The second aspect of this DC level procedures required "pickers," the DC personnel who retrieved pill bottles off the shelves and placed them into totes for shipping, to look for "questionable" orders while picking.

389. The only review of the orders identified by the DC level procedures was calling the pharmacy to make sure the order had not been entered in error. Walgreens admitted this procedure was not intended to detect suspicious orders.

390. There is no evidence that any orders were ever reported as suspicious or halted as a result of Walgreens' DC level policies. There is no evidence these procedures resulted in timely reporting of, due diligence on, or non-shipment of any order, including those listed as being "suspicious" on the Suspicious Control Drug Order reports.

391. Walgreens' documents effectively acknowledge that these were not true anti-diversion measures, and it recognized internally that it did not begin creating a suspicious order monitoring ["SOM"] system until March 2008. In March 2008, Walgreens finally formed a five department "team" to "begin creating" a SOM program. The new SOM program was not piloted until more than a year later, in August 2009, and even then, the pilot included orders from just seven stores. Not until September 2010 would the program, implemented in pieces and phases, be rolled out chain-wide, and from that point it took several more years to fully implement.

392. Through 2012, Walgreens continued to populate the Suspicious Control Drug Order report with thousands of orders that exceeded Walgreens' "three times" test, showing that Walgreens' post-2009 SOM program did little to mitigate the extraordinary volume of controlled substances being shipped by Walgreens to its pharmacies.

(4) Even as it Rolled Out its New SOM Program, Walgreens Left Significant Gaps and Loopholes in Place and Failed to Report and Perform Due Diligence on Orders It Flagged.

393. Walgreens did not prioritize compliance when instituting its SOM system. Testimony from the Senior Director of the Walgreen's Pharmaceutical Integrity Department, which is charged with supervising Walgreens' SOM system, revealed that even as late as 2012, 2013, and 2014, Walgreens treated the SOM system as an inventory control mechanism rather than as a compliance control mechanism.

394. The SOM program had significant loopholes. For the first few years, the program did not include orders that Walgreens stores were also placing to outside vendors, like Defendants Cardinal Health and Amerisource Bergen, effectively permitting double-dipping.

395. The SOM system also allowed Walgreens' stores to transfer controlled substances between stores and did not review these transfers (known as "interstores") within the SOM program, so that these transfers were not factored into SOM analytics. Stores could also place ad hoc "PDQ" ("pretty darn quick") orders for controlled substances outside of their normal order days and outside the SOM analysis and limits. Walgreens could even remove a store entirely from SOM review.

396. Starting in 2010, certain orders that exceeded store-based limits imposed by Walgreens' new SOM system were reduced to the store limit and shipped out. These orders were not reported to the DEA as suspicious, nor were they halted for review. The DEA found that Walgreens' policy of reducing and then filling and shipping suspicious orders without reporting them violated the law.

397. Walgreens' post-2009 SOM system flagged thousands of items per month as being suspicious. Internal Walgreens documents indicate that, in July 2011 alone, up to 20,699 orders for controlled substances were "marked suspicious" by the new algorithm. However, very few of these orders received any review, and any review performed was nominal at best. Meanwhile, Walgreens failed to adequately staff the program and train its employees about its requirements.

398. Walgreens cited two people as being primarily responsible for performing due diligence on suspicious orders in the 2009-2012 time period under the new SOM system. The first was a representative from the Loss Prevention department who said her department was

"not equipped" to handle review and data analysis for the hundreds of pages of reports being compiled nationwide each week. The second was Barbara Martin, who estimated that she spent somewhere between one and three hours a week reviewing suspicious orders, reviewing only between 10 and 100 of the thousands of orders that were deemed suspicious under the new algorithm.

399. As a result of a DEA investigation, Walgreens formed the Pharmaceutical Integrity Team ("Rx Integrity Team") in 2012, purportedly to make sure that those types of failures did not continue. However, the group's true role was protecting Walgreens' Distribution Centers and stores from losing their DEA licenses. The effort was only for show. Walgreens never provided the Rx Integrity Team the resources needed to achieve due diligence on the large number of orders identified by Walgreen's SOM program for the company's 5,000 plus stores.

400. In December 2012, the further enhanced SOM system flagged "14,000 items that the stores ordered across the chain that would have to be investigated" before they could be shipped.[189] Walgreens admitted that, yet again, it lacked sufficient resources to timely review these orders. Walgreens noted that "[t]he DEA would view this as further failures of our internal processes, which could potentially result in additional pharmacies and distribution centers being subjected to regulatory actions and ultimately prohibited from handling controlled substances." When these 14,000 orders were flagged, the Rx Integrity Team consisted of fewer than five people.[190] Even at its height, the Rx Integrity Team had only 11 employees. Instead of

[189] Supplemental and Amended Allegations to Be Added To "Short Form For Supplementing Complaint And Amending Defendants And Jury Demand," *Co. of Trumbull, Ohio v. Purdue Pharma, L.P. et al. and Co. of Lake, Ohio v. Purdue Pharma L.P., et al*., No. Doc. 2206-2, 73, N. 48 (WAGMDL000659270) (hereinafter "Lake Co. Complaint").
[190] *Id*. at 74, N. 49 (Polster Dep., at 24:3-15).

sufficiently staffing the SOM program, Walgreens recognized it had the ability to control its due diligence workload by increasing the stores' ceiling levels, and thereby reducing the number of orders that would hit that ceiling and result in a flag.

401. Yet, even in 2013, orders being flagged as suspicious for review before shipment were "a week old" before they made it to the review team, often "ha[d] already been shipped," and were not being reported.

402. Walgreens never equipped its distribution operations to monitor, report, and halt suspicious orders, or otherwise effectively prevent diversion. When it became clear Walgreens would need to devote significant resources to achieve compliance, Walgreens chose instead to cease controlled substance distribution altogether.

403. Indeed, with respect to Walgreens' suspicious order monitoring system for its wholesale distribution, the MDL 2804 Court has denied a motion for summary judgment contesting the evidence regarding the inadequacy of its SOM system in that litigation. See Order [Denying Walgreens' Motion for Summary Judgment], MDL No. 2804, Doc. 2569 (N.D. Ohio Sept. 4, 2019).

(5) Walgreens Failed to Put in Place Adequate Policies to Guard Against Diversion at the Pharmacy Level.

404. Although Walgreens purported to have in place "Good Faith Dispensing" ("GFD") Policies for many years, it failed to meaningful apply policies and procedures, or to train employees in its retail pharmacies on identifying and reporting potential diversion.

405. Despite knowing that prescribers could contribute to diversion, and having a separate and corresponding duty with respect to filling prescriptions, from at least 2006 through 2012, Walgreens' dispensing policies, which it titled "Good Faith Dispensing", or "GFD", explicitly instructed pharmacists who "receive[] a questionable prescription" or otherwise were

"unable to dispense a prescription in good faith" to "contact the prescriber" and, if "confirm[ed]" as "valid" by the prescriber, to then "process the prescription as normal." Walgreens provided only vague criteria for suspicious circumstances, which became meaningless if a prescriber "confirm[ed]" the prescription as "valid," by calling the prescriber. Despite internally recognizing that "a prescriber of a controlled substance prescription [may be] involved in diversion," Walgreens' GFD policies continued to endorse calling the doctor as a greenlight to any "questionable" prescription.

406. In 2012, Walgreens finally removed the "process the prescription as normal" language from its formal GFD policies, admitting that under the law "it is not enough to get confirmation that the prescriber wrote the prescription." However, Walgreens still failed to ensure it complied with its duties.

407. Upon information and belief, Walgreens failed to adequately train its pharmacists and pharmacy technicians on how to prevent diversion, including what measures and/or actions to take when a prescription is identified as phony, false, forged, or otherwise illegal, or when other suspicious circumstances are present.

408. Indeed, during a 2009 DEA investigation into Walgreens dispensing noncompliance, Walgreens internally noted that it currently had "no training" for employees dispensing controlled substances. Meanwhile, Walgreens corporate officers turned a blind eye to these abuses. In fact, a Walgreens corporate attorney suggested, in reviewing the legitimacy of prescriptions coming from Florida, that "if these are legitimate indicators of inappropriate prescriptions perhaps we should consider not documenting our own potential noncompliance," underscoring Walgreens' attitude that profit outweighed compliance with the law or protecting public health.

409. Ultimately, in 2011, Walgreens and the DEA entered a Memorandum of Agreement ("MOA") regarding all "Walgreens . . . pharmacy locations registered with the DEA to dispense controlled substances," requiring Walgreens to implement significant nationwide controls lacking in its operations. Walgreen Co. was required to create a nationwide "compliance program to detect and prevent diversion of controlled substances as required by the … (CSA) and applicable DEA regulations." Pursuant to the MOA, the "program shall include procedures to identify the common signs associated with the diversion of controlled substances including but not limited to, doctor shopping and requests for early refills" as well as "routine and periodic training of all Walgreens walk-in, retail pharmacy employees responsible for dispensing controlled substances on the elements of the compliance program and their responsibilities under the CSA." Further, Walgreens was required to "implement and maintain policies and procedures to ensure that prescriptions for controlled substances are only dispensed to authorized individuals pursuant to federal and state law and regulations."

410. Walgreens would also make more promises in a 2013 MOA with the DEA, described further below, related to failures that led to the ISOs described above.

411. Even after the development and a relaunch of its GFD policy in response to settlements with the DEA, however, Walgreens "RxIntegrity" presentation focused on certain Walgreens markets, but also assessing "average market" trends, reporting that "pharmacists [were] not being too strict with GFD, nor [were] they losing volume."

412. As with distribution, Walgreens failed to allocate appropriate resources to dispensing compliance and supervision. Walgreens has approximately 26,000 pharmacists, each of whom may receive as many as 400-500 prescriptions a day. In 2013, however, Walgreens internally reported that its District Managers and Pharmacy Supervisors were "challenged to get

into the stores" and in a 90-day period, more than a thousand stores did not receive a visit from the managers or supervisors. These supervisory personnel were assigned a "high number of stores" and their time was consumed with "people processes, business planning, market and district meetings," such that supervision in store was being handled informally by "community leaders" who have "limited formal authority."

413. A Walgreens internal audit performed after the 2013 DEA settlement confirms that Walgreens' supervision and compliance failures continued. Among other failings, the audit team noted no formal monitoring program existed to confirm that pharmacies across the chain are complying with controlled substance documentation and retention requirements, no monitoring outside the deficient "store walk program" existed to monitor target drug Good Faith Dispensing requirements and no corporate reporting was being generated, and employees were failing to timely complete Good Faith Dispensing training, such that, at the time of the audit, over 35,000 employees had not completed their required training for that year. Management's response largely was to seek to incorporate additional compliance measures into the store walk procedure. However, documents from 2016 regarding monthly store compliance walks indicate that during the monthly "Compliance Walks" to "verify compliance … [with] regulatory requirements in… pharmacy areas," substantially no dispensing compliance supervision occurred outside of ensuring the pharmacy was verifying the patient's address on 5 sample prescription fills.

414. Unsurprisingly, compliance with GFD and TD GFD has been poor. For example, in 2014 Walgreens discovered a pharmacist who failed to follow GFD for 5 to 6 months without being discovered by supervisors. In 2014, Rx Integrity noted dozens of stores

dispensing opioids without performing the required checks. In certain cases, the pharmacists were unaware of the GFD procedures or had been told by supervisors to disregard them.

415. In 2015, Walgreens performed a "business continuity" audit of a random sample of approximately 2,400 pharmacies to determine whether Walgreens was "compliant with the policies/procedures put in place" regarding dispensing pursuant to Walgreens' agreement with the DEA. In Walgreens' own words, "Results were unfavorable." Fewer than 60% of stores were complying with TD GFD with respect to filled prescriptions, 1,160 stores did not have a single refused prescription, and an additional 1,182 stores had refused fewer than 25 prescriptions total in a 9-month period. Only 63 out of 2,400 pharmacies had refused 26 or more prescriptions during that same 9-month period in 2015.

(6) Walgreens Discouraged Outside Vendors from Exercising Their Own Oversight.

416. The "Big Three" distributors, Defendant Cardinal Health, Defendant McKesson, and Defendant AmerisourceBergen, gave deferential treatment to National Retail Pharmacy Defendants. An internal Cardinal Health document for example, stresses that "certain chain pharmacies refuse to allow any sort of administrative inspection by Cardinal Health or to make certifications" and that large, national chains can "take their billions upon billions of dollars in business to any wholesaler in the country."

417. Thus, for example, in 2008, Defendant Cardinal Health prepared talking points for a National Association of Chain Drug Stores ("NACDS") Conference about its planned retail chain SOM program, making it clear that the program would "minimize the disruption" to retail chains and that they would "work together" with the pharmacies " to ensure that our Suspicious Order Monitoring program for retail chains does not interrupt" business. Cardinal Health also provided warnings to chain pharmacies, including Walgreens, that they were

approaching thresholds so that the chains could avoid triggering SOM reporting and adjust ordering patterns by, for example, delaying orders or, more often, obtaining a threshold increase. Such "early warnings" were so helpful to Walgreens that as of 2012 Walgreens adopted the concept for its own SOM system for self-distribution, noting internally that by "flagging the stores at 75%," it could "avoid cutting/reducing orders and subsequently not have to report a SOM to the DEA."

418. In 2013, Walgreens entered a 10-year agreement with Defendant AmerisourceBergen. The shift to Defendant AmerisourceBergen as its exclusive supplier prompted Defendant Cardinal Health to complain: "we bailed you guys out when you had your [DEA] issues."

419. By 2017, Walgreens accounted for 30% of Defendant AmerisourceBergen's revenue. AmerisourceBergen was similarly deferential, allowing Walgreens to "police their own orders" and block any order to AmerisourceBergen that would exceed AmerisourceBergen's threshold thus triggering a suspicious order needing to be sent to the DEA from AmerisourceBergen. Additionally, when AmerisourceBergen received orders from Walgreens "outside the expected usage," Walgreens and AmerisourceBergen met to discuss adjusting thresholds or using "soft blocking." Contrary to DEA guidance and its own stated policy, AmerisourceBergen also shared the threshold limits set by its "order monitoring program" with Walgreens, and also provided Walgreens with weekly SOM statistics. AmerisourceBergen generally would not take action on Walgreens orders that exceeded its thresholds without first talking to Walgreens.

420. Walgreens also owns 26% of Defendant AmerisourceBergen's stock. In 2018, after a coalition of AmerisourceBergen shareholders sought greater transparency from its Board

related to the "financial and reputational risks associated with the opioid crisis," Walgreens, together with other insiders, reportedly leveraged this position to defeat the proposal, which enjoyed majority support among the independent shareholders.

c) Walmart

421. Walmart is the largest private employer in the United States by far. It employs more than 1.5 million people. But for years, Walmart chose not to assign a single employee to design or operate a system to detect suspicious orders of controlled substances. Walmart chose to do nothing while hundreds of thousands of people were dying, and Walmart waited until 2014 to begin to take meaningful action. By that time, it was too late.

(1) Walmart Lacked a Suspicious Order Monitoring System for Most of the Relevant Period.

422. Like other National Retail Pharmacy Defendants, Walmart self-distributed opioids to its pharmacies in its retail stores, including the 341 stores in Florida. Specifically, Walmart operated registered distribution centers to supply its own pharmacies with controlled substances from the early 2000s until 2018 when it ceased self-distributing controlled substances. Walmart's conduct is particularly troubling given that it acted both as a self-distributing and dispensing pharmacy for such a long period of time.

423. Prior to 2011, Walmart had designed no formal system to identify suspicious orders of controlled substances and, thus, totally failed to meet its statutory obligations.

424. Walmart has claimed that its hourly employees and associates -- who were also responsible for filling orders at Walmart Distribution Centers -- 9 in Florida -- monitored the orders they were filling for unusual size, pattern, and frequency. Typically, this "review" involved between 700 and 800 orders a day. Walmart has also claimed that these hourly

associates were instructed to alert a supervisor if an order appeared unusual based on their experience and memory.

425. Upon information and belief, Walmart can produce no written evidence of any such instructions to Walmart associates, no evidence of any training that would be required to implement such a procedure, or anyone actually being alerted about an unusual order or performing any follow up inquiry.

426. Walmart failed to provide any guidance to the associates as to what constitutes a "suspicious" order. Instead, Walmart emphasized its associates' subjective judgment based on their "knowledge and experience" as distribution center employees. There is no evidence that any Walmart employee ever flagged an order as suspicious prior to 2011.

427. Walmart purportedly implemented a "monitoring program" that would identify suspicious orders of controlled substances in 2011. This system purportedly was in place until 2015.

428. Walmart's monitoring program was insufficient to identify suspicious orders of controlled substances. The program flagged only very large orders of controlled substances. Specifically, it flagged weekly orders for controlled substances of 50 bottles (5,000 dosage units) or more and orders or more than 20 bottles (2,000 dosage units) that were 30% higher than a rolling four-week average for that item. Orders under 2,000 units per week were never flagged, meaning that a pharmacy could order 8,000 units per month without ever being flagged. Moreover, that meant that even if an order were more than 30% greater than the four-week average, it could not draw an alert unless it also was more than 20 bottles.

429. Under this system, an alert did not mean Walmart would report the order or halt it pending necessary due diligence. To the contrary, upon information and belief, Walmart

never reported an order flagged by its monitoring program to the DEA as suspicious. In addition, rather than halting the order, Walmart simply cut the order to the amount of the 50 bottles threshold and shipped it. Walmart never reported cut orders to the DEA. Although information regarding flagged orders was available and sent daily to Walmart's headquarters in Arkansas ("Home Office"), no one from the Home Office ever reviewed or took any action regarding flagged orders.

430. This practice continued until mid-2012, when Walmart implemented "hard limits" on opioid orders. Under this approach, weekly orders of Oxycodone 30mg ("Oxy 30") were automatically reduced to 20 bottles. Still, Walmart failed to report the orders to the DEA.

431. During this time period, Walmart also monitored weekly orders of other controlled substances in quantities of more than 20 bottles. Specifically, an "Over 20 Report" was provided to the Home Office in the morning and if nothing was done by mid-afternoon, the orders were filled and shipped. Upon information and belief, there is no evidence of any order, in fact, being held or reviewed pursuant to this practice.

432. Further, cutting the order did not mean that the Walmart pharmacy would not receive the full supply. Walmart pharmacies also purchased opioids from outside suppliers, including McKesson and AmerisourceBergen. Pharmacies could place another order with these outside vendors to make up the difference, or in some cases, have orders fulfilled by both Walmart and a third-party distributor at the same time. Thus, even though Walmart had the ability to monitor such orders, it chose not to, which allowed its pharmacies to surpass its already high thresholds by simply ordering drugs from a third party.

433. Walmart knew that its monitoring program could not fulfill its obligations to prevent diversion. For example, in 2013, Walmart acknowledged in an internal presentation that

it had not yet designed a compliant system for suspicious order identification, monitoring, and reporting. It was not until 2014 that Walmart's written policies and procedures required orders of interest to be held and investigated.

(2) Walmart's "Enhanced" Monitoring Program Fails to Remedy Deficiencies in its Monitoring Program.

434. In 2015, Walmart enhanced its suspicious order monitoring policy by implementing store-specific thresholds. Upon information and belief, it based these thresholds on the standard deviation of a specific pharmacy's order history for each controlled substance. The thresholds also included minimum amounts, below which no orders were flagged under any circumstance, regardless of pattern or frequency.

435. Walmart's corporate designee, testifying on its behalf in MDL-2804, conceded that thresholds were set for business purposes, not for the purpose of "main[taining] of effective controls against diversion . . . into other than legitimate . . . channels . . . ." 21 U.S.C. §823(a)(1), (b)(1). Further, for almost all Walmart pharmacies, this minimum was set at 2,000 dosage units per week (or 8,000 dosage units per month).

436. As for Walmart's suspicious order monitoring system for its wholesale distribution, the MDL-2804 Court has denied a motion for summary judgment contesting the evidence regarding the inadequacy of Walmart's suspicious order monitoring efforts in that litigation. *See* Opinion and Order Denying Walmart's Motion for Summary Judgment, MDL No. 2804, Doc. 3102 (N.D. Ohio Jan. 27, 2020). In doing so, it "noted[d] the record evidence suggests obvious deficiencies that a layperson could plainly recognize." *Id.* at 4, n.12.

3. The National Retail Pharmacy Defendants Put Profits Before Safety.

a) National Retail Pharmacy Defendants Employed Performance Metrics That Inevitably Led to Diversion.

437. Not only have the National Retail Pharmacy Defendants lacked (and failed to implement) adequate policies and procedures to guard against diversion, but National Retail Pharmacy Defendants, upon information and belief, and other chain pharmacies compounded this problem by implementing performance metrics and prescription quotas for retail stores that contributed to supplying of a black market.

438. In connection with the DEA's investigations described above, the DEA found evidence that Walgreens had a corporate policy encouraging increased sales of oxycodone.[191] As the DEA's September 2012 Order to Show Cause and Immediate Suspension of Registration explains:

> In July 2010, Walgreens' corporate headquarters conducted an analysis of oxycodone dispensing for the prior month at its Florida retail pharmacies and produced an 11 page spreadsheet, ranking all Florida stores by the number of oxycodone prescriptions dispensed in June. The spreadsheet was sent to Walgreens' market pharmacy supervisors in Florida on July 29, 2010, with the admonition that they "look at stores on the bottom end .... We need to make sure we aren't turning legitimate scripts away. Please reinforce." A corporate market director of pharmacy operations did reinforce this message to Florida market pharmacy supervisors, highlighting that their "busiest store in Florida" was filling almost 18 oxycodone prescriptions per day, yet "We also have stores doing about 1 a day. Are we turning away good customers?"

439. In 2011, Walgreens' project to "Increase Rx Sales and Prescription Counts" instructed pharmacies to "improve C2 business" —*i.e.*, dispense more Schedule II controlled substances. This focus on increasing controlled substance dispensing—including opioids—continued even after the DEA investigation and $80 million fine.

[191] Lake Co. Complaint (WAGMDL00387654-666) (September 13, 2012 Order to Show Cause and Immediate Suspension of Registration to Walgreens's Jupiter, Florida Distribution Center)).

440. In 2014, Walgreens Rx Integrity department created a "Pharmacist Controlled Substance Dispensing Opportunities" tool to "identify pharmacists that are dispensing a low rate of controlled substances," and help pharmacists "feel more comfortable in filling controlled substances," specifically focusing on pharmacists dispensing low rates of opioids like "hydromorphone, oxycodone, methadone… hydrocodone," and the cocktail drugs comprising the rest of the "holy trinity" of abuse, such as "carisoprodol… [and] alprazolam."

441. Walgreens also had a bonus program that factored prescription volume into bonus calculations and served as an incentive for pharmacies and pharmacy technicians to ignore the "red flags" of diversion. The corporate push for speed (or volume) deterred pharmacists from taking the time to properly examine the prescriptions before them and exercising their corresponding responsibility to prevent diversion.

442. Indeed, Walgreens had a tool, the "PhLOmometer" that tracked the time to fill a prescription. A March 2013 memo confirms that volume targets included controlled substances as late as 2013 and even after adopting the GFD policy. Specifically, the memo states, as the response to an "[a]nticipated question" that "GFD concerns doesn't relieve you from trying to attain the numbers that have been set for you." When considering high Schedule II dispensing at a particular pharmacy in New Jersey in 2012, as the opiate crisis raged, the pharmacy supervisor pushed back against any attempt to reduce the oxycodone supply, focusing on the impact the reduction would make on filled prescriptions and "the bonus tied to" one pharmacy employee.

443. Only as part of its 2013 settlement with the DEA did Walgreens agree to exclude controlled substances calculations from bonus calculations from 2014 forward. This resulted in a 21% reduction in the number of stores purchasing the 80mg OxyContin – evidence that a

minimal effort to implement common sense controls had a tangible impact on sales of the most potent controlled substances (although that reduction did not last, as described above, and Walgreens' volume by 2014 had increased again).

444. CVS used performance metrics related to its own profits, which would rely, in part, upon the number of prescriptions dispensed. By 2010, CVS had implemented performance metrics that remain publicly available online. CVS's metrics system lacked any measurement for pharmacy accuracy or customer safety. They did, however, prioritize speed and volume, including by requiring pharmacists to meet wait- or fill-time expectations. Moreover, the bonuses for pharmacists are calculated, in part, on how many prescriptions that pharmacist fills within a year. Opioid prescriptions were even included in the volume goals until 2013. Even in 2020, pharmacists described CVS as the "most aggressive chain in imposing performance metrics."[192]

445. This pressure and focus on profits has necessarily deterred the National Retail Pharmacy Defendants' pharmacies from carrying out their obligations to report and to decline to fill suspicious prescriptions and to exercise due care in ascertaining whether a prescription is legitimate.

446. In 2013, the National Association of Boards of Pharmacy ("NABP"), passed a resolution which stated that "performance metrics, which measure the speed and efficiency of prescription work flow by such parameters as prescription wait times, percentage of prescriptions filled within a specified time period, number of prescriptions verified, and number of immunizations given per pharmacist shift, may distract pharmacists and impair professional judgment" and "the practice of applying performance metrics or quotas to pharmacists in the

[192] Ellen Gabler, How Chaos at Pharmacies Is Putting Patients at Risk, New York Times, (Jan. 31, 2020), https://www.nytimes.com/2020/01/31/health/pharmacists-medication-errors.html.

practice of pharmacy may cause distractions that could potentially decrease pharmacists' ability to perform drug utilization review, interact with patients, and maintain attention to detail, which could ultimately lead to unsafe conditions in the pharmacy."[193]

447. Still, according to a 2016 investigation by the Chicago Tribune, as chain pharmacies increasingly promote quick service, "pharmacists frequently race through legally required drug safety reviews — or skip them altogether," missing dangerous drug combinations in the process.[194]

448. In March 2020, journalists also revealed that Walmart not only ignored reports of suspicious activity from pharmacists concerned that they were filling prescriptions for pill mills, but the company considered these pharmacists' focus misdirected. One internal email, reviewed by ProPublica, showed that in response to a question from a regional manager in 2015 about documenting pharmacists' concerns about doctors believed to be operating pill mills, Walmart's director of Health and Wellness Practice Compliance, Brad Nelson, wrote that "We have not invested a great amount of effort in doing analysis on the data since the agreement [requiring such reporting] is virtually over. Driving sales and patient awareness is a far better use of our Market Directors and Market manager's time.[195]

b) National Retail Pharmacy Defendants Worked Together to Increase Their Profits and Lobbied Against Restrictions on Opioid Use and DEA Enforcement.

[193] NAPB, Performance Metrics and Quotas in the Practice of Pharmacy (Resolution 109-7-13) (June 5, 2013), https://nabp.pharmacy/newsroom/news/performance-metrics-and-quotas-in-the-practice-of-pharmacy-resolution-109-7-13/

[194] Sam Roe, Ray Long, and Karisa King, Contract Reporters, Pharmacies Miss Half of Dangerous Drug Combinations, Dec. 15, 2016, https://www.chicagotribune.com/investigations/ct-drug-interactions-pharmacy-met-20161214-story.html.

[195] Jesse Eisinger and James Bandler, Walmart Was Almost Charged Criminally Over Opioids. Trump Appointees Killed the Indictment., ProPublica, (March 25, 2020), https://www.propublica.org/article/walmart-was-almost-charged-criminally-over-opioids-trump-appointees-killed-the-indictment.

449. Walgreens and the other National Retail Pharmacy Defendants recognized the importance of controlling and influencing trade groups such as the National Association of Chain Drugstores ("NACDS") in the context of influencing policy related to opioid drug abuse and diversion. The efforts taken by the NACDS and other trade groups on behalf of Defendants were so important to their bottom line that no expense was spared in supporting such groups. Walgreens took a particularly aggressive view of this mutually beneficial relationship, at times, being its top donor across the country.

450. NACDS worked with the Healthcare Distribution Alliance ("HDA"), the Alliance to Prevent the Abuse of Medicines ("APAM"), and the Pharmaceutical Compliance Forum ("PCF") to support the Marino Blackburn Bill, also known as S.483 or the "Marino Bill." NACDS and Defendants intended the Marino Bill to "tie the hands" of the DEA to "actively and aggressively address diversion and compliance with the CSA." NACDS worked together with others in the opioid supply chain to influence the language in the bill to make it most favorable for them and more restrictive on the DEA. Notably, masking the influence of industry, when APAM was asked to sign on to a 2014 letter of support it was "signed by the Alliance, not the individual members." The final letter that was sent to Senators Hatch and Whitehouse was signed by the members of PCF, as well as APAM, NACDS, AAPM and the U.S. Pain Foundation.

451. The Marino Bill effectively removed the DEA's ability to issue immediate suspension orders regarding manufacturer or distributor registrations. The Marino Bill permitted a non-compliant registrant an opportunity to cure its noncompliance before the DEA could take enforcement action and changed the standard on which revocation occurred. In the

midst of a growing opioid crisis, the Marino Bill removed the most effective deterrent and constrained DEA enforcement actions.

452. In August 2011, NACDS worked with others on a joint letter opposing DEA fee increases for registrants intended to fund the "hir[ing of] more agents and do[ing] more inspections."

453. HDA's Crisis Handbook, developed in 2013, was a direct response to the "threats" perceived by HDA's members and affiliates, including National Retail Pharmacy Defendants, to their bottom line: profits derived from the distribution and sale of prescription opioids.[196] National Retail Pharmacy Defendants did, and continue to, rely on and employ the strategies discussed in the Crisis Playbook. Curiously, there are no slides on how best HDA and its members, including National Retail Pharmacy Defendants, might work to curb the crisis that is the opioid epidemic.

454. In 2016, the NACDS Policy Council discussed ongoing efforts to shape opioid legislation, including their success in removing a requirement that pharmacists have to check their state drug monitoring program before filling controlled prescriptions.[197] NACDS also fought regulatory efforts to require National Retail Pharmacy Defendants to use available dispensing related data and red flags to prevent diversion, opposing what it described as "recent DEA actions in which DEA is expecting pharmacists to be enforcement agents with respect to prescriptions for pain medications."

455. NACDS and HDA sought to slow down and impede DEA enforcement activities by requiring the DEA to "work with the [Food and Drug Administration] FDA on all drug diversion issues," ostensibly because the DEA's diversion enforcement activities – including

[196] Lake Co. Complaint (ABDCMDL00278063).
[197] *Id.* (WAGMDL00605718) (including Walgreens & Walmart).

"clos[ing] drug distribution centers and pharmacies" and "actions against pharmacies" – were harmful in "leading to patients not being able to receive their medications." This purported concern, however, was industry code for impediments to sales.

c) National Retail Pharmacy Defendants Worked With the Manufacturer Defendants to Promote Opioids and Bolster Their Profits at the Expense of Communities.

456. National Retail Pharmacy Defendants also worked in concert with Manufacturer Defendants and non-joined manufacturers to ensure that the false messaging surrounding the treatment of pain and the true addictive nature of opioids was consistent and geared to increase profits for all stakeholders.

457. For example, as early as 2001, CVS worked closely with Purdue and its un-branded marketing arm, Partners Against Pain ("PAP") to "fight back" against allegations (later proved to be true) that Purdue's Oxycontin was being abused at alarming rates. It was Purdue's Partners Against Pain website that Purdue, and its "Partners" including CVS, used to make the claims that the risk of addiction associated with Oxycontin was very small.

458. Purdue worked together with CVS to ensure that CVS's own pharmacists were trained by Purdue on many of the misleading marketing messages that would later sustain a 2007 criminal guilty plea and $600 million fine between Purdue and the DOJ for misleading regulators, doctors, and patients about Oxycontin's risk of addiction and its potential for abuse. CVS's ties to PAP were so deep that CVS even put CVS's own logo communications from its "partner."

459. CVS was so eager to ally itself with Purdue and its partners that it solicited Purdue for its participation in co-hosting Continuing Education programs for healthcare providers and pharmacists regarding training on diversion of prescription opioids.

460. CVS's role was not limited to expanding the market for prescription opioids. CVS worked hard to ensure that demand for prescription opioids was not only sustained but multiplied. It did so through its marketing, advertising, and promotional efforts both on its own and in concert with other stakeholders.

461. CVS worked with Defendant Endo to increase patient adherence to continuing their use of opioids. In fact, CVS played such an important part in the promotion of Endo's Opana ER that it was included as having a crucial role in carrying out one of key sales tactics included in Endo's 2012 Business Plan.

462. Through a company called Catalina Health ("Catalina"), Defendant Endo was able to target Oxycontin patients in areas where Opana ER, a highly abused opioid manufactured by Endo, had preferred formulary status. Catalina in turn worked to create a brand loyalty program that kept new patients on Endo's opioids. CVS, through its pharmacy retention programs, sent letters to the patients' homes to encourage them to stay on Opana – even though prolonged use of opioids increases the risk of addiction, and even though patients in pain presumably need no reminder to continue to take their pain medications. CVS formalized its agreement to promote, market and advertise Endo's opioid products via its "CVS Carecheck Plus Patient Education Service".

463. CVS disseminated materials promoting Opana ER nationwide.

464. CVS likewise helped Defendant Actavis promote its opioids by participating with Defendant Cardinal's Marketing and Business Development team in programs designed to offer rebates and off-invoice discounts on products, with the aim being to "move product."

465. CVS made at least one pitch to Insys to help sell its incredibly potent opioid, Subsys, a liquid form of fentanyl.

466. Working with Purdue as early as 2001, Walgreens played a pivotal role in expanding the market and ensuring the demand and supply for prescription opioids would grow too exponentially. Purdue was particularly interested in using what Walgreens described to Purdue as its Regional Level Market Programs to educate pharmacists and patients on the benefits of Purdue's OxyContin. In fact, Purdue leveraged its relationship with Walgreens and their mutually beneficial goal of growing the opioid business to ensure that Purdue had input into Walgreens "corporate guidelines" to which Walgreens pharmacists were "expected to follow" when it came to the dispensing of prescription opioids.

467. Walgreens also used its corporate oversight abilities to identify stores it believed were not filling enough oxycodone to make sure they weren't "turning away good customers" and encouraging stores to use continuing education created by opioid manufacturers to inform their decisions regarding dispensing.

468. Starting in at least 1999, Purdue sponsored Walgreens' pharmacy continuing education programs designed to encourage stores to "get on the Pro Pain Management Band Wagon." Purdue was thrilled with the response and assistance it received from Walgreens when Purdue presented on "Pain Management for the Pharmacist." At the beginning of each Purdue sponsored meeting, a Walgreens pharmacist made a presentation on his store and the program implemented. His store actively advertised to area doctors and patients that they were a "full service" pain management pharmacy. This service included providing a list to physicians' offices of all Schedule IIs they had in stock (and they had everything), accepting "verbal orders" for Schedule II analgesics before presentation of the original prescription at the store to decrease "waiting time", allowing partial fills on Schedule II prescriptions in terminal patients,

and accepting after hours "emergency Schedule II prescriptions" without a hassle. Purdue praised the pharmacist's actions as "fantastic."

469. Walgreens' use of pro-opioid continuing education continued as the opioid crisis grew. For example, Walgreens' Market Director of Pharmacy Operations recommended that Walgreens District Managers and Pharmacy Supervisors attend a continuing education program titled ""The Pharmacists' Role in Pain Management: A Legal Perspective," which was available on-line at RxSchool.com. This program was one in a long line of pharmacist "education" programs that Purdue developed as part of its strategy to disseminate "a new school of thought" about opioids. Through these programs, Purdue and the National Retail Pharmacy Defendants disseminated fraudulent information that redefined the red flags of abuse or diversion in an effort to correct pharmacists' "misunderstanding" about pain patients and the practice of pain management. Purdue took what it called an "aggressive role" in the education of Walgreens' and other National Retail Pharmacy Defendants' pharmacists on pain management issues.

470. Walgreens' Market Director of Pharmacy Operations also recommended a second continuing education program titled "Navigating the Management of Chronic Pain: A Pharmacist's Guide," which Defendant Endo sponsored. One of the presenters was Kenneth Jackson, a co-author of the CE program titled "Use of Opioids in Chronic Noncancer Pain," which Purdue sponsored. Released in April 2000, it was designed to eliminate "misconceptions about addiction, tolerance and dependence" and contained many of the same messages as the pharmacist guide he authored.

471. Walgreens also presented the video, The Pharmacist's Role in Pain Management - A Legal Perspective at mandatory meetings for pharmacy managers. This continuing education program was also sponsored by Purdue, was similar to the earlier presentations, and

was also disseminated to Walgreens' pharmacists in June 2011. Released in 2009, the program was presented by Jennifer Bolen, JD. Ms. Bolen was a frequent speaker for Purdue and other opioid manufacturers, and served as Special Counsel for the American Academy of Pain Medicine (a known front group for opioid manufacturers).

472. The meeting caused Walgreens' pharmacists who had stopped filling prescriptions for controlled substances to start filling them again.

4. Multiple Enforcement Actions Against the National Retail Pharmacy Defendants Confirms Their Compliance Failures

473. The National Retail Pharmacy Defendants have long been on notice of their failure to abide by state and federal law and regulations governing the distribution and dispensing of prescription opioids. Indeed, several of the National Retail Pharmacy Defendants have been repeatedly penalized for their illegal prescription opioid practices. Upon information and belief, based on the widespread nature of these violations, these enforcement actions are the product of, and confirm, national policies and practices of the National Retail Pharmacy Defendants.

474. Numerous state and federal prosecutions have occurred in which prescription opioid pills were procured from National Retail Pharmacy Defendants. The allegations in this complaint do not attempt to identify all these prosecutions, and the information below is just as an example.

a) CVS

475. CVS is a repeat offender and recidivist: the company has paid fines totaling over $40 million as the result of a series of investigations by the DEA and the DOJ. It nonetheless treated these fines as the cost of doing business and has allowed its pharmacies to continue dispensing opioids in quantities significantly higher than any plausible medical need would require, and to continue violating its recordkeeping and dispensing obligations under the CSA.

476. Confirming its systemic failures to implement and adhere to adequate controls against diversion, CVS has repeatedly faced enforcement actions. In May 2020, CVS's Omnicare subsidiary agreed to pay a $15.3 million civil penalty as part of a settlement with the DEA resolving allegations that it improperly dispensed opioids and other controlled substances to long-term care facilities without a valid prescription.

477. In March 2019, CVS Pharmacy, Inc. (including all of its relevant subsidiaries and affiliates) entered into a $535,000 settlement with the U.S. Attorney's Office for the District of Rhode Island, acting on behalf of the United States, and the DEA's Providence Office. In connection with the settlement, a DEA agent stated: "Pharmacies put patients at risk when they dispense Schedule II narcotics, which have the highest potential for abuse, without a valid and legal prescription.[198]

478. In August 2018, CVS paid $1 million to resolve allegations that CVS pharmacies throughout the Northern District of Alabama violated record-keeping requirements under the CSA and its implementing regulations, the largest civil fine paid in Alabama by a DEA registrant.

[198] Press Release: CVS to pay $535,000 for filling invalid prescriptions, U.S. Drug Enforcement Administration (Apr. 16, 2019), https://www.dea.gov/press-releases/2019/04/16/cvs-pay-535000-filling-invalid-prescriptions.

479. In June 2018, CVS paid $1.5 million to resolve allegations that CVS pharmacies in Long Island, New York failed to timely report the loss or theft of controlled substances, including hydrocodone, recognized as one of the most commonly diverted controlled substances.

480. In July 2017, CVS entered into a $5 million settlement with the U.S. Attorney's Office for the Eastern District of California regarding allegations that its pharmacies failed to keep and maintain accurate records of Schedule II, III, IV, and V controlled substances. The fine followed numerous others throughout the country.

481. In February 2016, CVS paid $8 million to settle allegations made by the DEA and the DOJ that from 2008 to2012, CVS stores and pharmacists in Maryland violated their duties under the CSA and filling prescriptions with no legitimate medical purpose.

482. In October 2016, CVS paid $600,000 to settle allegations by the DOJ that stores in Connecticut failed to maintain proper records in accordance with the CSA.

483. In September 2016, CVS entered into a $795,000 settlement with the Massachusetts Attorney General in which CVS agreed to require pharmacy staff to access the state's prescription monitoring program website and review a patient's prescription history before dispensing certain opioid drugs.

484. In June 2016, CVS agreed to pay the DOJ $3.5 million to resolve allegations that 50 of its stores violated the CSA by filling forged prescriptions for controlled substances—mostly addictive painkillers—more than 500 times between 2011 and 2014.

485. In August 2015, CVS entered into a $450,000 settlement with the U.S. Attorney's Office for the District of Rhode Island to resolve allegations that several of its Rhode Island stores violated the CSA by filling invalid prescriptions and maintaining deficient

records. The United States alleged that CVS retail pharmacies in Rhode Island filled a number of forged prescriptions with invalid DEA numbers, and filled multiple prescriptions written by psychiatric nurse practitioners for hydrocodone, even though these practitioners were not legally permitted to prescribe that drug. The government also alleged that CVS had recordkeeping deficiencies.

486. In May 2015, CVS agreed to pay a $22 million penalty following a DEA investigation that found that employees at two pharmacies in Sanford, Florida, had dispensed prescription opioids, "based on prescriptions that had not been issued for legitimate medical purposes by a health care provider acting in the usual course of professional practice. CVS also acknowledged that its retail pharmacies had a responsibility to dispense only those prescriptions that were issued based on legitimate medical need."

487. In September 2014, CVS agreed to pay $1.9 million in civil penalties to resolve allegations it filled prescriptions written by a doctor whose controlled-substance registration had expired.

488. In 2013, CVS agreed to pay $11 million to resolve allegations it violated the CSA and related federal regulations at its retail stores in Oklahoma and elsewhere by: (1) creating and using "dummy" DEA registration numbers on dispensing records, including records provided to state prescription drug monitoring programs; (2) filling prescriptions from prescribers who lacked current or valid DEA numbers; and (3) substituting the DEA number of non-prescribing practitioners for the DEA numbers of prescribers on prescription records.

489. In August 2013, CVS was fined $350,000 by the Oklahoma Pharmacy Board for improperly selling prescription narcotics in at least five locations in the Oklahoma City metropolitan area.

490. Dating back to 2006, CVS retail pharmacies in Oklahoma and elsewhere intentionally violated the CSA by filling prescriptions signed by prescribers with invalid DEA registration numbers.

b) Walgreens

491. Walgreens also has been penalized for serious and flagrant violations of the CSA. Indeed, Walgreens agreed to the largest settlement in DEA history at the time—$80 million—to resolve allegations that it committed an unprecedented number of recordkeeping and dispensing violations of the CSA, including negligently allowing controlled substances such as oxycodone and other prescription painkillers to be diverted for abuse and illegal black market sales.

492. The settlement resolved investigations into, and allegations of, CSA violations in Florida, New York, Michigan, and Colorado that resulted in the diversion of millions of opioids into illicit channels.

493. Walgreens' Florida operations at issue in this settlement highlight its egregious conduct regarding diversion of prescription opioids. Walgreens' Florida pharmacies each allegedly ordered more than one million dosage units of oxycodone in 2011—more than 10 times the average amount.

494. They increased their orders over time, in some cases as much as 600% in just 2 years, including, for example, supplying a town of 3,000 with 285,800 orders of oxycodone in a 1-month period.

495. Walgreens' settlement with the DEA stemmed from the DEA's investigation into Walgreens' distribution center in Jupiter, Florida, which was responsible for significant opioid diversion in Florida. According to the Order to Show Cause, Defendant Walgreens'

corporate headquarters pushed to increase the number of oxycodone sales to Walgreens' Florida pharmacies and provided bonuses for pharmacy employees based on number of prescriptions filled at the pharmacy to increase oxycodone sales. In July 2010, Walgreens ranked all of its Florida stores by the number of oxycodone prescriptions dispensed in June of that year and found that the highest-ranking store in oxycodone sales sold almost 18 oxycodone prescriptions per day. All of these prescriptions were filled with opioids originating from the Walgreens Jupiter Distribution Center.

c) Walmart

496. Walmart paid a $637,000 fine to settle an action by federal prosecutors against five Walmart and Sam's Club Pharmacies in Texas, alleging that they failed to keep records required to help prevent diversion of controlled substances as required by the CSA. Specifically, "accountability audits did not match the drugs on hand, revealing major overages and shortages in the accountability of controlled substances, and there were missing invoices for controlled substances all in violation of the CSA."[199] A U.S. Attorney further explained that "[b]ecause of the pharmacies' lack of proper record keeping, a variety of Schedule II, III, IV and V controlled substances were lost or stolen and possibly diverted."[200]

497. September 2018 minutes of an Oklahoma State Board of Pharmacy meeting reflect that an Oklahoma "Wal-Mart Pharmacy was charged with multiple violations of state and federal regulations and rules including establishing and maintaining effective controls against diversion of prescription drugs."[201] Walmart agreed to pay a fine to resolve those alleged violations.

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[199] Associated Press, *Wal-Mart Settles Drug Records Accusation*, (Jan. 7, 2009), http://prev.dailyherald.com/story/?id=262762.
[200] *Id.*
[201] Minutes September 26, 2018, Oklahoma State Board of Pharmacy,

498. A prosecution against a Virginia prescriber revealed failures at Walmart pharmacies from 2007 to 2012. A Decision and Order in that case revealed that a Walmart pharmacy would fill prescriptions pursuant to a telephone message from a staff member of the prescriber, purportedly on behalf of the prescriber, even though the staff member failed to provide this prescriber's DEA number.[202] By mid-November 2008, 3 Walmart pharmacies had dispensed more than 200 hydrocodone prescriptions and refills on behalf of this prescriber. In 2012, this prescriber learned that someone was fraudulently using his DEA number. He called a Walmart pharmacy regarding refill requests faxed from his office and advised "that somebody was fraudulently using [his] DEA number."[203] Although he asked that his DEA number be blocked, the same Walmart pharmacy filled another 2 prescriptions after this alert. Although Walmart did not face sanctions for its conduct, the Opinion and Order described "the fact that prescriptions which were missing [the] Respondent's DEA number were routinely filled notwithstanding that they were facially invalid," and "that the prescriptions were for hydrocodone in quantities and dosings that were clearly outside the scope of what is usually prescribed by podiatrists" as "deeply disturbing."[204]

F. Defendants targeted their illegal conduct nationwide, including in Florida.

499. Florida has been hit hard by the opioid epidemic. In Florida, the opioid epidemic led to increased opioid use, opioid related deaths, and births of children exposed to opioids *in utero* and NOWS births between 1999 and now.

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https://www.ok.gov/pharmacy/documents/Min%20September%202018.pdf (last visited Oct. 22, 2020).
[202] DOJ, DEA, Docket No. 15-26, [FR Doc. No. 2017-13158] Peter F. Kelly, D.P.M.; Decision and Order, https://www.deadiversion.usdoj.gov/fed_regs/actions/2017/fr0623.htm.
[203] *Id.*
[204] *Id.*

500. In Florida, in 2020, 7,842 opioid-related deaths were reported, 6,089 of which were reported as the sole cause of death, a 42% increase over 2019.[205] In 2010, approximately 2 out 1,000 babies born in Florida hospitals were diagnosed with NOWS; in 2016, more than 5 out 1,000 babies born in Florida hospitals were diagnosed with NOWS.[206]

G. Plaintiff School Districts Have Been Damaged As A Result Of Defendants' Illegal Conduct.

501. Florida public school districts have not been spared the ravages of the opioid epidemic: staff, parents, and students have fallen victim to opioid addiction. And children born to opioid-addicted parents are innocent victims of the epidemic, with their lives permanently impaired by addiction from time *in utero*. About 75 to 90 percent of children exposed to opioid use in the womb are born with NOWS.[207] NOWS is essentially the process of the newborn infant going through withdrawal from the *in utero* drug addiction, and it is a condition that comes with serious and often chronic developmental disabilities. A disproportionate number of these children require enhanced educational services, including, but not limited to special education programs. Post-birth exposure to family members' addiction to opioids, and often death, causes children to also require enhanced education services. Students addicted to opioids also require enhanced education services.

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[205] Drugs Identified in Deceased Persons by Florida Medical Examiners https://www.fdle.state.fl.us/MEC/Publications-and-Forms/Documents/Drugs-in-Deceased-Persons/2020-Annual-Drug-Report FINAL.aspx, p.ii.

[206] HCUP Fast Stats- Neonatal Abstinence Syndrome (NAS) Among Newborn Hospitalizations, Agency for Healthcare Research and Quality, https://www.hcup-us.ahrq.gov/faststats/NASServlet?radio-2=on&location1=FL&characteristic1=01C11&location2=&characteristic2=01C11&expansionInfoState=hide&dataTablesState=hide&definitionsState=hide&exportState=hide

[207] Denise J. Maguire, et al., Long-Term Outcomes of Infants with Neonatal Abstinence Syndrome, 35 Neonatal Network 5 (2016).

502. Opioid-exposed and NOWS children have 2.7 times the odds of having a severe intellectual disability;[208] 2.43 times the odds of having autism spectrum disorder;[209] are 2.5 times more likely to fail to meet educational standards in third through seventh grade;[210] and they are more than 10 times more likely to be diagnosed with ADHD.[211]

503. Plaintiff school districts are required by state and federal law to make significant expenditures to accommodate and educate students with special learning needs.

504. Federal law also requires Plaintiff school districts to expend resources to actively seek out and identify all children from birth through age 21 in their districts who may be eligible for special education and related services, to evaluate such children, and provide them with appropriate services.[212]

505. Plaintiff school districts have shouldered the increased cost of educating students who were exposed to prescription opioids *in utero,* who are affected by their family members' opioid addition or death, and who themselves are addicted to opioids as a result of the opioid epidemic that Defendants purposely caused. Plaintiff school districts will continue to bear the

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[208] Su Lynn Yeoh; John Eastwood, FRACP, Ph.D.; Ian M. Wright, MBBS, FRACP; Rachael Morton, MScMed, Ph.D.; Edward Melhuish, Ph.D.; Meredith Ward, MBBS, FRACP, Ph.D.; Ju Lee Oei, MBBS, FRACP, MD, *Cognitive and Motor Outcomes of Children With Prenatal Opioid Exposure: A Systematic Review and Meta-analysis*, 2 JAMA Network Open 7 (2019), doi:10.1001/jamanetworkopen.2019.7025.

[209] Rubenstein, E., Young, J. C., Croen, L. A., DiGuiseppi, C., Dowling, N. F., Lee, L-C., ... Daniels, J., *Brief Report: Maternal Opioid Prescription from Preconception Through Pregnancy and the Odds of Autism Spectrum Disorder and Autism Features in Children*, 49 Journal of Autism and Developmental Disorders (2018), https://doi.org/10.1007/s10803-018-3721-8.

[210] Oei JL, Melhuish E, Uebel H, et al. *Neonatal abstinence syndrome and high school performance*, 139 Pediatrics 2 (2017).

[211] Eivind Sirnes, Leif Oltedal b,c, Hauke Bartsch d, Geir Egil Eide, Irene B. Elgen, Stein Magnus Aukland. Brain morphology in school-aged children with prenatal opioid exposure: A structural MRI study, Early Human Development 106–107 (2017). In addition, eighty percent of children with ADHD receive school-based services via federally mandated Individual Education Plans (IEP) or services under Section 504 of the Rehabilitation Act. Melissa L. Danielson, MSPH, Susanna N. Visser, DrPH, Andrea Chronis-Tuscano, Ph.D., and George J. DuPaul, Ph.D. A National Description of Treatment among United States Children and Adolescents with Attention-Deficit/Hyperactivity Disorder. 192 J Pediatr. 240–46.e1. (2018), doi: 10.1016/j.jpeds.2017.08.040.

[212] 34 C.F.R. § 300.111.

financial burden of educating these students for the foreseeable future, as subsequent birth cohorts reach school age.

506. Plaintiff school districts also provide medical insurance coverage, workers' compensation, and long-term disability insurance to their employees. Plaintiff school districts that are self-insured have paid for claims for prescription opioids and treatment for addiction to prescription opioids for its employees and family members through insurance and workers compensation. Upon information and belief, many of these prescription opioids were inappropriately prescribed to treat chronic pain.

V. CLASS ALLEGATIONS

507. Plaintiff brings this action pursuant to Rule 23 of the Federal Rules of Civil Procedure on behalf of all independent public school districts in the state of Florida.

508. Plaintiff is a member of the Class it seeks to represent.

509. The proposed class definition is intended to be subject to revision if facts adduced in discovery suggest desirable or necessary refinements to it.

510. The members of the Class are sufficiently numerous that joinder of all members is impracticable. There are 67 independent public school districts in Florida.

511. Questions of fact and law common to the members of the Class that are both well-suited to class-wide adjudication and predominate over any questions affecting only individual Florida public school districts. These common, predominating questions include, but are not limited to: a) Whether the Defendants conspired and violated RICO in the marketing and dissemination of prescription opioids; b) Whether Defendants were, or reasonably should have been, aware that prescription opioids were highly addictive, not proper for long-term treatment, were being over-prescribed, and were causing an addiction epidemic leading to addiction, joblessness, homelessness, and death among users; c) Whether Defendants were, or reasonably

should have been, aware that use of prescription opioids in pregnant women leads to NOWS, also called NAS, with children born with NOWS exhibiting higher rates of behavioral and emotional disorders and cognitive disabilities, necessitating special education services; d) Whether children living in opioid-afflicted households disproportionately require and qualify for enhanced educational services, including special education services; e) Whether students who are opioid addicted require enhanced educational services including special education services; f) Whether Manufacturer Defendants misrepresented that prescription opioids were not highly addictive and were in fact proper for long term use; g) Whether Defendants took reasonable steps to warn Florida doctors, pharmacists, pregnant women, and the public of the highly addictive qualities of prescription opioids and the potentially catastrophic results of opioid use during pregnancy; and h) Whether Defendants were negligent.

512. Plaintiff's claims are typical of the claims of other class members in that they have experienced a measurable increase in rates of 1) opioid-related learning disabilities among children of opioid-addicted parents for whom it is required to provide enhanced education and services, including under the Americans with Disabilities Act, Section 504 of the Rehabilitation Act of 1973, and the Individuals with Disabilities Education Act to provide special education resources; 2) addiction among employees for whom it provides healthcare; and 3) addiction among students, for whom it provides counseling, special education, and crisis intervention.

513. Plaintiff will fairly and adequately represent and protect the interests of the class. Plaintiff has retained experienced and accomplished counsel who are able and prepared to expend the resources necessary to litigate this case. A class action is superior to other methods for fairly and efficiently adjudicating this controversy. Alternatively, class-wide liability under the theories advanced in this complaint could properly be certified under Rule 23(c)(4).

VI. CAUSES OF ACTION

COUNT I: VIOLATION OF RACKETEER INFLUENCED CORRUPT ORGANIZATIONS ACT (18 U.S.C. §1962-(c)–(d))

514. Plaintiff re-alleges and incorporates by reference the foregoing allegations as if they were fully set forth herein.

515. Count I is brought by Plaintiff on behalf of itself and the Class.

516. The Racketeer Influenced Corrupt Organizations Act ("RICO") makes it "unlawful for any person employed by or associated with any enterprise engaged in, or the activities of which affect, interstate or foreign commerce, to conduct or participate, directly or indirectly, in the conduct of such enterprise's affairs through a pattern of racketeering activity." 18 U.S.C. §1962(c).

517. At all relevant times, Defendants have been "person[s]" under 18 U.S.C. §1961(3) because they are capable of holding, and do hold, a "legal or beneficial interest in property."

518. RICO makes it unlawful for "any person to conspire to violate" the provisions of 18 U.S.C. §1962(c). 18 U.S.C. §1962(d).

519. As a direct and proximate result of their fraudulent scheme and common course of conduct, Defendants extracted billions of dollars of profit. As explained in detail below, Defendants' years-long misconduct violated 18 U.S.C. §1962(c)-(d).

A. The Enterprise

520. At all relevant times, a RICO opioid enterprise, or several thereof, within the meaning of 18 U.S.C. §1961(4), ("The Enterprise") was operated by a group of individuals associated in fact, though not a collective legal entity. The Enterprise: (a) existed separately from each of its component entities; (b) existed separately from the pattern of racketeering in which

each of its component entities engaged; and (c) constituted an ongoing organization consisting of legal entities, including, but not limited to, Defendants.

521. As alleged herein, at all relevant times, Defendants, along with non-joined manufacturers, (collectively the "participants") moved aggressively to capture a large portion of the opioid sales market. In so doing, the participants, through The Enterprise, pursued an aggressive nationwide campaign exaggerating the concept of under-treatment of pain and deceptively marketing opioids as being: (a) rarely, if ever, addictive; (b) safe and effective for the treatment of chronic long-term pain and everyday use; (c) abuse resistant or deterrent; and/or (d) safe and effective for types of pain for which the drugs were not approved. All participants knowingly failed to report suspicious orders as required by state and federal law, thereby inundating the market with opioids.

522. Defendants, along with non-joined manufacturers and other entities and individuals, associates in fact, conducted or engaged in the affairs of, and were employed by or associated with, The Enterprise to deceive opioid prescribers, the public, and regulators into believing that: (a) opioids were safe and effective for the treatment of long-term chronic pain; (b) opioids presented minimal risk of addiction; and/or (c) the participants were in compliance with their state and federal reporting obligations. The participants sought, through The Enterprise, to maximize revenues from the design, manufacture, sale, and distribution of opioids which, in fact, were highly addictive and often ineffective and dangerous when used for chronic long-term, and other types of, pain.

523. The participants in The Enterprise have a separate existence from The Enterprise, including distinct legal statuses, different offices and roles, bank accounts, officers, directors, employees, individual personhood, reporting requirements, and financial statements.

524. The Enterprise operated with a common communication network by which the participants and associates in fact exchanged information regularly through the use of wires and mail. The Enterprise used this common communication network for the purpose of deceptively marketing, selling, and distributing opioids to the general public. When participants'products, sales, distributions, and failure to report suspicious sales were contested by other parties, the participants, and associates in fact, took action to hide the scheme to continue its existence.

525. The participants in The Enterprise have systematically linked to each other through corporate ties, contractual relationships, financial ties, and the continuing coordination of activities. Through The Enterprise, the participants functioned as a continuing unit with the purpose of furthering the illegal scheme and their common purposes of increasing revenues and market share and minimizing their losses. Each participant reaped the bounty generated by The Enterprise by sharing the benefit derived from increased sales of opioids and other revenue generated by the scheme to defraud prescribers, patients, and those paying for prescribed opioids, and by failing to report suspicious sales.

526. The Enterprise has engaged in deceptive marketing of opioids as non-addictive, and as safe and effective for chronic long-term pain and for uses that are not FDA-approved. The Enterprise continues to not report suspicious sales. The Enterprise has engaged in such activity to maximize opioid sales and profits. To fulfill this purpose, The Enterprise has advocated for, and caused the over-prescription and over-distribution of opioids by marketing, promoting, advertising, and selling opioids throughout the nation, including Florida, and across state boundaries and by failing to report suspicious sales. The participants' receipt of monies from these activities has consequentially affected interstate and foreign commerce. The Enterprise's

past and ongoing practices thus constitute a pattern of racketeering activity under 18 U.S.C. §1961(5).

527. Each participant and associates in fact of The Enterprise furthered the ends of The Enterprise through the acts and omissions pled in this complaint.

528. Defendants, through The Enterprise, relentlessly promoted opioids to prescribers, regulators, and the public as having little to no risk of addiction, and as being safe and effective for the treatment of chronic, long-term pain and other common, everyday uses. Their success in maximizing sales was due to their tight collaboration through, and in collaboration with, the pain foundations—a formidable partnership that marketed to hundreds of thousands of prescribers across the country. The relationship was strengthened, in part, by individuals, including physicians, that held different leadership roles at different times across the various entities participating in The Enterprise over the years.

529. On numerous occasions, Defendants, through The Enterprise, funded the pain foundations' marketing efforts. They specifically chose to partner with the pain foundations and individual physicians to publish and otherwise disseminate misleading pro-opioid material, knowing the public and prescribers would be more receptive to statements made by what they perceived to be scholarly, neutral, third-party sources.

530. Furthermore, Defendants, through The Enterprise, knowingly failed to design and operate a system to monitor suspicious orders of controlled substances and failed to notify the appropriate DEA field division offices in their areas of suspicious orders, including "orders of unusual size, orders deviating substantially from a normal pattern, and orders of unusual frequency." 21 C.F.R. §1301.74(b).

531. Defendants, through The Enterprise, worked together by:

(a) planning to deceptively market and manufacture opioids that were purportedly non-addictive, safe, and effective for the treatment of chronic long-term pain;

(b) concealing the addictive qualities and risks of opioids from prescribers and the public;

(c) misleading the public about the addictive nature, safety and efficacy of opioids;

(d) otherwise misrepresenting or concealing the highly dangerous nature of opioids from prescribers and the public;

(e) illegally marketing, selling, and/or distributing opioids;

(f) collecting revenues and profits from the sale of such products for uses for which they are unapproved, unsafe, or ineffective; and/or

(g) failing to report suspicious sales as required by the CSA.

532. To achieve their common goals, Defendants, through The Enterprise, hid from the general public the full extent of the unsafe and ineffective nature of opioids for chronic and other types of pain as described herein. Defendants, through The Enterprise, suppressed and/or ignored warnings from third parties, whistleblowers, and governmental entities about the addictive, unsafe, and often ineffective nature of opioids.

533. The foregoing allegations support that Defendants, through The Enterprise, were part of an association of entities that shared a common purpose, had relationships across various associates in fact of The Enterprise, and collaborated to further the goals of The Enterprise for a continuous period of time. The Manufacturer Defendants and non-joined manufacturers, as participants in The Enterprise, knowingly and intentionally engaged in deceptive marketing practices and incentivized pain foundations, marketing firms, and physicians to do so as well. All Defendants, as participants in The Enterprise, knowingly and intentionally failed to report suspicious orders as required by state and federal law and inundated the market with opioids.

B. Mail and Wire Fraud

534. To attempt to carry out and to carry out the scheme to defraud, Defendants knowingly conducted and participated, directly and indirectly, in the conduct of the affairs of The Enterprise through a pattern of racketeering activity within the meaning of 18 U.S.C. §§1961(1), 1961(5) and 1962(c). And The Enterprise employed the use of the mail and wire facilities, in violation of 18 U.S.C. §§1341 (mail fraud) and 1343 (wire fraud).

535. Specifically, Defendants, through The Enterprise, have committed, conspired to commit, and/or aided and abetted in the commission of at least 2 predicate acts of racketeering activity (*i.e.*, violations of 18 U.S.C. §§1341 and 1343) within the past 4 years. The multiple acts of racketeering activity which the participants, through The Enterprise, committed or aided and abetted were related to each other and also posed a threat of continued racketeering activity. They therefore constitute a "pattern of racketeering activity." The racketeering activity was made possible by The Enterprise's regular use of the facilities, services, distribution channels, and employees of The Enterprise. The Enterprise committed fraud by using the mail, telephone, and Internet to transmit mailings and wires in interstate or foreign commerce.

536. Defendants, through The Enterprise, devised and knowingly carried out a material scheme and/or artifice to defraud regulators, prescribers, and the public to obtain money at the cost of the Plaintiff and the Class through materially false or fraudulent pretenses, representations, promises, or omissions of material facts. The Enterprise committed these racketeering acts intentionally and knowingly with the specific intent to advance the illegal scheme.

537. The participants, through The Enterprise, committed predicate acts of racketeering, 18 U.S.C. §1961(1), including:

(a) Mail Fraud: Violated 18 U.S.C. §1341 by sending and receiving, and by causing to be sent and/or received, materials via U.S. mail or commercial interstate carriers for the purpose of executing the unlawful scheme to deceptively market, sell, and distribute the opioids by means of false pretenses, misrepresentations, promises and omissions; and

(b) Wire Fraud: Violated 18 U.S.C. §1343 by transmitting and/or receiving, and by causing to be transmitted and/or received, materials by wire for the purpose of executing the unlawful scheme to defraud and obtain money on misrepresentations and false pretenses, promises and omissions.

538. The Enterprise's use of the mails and wires include, but are not limited to, the transmission, delivery, and shipment of deceptive marketing materials, the filling of suspicious orders, and the misleading of regulators and the public as to their compliance with state and federal reporting obligations. These materials would not have been delivered, orders would not have been filled, and regulators would have not been misled but for Defendants' illegal scheme through The Enterprise, including:

(a) the FSMB's publication of opioid prescribing guidelines titled, "Responsible Opioid Prescribing: A Physician's Guide," by Fishman;

(b) the FSMB's publication of "Responsible Opioid Prescribing: A Clinician's Guide (Second Edition, Revised and Expanded)," by Fishman;

(c) the APF's publication of Exit Wounds;

(d) the AAPM's "consensus statement" and educational programs featuring Fine;

(e) the APA's publication and dissemination of "Prescription Pain Medication: Preserving Patient Access While Curbing Abuse";

(f) false or misleading communications to the public and to regulators;

(g) failing to report suspicious orders as required by state and federal law;

(h) sales and marketing materials, including slide decks, presentation materials, purported guidelines, advertising, web sites, product packaging, brochures, labeling and other writings which misrepresented, falsely promoted and concealed the true nature of opioids;

(i) documents intended to facilitate the manufacture and sale of opioids, including bills of lading, invoices, shipping records, reports and correspondence;

(j) documents to process and receive payment for opioids, including invoices and receipts;

(k) payments to the foundations and physicians that deceptively marketed the participants' opioids;

(l) deposits of proceeds; and

(m) other documents and things, including electronic communications.

539. The Enterprise also used the internet and other electronic facilities to carry out the scheme and conceal the ongoing fraudulent activities. For example, Manufacturer Defendants made misrepresentations about opioids on their websites, YouTube, and through online ads, all of which were intended to mislead prescribers and the public about the safety, efficacy and non-addictiveness of opioids.

540. The Enterprise also communicated by U.S. mail, by interstate facsimile, and by interstate electronic mail with various affiliates, regional offices, divisions, distributors, regulators, and other third-party entities in furtherance of the scheme. The mail and wire transmissions described in this complaint were made in furtherance of The Enterprise's scheme and common course of conduct to deceive prescribers, consumers, and regulators, oversupply the market, and fail to report suspicious sales.

541. Many of the precise dates of the fraudulent uses of the U.S. mail and interstate wire facilities have been concealed and they cannot be alleged with specificity without access to Defendants' and The Enterprise associates in fact's books and records. However, Plaintiff has described the types of predicate acts of mail and/or wire fraud that occurred. The secretive nature of The Enterprise's activities made the unlawful tactics discussed in this complaint even more deceptive and harmful.

542. The foregoing allegations support that Defendants, through The Enterprise: (a) engaged in a pattern of racketeering activity by repeatedly engaging in wire and mail fraud to deceptively market their products through the use of both print and electronic outlets; and (b) engaged in a pattern of racketeering activity by repeatedly engaging in wire and mail fraud to deceive regulators and oversupply the market while failing to report suspicious sales.

C. Conspiracy Allegations

543. Defendants have not undertaken the practices described herein merely in parallel, but, rather, as part of a common scheme and conspiracy. In violation of 18 U.S.C. §1962(d), Defendants conspired, through The Enterprise, to violate 18 U.S.C. §1962(c), as described in this complaint.

544. Defendants conspired to incentivize and encourage various other persons, firms and corporations, including third-party entities and individuals not named as defendants in this complaint, to carry out offenses and other acts in furtherance of the conspiracy. Defendants conspired to increase or maintain revenues, increase market share, and/or minimize losses for themselves and their other collaborators throughout the illegal scheme and common course of conduct. To achieve this goal, Defendants, through The Enterprise, engaged in the aforementioned predicate acts on numerous occasions and, with knowledge and intent, agreed to the overall objectives of the conspiracy and participated in the common course of conduct to commit acts of fraud and indecency in defectively marketing and/or selling opioids through the use of mail and wire fraud.

545. Indeed, for the conspiracy to succeed, Defendants had to agree to deceptively market, sell, and/or distribute opioids while failing to report suspicious sales. The unanimity of the marketing tactics and failure to report suspicious sales gave credence to their misleading

statements and omissions to prescribers, patients and those paying for prescribed opioids, and regulators, and directly caused opioids to inundate the nation, including Florida.

546. Defendants, through The Enterprise, knew and intended that government regulators, prescribers, consumers, and governmental entities would rely on the collective material misrepresentations and omissions that were made through The Enterprise about opioids and suspicious sales, and knew and recklessly disregarded the harm that would be suffered in Florida and across the nation.

547. The Enterprise knew that by partnering with the pain foundations and individual physicians who carried a more neutral public image, they would be able to attribute more scientific credibility to their products, thereby increasing Defendants opioid sales and profits.

548. The Enterprise knew that by filling, and failing to report, suspicious sales, they would significantly increase the Defendants' opioid sales and profits.

549. The foregoing illustrates Defendants' liability under 18 U.S.C. §1962(d), by their engaging in racketeering and conspiring to achieve the common goal of maximizing opioid sales and profits.

550. As described herein, Defendants, through The Enterprise, engaged in a pattern of related and continuous predicate acts for years. The predicate acts constituted a variety of unlawful activities, each conducted with the common purpose of obtaining significant monies and revenues, based on their misrepresentations and omissions. The predicate acts also had the same or similar results, participants, victims, and methods of commission. The predicate acts were related and not isolated events. The predicate acts all had the purpose of generating significant revenue and profits for those engaged in The Enterprise. The predicate acts were

committed or caused to be committed by The Enterprise to benefit Defendants and in furtherance of the fraudulent scheme.

551. As alleged in this complaint, scores of insurers, Florida prescribers, and Florida citizens and residents, relied on participants' representations and omissions through The Enterprise.

552. Plaintiff's and the Class' injuries were directly proximately caused by the racketeering activity set out in this complaint.

553. As a direct and proximate result of Defendants' and other participants' conduct and pattern of racketeering activity to benefit themselves, Plaintiff and the Class have suffered injury and damages, including, but not limited to, significant expenses for: 1) special education programs for students (a) exposed to opioids *in utero* (NOWS), (b) for students with emotional and behavioral damages resulting from living in households afflicted by opioids, and (c) for students addicted to opioids; 2) health services; 3) health insurance; and 4) disability payments and other employee services including opioid addiction treatment and overdose prevention. Thus, the violations of 18 U.S.C. §1962(c)-(d) have directly and proximately caused injuries and damages to Plaintiff and the Class, and Plaintiff and the Class are entitled to bring this action for three times the actual damages, as well as injunctive/equitable relief, costs and reasonable attorneys' fees in accordance with 18 U.S.C. §1964(c).

COUNT II: VIOLATION OF FLORIDA RICO, FLORIDA STATUTE §895.01, *ET SEQ*

554. Plaintiff re-alleges and incorporates by reference the foregoing allegations as if they were fully set out herein.

555. Count II is brought by Plaintiff on behalf of itself and the Class against Defendants.

556. This is a claim for civil relief under Section 895.05(1), F.S., of the Racketeer Influenced and Corrupt Organization Act ("Florida RICO").

557. At all relevant times, Defendants are and has been a "person" under Florida RICO.

558. Florida RICO makes it "unlawful for any person who has with criminal intent received any proceeds derived, directly or indirectly, from a pattern of racketeering activity or through the collection of an unlawful debt to use or invest, whether directly or indirectly, any part of such proceeds, or the proceeds derived from the investment or use thereof, in the acquisition of any title to, or any right, interest, or equity in, real property or in the establishment or operation of any enterprise." §895.03(1), F.S.

559. As set out in Count I above, "Violation of RICO 18 U.S.C. §1961, *et seq*.," Defendants knowingly and deliberately engaged in a pattern of racketeering activity under §§895.02(7), 895.02(8)(a) and (b), F.S., by multiple incidences of designing plans, and enabling The Enterprise members, to aggressively and deceptively market, promote, distribute, and sell their opioids throughout Florida over-emphasizing what was represented to be the under-treatment of pain and by deliberately deceiving Florida opioid prescribers, the Florida public, and regulators by fraudulently marketing opioids as being: (a) rarely, if ever, addictive; (b) safe and effective for the treatment of chronic long-term pain and everyday use; (c) abuse-resistant or deterrent; and/or (d) safe and effective for types of pain for which the drugs were not approved.

560. Defendants along with other of The Enterprise participants associated in fact and schemed in the deceptive marketing, promotion, distribution, and sale of opioids in Florida and operated The Enterprise, within the meaning of §895.02(5), F.S.

561. Through this illegal enterprise, Defendants, as co-conspirators, engaged in a pattern of racketeering activity that enabled Defendants and other participants of The Enterprise to deceptively market, promote, distribute, and sell opioids in Florida and to fail to report suspicious sales, in violation of §895.03(1), F.S.

562. Defendants furthered the goals of The Enterprise through the multiple acts and omissions, alleged above in this Complaint, which affected Florida, Plaintiff, and the Class.

563. As described above, as a direct and proximate result of this criminal scheme and common course of conduct, Defendants were able to extract billions of dollars of profit for the Defendants and other participants of The Enterprise. As alleged in detail above, Defendants' years-long misconduct violated §895.03(01), F.S., and applicable regulations.

564. As alleged above, Defendants and persons associated in fact with The Enterprise, did knowingly conduct and participate, directly and indirectly, in the conduct of the affairs of The Enterprise through a pattern of racketeering activity within the meaning of 18 U.S.C. §§1961(1), 1961(5) and 1962(c) and thus §§895.02(7), (8)(a) and (b), F.S., in that Defendants employed the use of the mail and wire facilities, in violation of 18 U.S.C. §§1341 (mail fraud) and 1343 (wire fraud).

565. Specifically, as alleged above, Defendants committed, conspired to commit, and/or aided and abetted in the commission of more than 2 predicate acts of racketeering activity from at least 2009 to 2018, incidences occurring within 5 five years of the date of this Complaint in violation of §895.02 (7), F.S. The multiple acts of racketeering activity which Defendants committed, conspired, or aided and abetted in the commission of were

related to each other and also posed a threat of continued racketeering activity. They therefore constitute a "pattern of racketeering activity." The racketeering activity was made possible by Defendants' regular use of the facilities, services, distribution channels and employees of Defendants and other participants of The Enterprise. Defendants participated in the scheme by using the mail, telephone and internet to transmit mailings and wires in Florida commerce.

566. The foregoing allegations support that: (a) Defendants engaged in a pattern of racketeering activity by repeatedly engaging in wire and mail fraud to deceptively market Defendants' and other participants' of the Enterprise opioid products through the use of both print and electronic outlets in Florida; and (b) by Defendants engaged in a pattern of racketeering activity by repeatedly engaging in wire and mail fraud to deceive regulators and to oversupply the Florida market, while failing to report suspicious sales.

567. Plaintiff and the Class were directly and proximately injured by Defendants' racketeering activity, which caused and/or contributed to the opioid epidemic in Florida affecting Florida students, and through Defendants' misleading and false marketing, misstatements, and omissions, Plaintiff and the Class have been forced to bear the continuing costs caused by the effects of the opioid epidemic upin Florida's public education system.

568. Defendants' violations of 18 U.S.C. §1962(c)-(d) and §895.03(1), F.S., have directly and proximately caused injuries and damages to Plaintiff and the Class as alleged in this Complaint, and Plaintiff and the Class bring this action in accordance with §895.05, F.S., and 18 U.S.C. §1964(c) damages, including, but not limited to, significant expenses for: 1) special education programs for students (a) exposed to opioids *in utero* (NOWS), (b) for students with

emotional and behavioral damages resulting from living in households afflicted by opioids, and (c) for students addicted to opioids; 2) health services; 3) health insurance; and 4) disability payments and other employee services including opioid addiction treatment and overdose prevention. Thus, the violations of 18 U.S.C. §1962(c)-(d) have directly and proximately caused injuries and damages to Plaintiff and the Class, and Plaintiff and the Class are entitled to bring this action for three times the actual damages, as well as injunctive/equitable relief, costs and reasonable attorneys' fees in accordance with 18 U.S.C. §1964(c).

COUNT III: CIVIL CONSPIRACY

569. Plaintiff re-alleges and incorporates by reference the foregoing allegations as if they were fully set out herein.

570. Count III is brought by Plaintiff on behalf of itself and the Class against Defendants.

571. Defendants engaged in a civil conspiracy in their unlawful marketing, distribution, and selling of opioids and/or efforts to boost the sale of opioids into Plaintiff's and the Class' school district communities. Defendants agreed to increase the sales of opioids by unfair, deceptive, and unconscionable means, in violation of federal and Florida controlled-substances laws.

572. Defendants engaged in a civil conspiracy to commit fraud and misrepresentation in conjunction with their unlawful marketing, distribution, and sales of opioids into Plaintiff's and the Class' school district communities.

573. Conspiring, Defendants unlawfully failed to act to prevent diversion and failed to monitor for, report, and prevent suspicious orders of opioids.

574. Conspiring, Defendants unlawfully marketed opioids in Plaintiff's and the Class' school district communities.

575. Conspiring, Defendants unlawfully created a public nuisance in Plaintiff's and the Class' school districts.

576. Defendants' conspiracy and acts in furtherance thereof are alleged in detail in this Complaint, and are specifically incorporated herein.

577. Defendants' overt acts in furtherance of this conspiracy include, but are not limited to:

a. Designing and implementing marketing messages that comprised untrue, false, unsubstantiated, and misleading marketing, directly and with and through third parties, in violation of 21 C.F.R. §202.1(e), thereby causing opioid drugs to be misbranded;

b. Designing and implementing marketing messages that promoted other purported advantages of prescription opioids, including but not limited to improved function and quality of life in violation of FDA regulations, including 21 C.F.R. §202.1(e);

c. Promoting higher sales, higher dose sales, and targeting the highest volume Florida prescribers of a highly abusable, addictive, and dangerous drug;

d. Promoting higher dose opioid prescriptions, known to pose greater risks; and

e. Targeting the highest Florida prescribing physicians, without addressing whether those prescribers may be engaged in abuse and diversion and should not be targeted, to induce them to increase prescriptions of opioids further.

578. The conspiracy was the product of an agreement with Defendants' close collaboration.

579. Defendants' conduct in furtherance of the conspiracy described herein was not mere parallel conduct. Defendants encouraged one another to act directly against their ordinary commercial interests and not to report the unlawful practices of competitors to the authorities and in seeking to avoid "strict" regulation.

580. Defendants acted with a common understanding or design to commit unlawful acts, as alleged herein, and acted purposely, intentionally, without a reasonable or lawful excuse, which directly caused the injuries alleged herein.

581. Defendants' conspiracy as well as its actions and omissions in furtherance thereof caused the direct and foreseeable losses alleged herein.

582. Defendants' actions demonstrated both malice, recklessness and a conscious disregard for the rights and safety of other persons, even though that conduct had a great probability of causing substantial harm.

583. Defendants' misconduct alleged in this case was ongoing and persistent for many years.

584. Defendants' misconduct alleged in this case does not concern a discrete event or discrete emergency of the sort a school district would reasonably expect to occur and is not part of the normal and expected costs of a public school district's existence.

585. The aforementioned conduct was a direct breach of the duty Defendants owed to Plaintiff and the Class, which was the proximate cause of Plaintiff and the Class suffering and continuing to suffer damages including, but not limited to, significant expenses for: 1) special education programs for students (a) exposed to opioids in *utero* (NOWS), (b) with emotional and behavioral damages resulting from living in households afflicted by opioids, (c) addicted to opioids; 2) health services; 3) health insurance; and 4) disability payments and other employee services including opioid addiction treatment and overdose prevention, for which Plaintiff and the Class demand compensatory, and punitive damages and all damages and relief allowed by law.

COUNT IV: COMMON LAW NUISANCE

586. Plaintiff incorporates and re-alleges the foregoing allegations as if they were fully set forth herein.

587. Count IV is brought by Plaintiff on behalf of itself and the Class.

588. Defendants' unlawful actions have created a public nuisance under Florida law.

589. Reasonably prudent entities in the prescription opioid supply chain would not have misrepresented the risks of prescription opioids, nor would they have overstated their benefits, through publications, CMEs, and other forms of direct and indirect marketing, and would have implemented basic controls—required under federal law—to prevent opioid diversion in the supply chain.

590. Defendants have intentionally, unlawfully, recklessly, and negligently either manufactured, marketed, distributed, or sold prescription opioids that Defendants knew, or reasonably should have known, would be diverted, causing widespread distribution of prescription opioids to the employees, parents, and students of the Plaintiff's school district and those of the Class, resulting in children born after damaging exposure to opioids before birth, students' damaged by living in opioid-afflicted households, student addiction to opioids, and employees addicted to opioids, imposing the nuisance burdening Plaintiff and the Class and resulting in direct costs to Plaintiff and the Class.

591. Defendants' unlawful and/or intentional distribution of opioids or causing opioids to be distributed without maintaining effective controls against diversion include Defendants' failure to effectively monitor for suspicious orders, report suspicious orders, and/or stopping shipment of suspicious orders of opioids, imposing the nuisance burdening Plaintiff and the Class and resulting in direct costs to Plaintiff and the Class.

592. Defendants' conduct in unlawfully distributing and selling prescription opioids, or causing such opioids to be distributed and sold, when Defendants knew, or reasonably should have known, such opioids will be diverted, possessed, and/or used unlawfully in Florida and nationwide, including in and around Plaintiff's and the Class' school districts, imposing the nuisance burdening Plaintiff and the Class and resulting in direct costs to Plaintiff and the Class.

593. Defendants' actions have been continuing and have produced a significant effect upon the public's right to education, health and safety.

594. Defendants' distribution of opioids while failing to maintain effective controls against diversion was prohibited by federal and Florida law.

595. Defendants' ongoing conduct produces an ongoing nuisance, as the prescription opioids that they allow and/or cause to be unlawfully distributed and possessed nationwide, including in Plaintiff's school district and those of the Class are diverted, leading to abuse, addiction, crime, health costs, and lasting damage to the mental and emotional health of children born of opioid-addicted parents or with opioid-addicted family members.

596. Defendants' conduct has an ongoing detrimental effect upon public health, safety, and welfare, and upon Florida public school districts', and Florida communities' freedom from disturbance and reasonable apprehension of danger to person and property, present and future.

597. Defendants are, have been, or should be aware of the unreasonable interference that their conduct has caused for the Plaintiff and the Class as they are in the business of manufacturing, marketing, selling, and distributing prescription drugs, including opioids, which are specifically known to Defendants to be dangerous under federal and Florida law.

598. Defendants' conduct in manufacturing, marketing, distributing, and selling prescription opioids, which the Defendants knew, or reasonably should have known, would and will

likely be diverted for non-legitimate, non-medically appropriate use, creates a strong likelihood that these illegal distributions of opioids will cause death and injuries within Plaintiff's and the Class' school districts and otherwise significantly and unreasonably interfere with Florida public health, safety, and welfare, and with Plaintiff's and the Class' ability to educate Florida children as mandated by law.

599. It was and is reasonably foreseeable to Defendants that their conduct will cause deaths and injuries to students and employees of Plaintiff and the Class, and will otherwise significantly and unreasonably interfere with public health, safety, and welfare, and with Plaintiff's and the Class' ability to educate Florida children as mandated by law.

600. The prevalence and availability of diverted prescription opioids in the hands of irresponsible persons and persons with criminal purposes not only causes Florida deaths and injuries, but also creates a palpable climate of fear among Florida students, parents, and employees of Plaintiff's and the Class' school districts where opioid diversion, abuse, and addiction are present, and where diverted opioids tend to be used frequently.

601. Stemming the flow of illegally distributed prescription opioids, and abating the nuisance caused by the illegal flow of opioids, will help to alleviate this problem, save lives, prevent injuries, and make Plaintiff's and the Class' school districts safer and more effective places to work and receive an education.

602. Defendants' conduct is a direct and proximate cause of injuries to Plaintiff and the Class, and costs borne by Plaintiff and the Class for increased special education needs, and is a significant and unreasonable interference with Plaintiff's and the Class' ability to educate Florida children as mandated by law.

603. Defendants' conduct constitutes a public nuisance and, if unabated, will continue to threaten the health, safety, and welfare of the students and employees of Plaintiff's and the Class' school districts, threatening the ability of Plaintiff and the Class to educate Florida children as mandated by law. Plaintiff and the Class have a clearly ascertainable right to abate the damages caused by this nuisance to the independent public school districts of Florida.

604. Defendants created this nuisance of the abuse of opioids in Florida, which are dangerously addictive, and the ensuing associated plague of prescription opioid and heroin addiction. Defendants knew the dangers to public health and safety that diversion of opioids would create. However, Defendants intentionally and/or unlawfully failed to maintain effective controls through proper monitoring, reporting, and refusal to fill suspicious orders of opioids. Defendants intentionally and/or unlawfully distributed opioids or caused opioids to be distributed without reporting, or refusing to fill suspicious orders, or taking other measures to maintain effective controls. Defendants intentionally and/or unlawfully continued to ship, and failed to halt, suspicious orders of opioids, and/or caused such orders to be shipped. Defendants intentionally and/or unlawfully marketed opioids in manners they knew to be false and misleading. Such actions were inherently dangerous.

605. Defendants also knew the prescription opioids have a high likelihood of being diverted. It was foreseeable to Defendants that, where Defendants marketed, distributed, and sold prescription opioids or caused such opioids to be distributed in Florida without maintaining effective controls against diversion, including monitoring, reporting, refusing shipment of suspicious orders of, and refusing dispersal of, the opioids would be diverted and create an opioid abuse nuisance in Florida and nationwide, including in and around Plaintiff's and the Class' public school districts.

606. Defendants acted with actual malice because Defendants acted with a conscious disregard for the rights and safety of other persons, as such conduct plainly has a great probability of causing substantial harm.

607. As a direct result of Defendants' conduct, Plaintiff and the Class have suffered and continued to suffer actual injury and damages, including, but not limited to, significant expenses for: 1) special education programs for students (a) exposed to opioids *in utero* (NOWS), (b) with emotional and behavioral damages resulting from living in households afflicted by opioids, and (c) addicted to opioids;2) health services; 3) health insurance; and 4) disability payments and other employee services including opioid addiction treatment and overdose prevention.

608. Plaintiff and the Class seek to abate the damages to the Florida public school districts resulting from the nuisance created by the Defendants' unreasonable, unlawful, intentional, ongoing, continuing, and persistent actions and omissions.

609. The public nuisance created by Defendants' actions is substantial and unreasonable—it has caused and continues to cause significant harm to Florida public school districts which must educate Florida children damaged by this nuisance, and the harm inflicted outweighs any offsetting benefit. The staggering rates of opioid and heroin use resulting from the Defendants' abdication of their gatekeeping and diversion prevention duties, and the Defendants' fraudulent marketing activities, have caused harm to Plaintiff and the Class.

610. Plaintiff and the Class seeks all legal and equitable relief as allowed by law, including, *inter alia*: injunctive and abatement relief; restitution; disgorgement of profits; compensatory, and punitive damages; all damages allowed by law to be paid by the Defendants; attorneys' fees and costs; and pre- and post-judgment interest.

COUNT V: NEGLIGENCE: VIOLATION OF STATUTORY DUTIES

611. Plaintiff incorporates and re-alleges the foregoing allegations as if they were fully set forth herein.

612. Count V is brought by Plaintiff on behalf of itself and the Class.

613. Reasonably prudent entities in the prescription opioid supply chain would not have misrepresented the risks of prescription opioids, nor would they have overstated their benefits, through publications, CMEs, and other forms of direct and indirect marketing, and would have implemented basic controls—required under federal law—to prevent opioid diversion in the supply chain.

614. Instead, Defendants violated their statutory duties related to marketing and selling controlled substances, and their duties to maintain effective controls against the diversion of opioids, to design and operate a system to identify suspicious orders of opioids, to halt unlawful sales of suspicious orders of opioids, and to notify the DEA of these suspicious orders.

615. Defendants failed to meet the standard of care established by statute while massive quantities of prescription opioids flowed into Plaintiff's and the Class' school districts. *See, e.g.*, the CSA, 21 U.S.C. §801 et seq; 21 C.F.R. §1301.74(b).

616. Every registrant—including each Defendant—is charged with being vigilant in deciding whether a customer, be it a pharmacy, wholesaler, or end customer, can be trusted to deliver or use controlled prescription narcotics only for lawful purposes.[213] Specifically, drug manufacturers, distributors, and pharmacies are required to maintain "effective control against

[213] *See* 21 U.S.C. §823(e).

diversion of particular controlled substances into other than legitimate medical, scientific, and industrial channels."[214]

617. Defendants breached their duties to exercise due care in the business of manufacturing, marketing, wholesale distribution, and selling of prescription opioids, including by filling unreasonably suspect opioid orders over and over again, and failing to impose basic controls to monitor, identify, investigate, limit, and report suspicious orders for opioids. The very purpose of these duties was to prevent the harms that have directly followed: diversion of highly addictive opioids for illegal and/or non-approved purposes; the causal connection between Defendants' conduct and the ensuing harm was entirely foreseeable.

618. Accordingly, Defendants breached their statutorily and regulatorily established duties of care, designed specifically to prevent the harms from the abuse and misuse of controlled substances, including opioids, by engaging in negligence *per se*, to the significant harm of Plaintiff and the Class.

619. Defendants' conduct was reckless, evincing a conscious disregard for and indifference to the consequences of their actions.

620. The aforementioned conduct was a direct breach of the duty Defendants owed to Plaintiff and the Class, which was the proximate cause of Plaintiff and the Class suffering damages including, but not limited to, significant expenses for: 1) special education programs for students (a) exposed to opioids in utero (NOWS), (b) with emotional and behavioral damages resulting from living in households afflicted by opioids, and (c) addicted to opioids; 2) health services; 3) health insurance; and 4) disability payments and other employee services

[214] 21 U.S.C. §823(a)(1) and §823(b)(1).

including opioid addiction treatment and overdose prevention, for which Plaintiff and the Class demand compensatory, and punitive damages and all damages and relief allowed by law.

COUNT VI: NEGLIGENCE

621. Plaintiff incorporates and re-alleges the foregoing allegations as if they were fully set forth herein.

622. Count VI is brought by Plaintiff on behalf of itself and the Class.

623. Defendants failed to act with reasonable care in the manufacturing, marketing, promoting, selling, and distributing opioids for the treatment of chronic pain.

624. Reasonably prudent entities in the prescription opioid supply chain would not have misrepresented the risks of prescription opioids, nor would they have overstated their benefits, through publications, CMEs, and other forms of direct and indirect marketing, and would have implemented basic controls—required under federal law—to prevent opioid diversion in the supply chain.

625. Defendants knew that opioids were highly addictive and inappropriate and unsafe for the treatment of chronic pain. Defendants knew of widespread prescription opioid addiction and abuse, and of diversion to illegal channels. Defendants also knew that the dangerous qualities of opioids bore a direct relationship to the volume of opioids being ordered, authorized, and prescribed.

626. Nonetheless, Defendants persisted in spreading misinformation and burying the truth about the safety and efficacy of opioids while making opioids readily available to Floridians without regard to the likely harm they would cause.

627. Defendants' misinformation campaign was intended to and did encourage Florida patients to ask for, Florida doctors to prescribe, and payors to pay for chronic opioid therapy.

628. Defendants' conduct was reckless, evincing a conscious disregard for and indifference to the consequences of their actions.

629. Defendants' conduct directly injured Plaintiff and the Class. Defendants' conduct caused Plaintiff and the Class 1) to pay for increased costs for special education and related services for students (a) exposed to opioids before birth, (b) living in households afflicted by opioids, and (c) addicted to opioids; 2) to pay for or otherwise reimburse the cost of countless unnecessary and/or inappropriate opioid prescriptions of their employees and family members, as well as the health care costs associated with opioid addiction, abuse, and treatment of them, whom the Defendants specifically targeted with their marketing schemes; 3) to pay employee disability payments; and 4) to pay increased health insurance costs.

630. Defendants knew of or should have known of the foreseeable injuries to Plaintiff and the Class caused by their failure to act with reasonable care. Defendants were aware that their goal of significantly expanding the marketplace for opioids depended in part on comprehensive coverage of opioids by insurers and third-party payors. Defendants also knew that their goal of increasing profits by promoting the prescription of opioids for chronic pain would lead directly to damaging exposure to opioids *in utero*, to an increase in health care costs for unnecessary and inappropriate opioid prescriptions to treat chronic pain, and the increased cost of health services and expenditures associated with the opioid epidemic for health care payors, such as Plaintiff and the Class.

631. The aforementioned conduct was a breach of the duty Defendants owed to Plaintiff and the Class, which was the proximate cause of Plaintiff and the Class suffering

damages including, but not limited to, significant expenses for: 1) special education programs for students (a) exposed to opioids *in utero* (NOWS), (b) with emotional and behavioral damages resulting from living in households afflicted by opioids, and (c) addicted to opioids; 2) health services; 3) health insurance; and 4) disability payments and other employee services including opioid addiction treatment and overdose prevention, for which Plaintiff and the Class demand compensatory, and punitive damages and all damages and relief allowed by law.

COUNT VII: NEGLIGENCE: FAILURE TO WARN

632. Plaintiff incorporates and re-alleges the foregoing allegations as if they were fully set forth herein.

633. Count VII is brought by Plaintiff on behalf of itself and the Class.

634. Manufacturer Defendants had knowledge of the risks and harms likely to result from the long-term opioid prescription and knew or should have known that harm would result from such use, including to Florida children exposed to opioids *in utero* and living in households afflicted by opioids.

635. To expand the market for opioids, however, Manufacturer Defendants engaged in a misinformation campaign to alter public perception of opioids, and to deceive doctors, federal regulators, and the public, including in Florida, about their addictive and unsafe qualities. Manufacturer Defendants perpetrated virtually uniform misrepresentations, concealments, and material omissions regarding the safety and efficacy of opioids for the treatment of chronic pain. Defendants failed to comply with their mandatory reporting requirements and instead took actions necessary to carry out their unlawful goal of selling prescription opioids without reporting suspicious orders or the diversion of opioids into the illicit market.

636. Because of barriers to prescribing opioids associated with their regulation as controlled substances, Manufacturer Defendants knew Florida doctors would not treat patients with common chronic pain complaints with opioids, and insurers and other third-party payors would not cover such treatment unless they were persuaded that opioids had real benefits and minimal risks.

637. Accordingly, Manufacturer Defendants spent millions of dollars on promotional activities and materials that falsely deny or minimize the risks of opioids while overstating the benefit of using them for chronic pain.

638. Manufacturer Defendants did not disclose to Florida prescribers, Florida patients, their third-party payors, or the Florida public that evidence in support of their promotional claims was inconclusive, non-existent, or unavailable, though providing such warnings and accurate information would not have imposed a burden. Rather, Manufacturer Defendants and other opioid manufacturers disseminated misleading and unsupported messages that caused the target audience to believe those messages were corroborated by scientific evidence.

639. Manufacturer Defendants' misinformation campaign was intended to and did encourage Florida patients to ask for, Florida doctors to prescribe, and their payors to pay for chronic opioid therapy.

640. Plaintiff and the Class thus, both directly and indirectly, were harmed by the misrepresentations as to the efficacy and safety of opioid drugs for the treatment of chronic pain as promoted by Manufacturer Defendants. Because Manufacturer Defendants controlled knowledge of the supposed tests on which the claims of opioid drugs' efficacy and safety were based, Plaintiff and the Class, as well as other third-party payors, and members of the Florida

medical community and Florida public, were obligated to rely on Manufacturer Defendants' representations about opioids. Further, Manufacturer Defendants perpetuated this reliance by taking the steps set out above to suppress the dissemination of any critical information about the use of opioids for chronic pain and ensure that they were authorized for coverage and broadly distributed.

641. Defendants knew of widespread prescription opioid addiction and abuse, and diversion to illegal channels, including through their financial incentives and information sharing arrangements.

642. Defendants also knew that widespread opioid addiction and abuse was harmful to the individuals consuming opioids, their unborn children, their friends, families, and communities, and those, like Plaintiff and the Class, responsible for paying for federally-mandated special education related services for children exposed to opioids *in utero*, for children living in households afflicted by opioids, for children addicted to opioids, as well as for health care costs associated with opioid addiction and abuse among their employees and their family members.

643. Apart from conspiracy alleged elsewhere in this complaint, Defendants knew, or should have known, that opioids were highly addictive and inappropriate and unsafe for the treatment of chronic pain yet failed to warn of those dangers and Defendants also knew that the dangerous qualities of opioids bore a direct relationship to the volume of opioids being ordered, authorized, and prescribed, yet failed to warn of those dangers.

644. Defendants' conduct was reckless, evincing a conscious disregard for and indifference to the consequences of their actions.

645. By failing to warn the Florida public, including prescribing Florida doctors, and Plaintiff and the Class of the dangers of opioids, Defendants' conduct directly injured Plaintiff and the Class, with Plaintiff and the Class suffering, and continuing to suffer, damages including, but not limited to, significant expenses for: 1) special education programs for students (a) exposed to opioids *in utero* (NOWS), (b) with emotional and behavioral damages resulting from living in households afflicted by opioids, and c) addicted to opioids; 2) health services; 3) health insurance; and 4) disability payments and other employee services including opioid addiction treatment and overdose prevention; and 5) unnecessary and/or inappropriate opioid prescriptions for their employees and family members, as well as the health care costs associated with their opioid addiction and abuse, for which Plaintiff and the Class demand compensatory, and punitive damages and all damages and relief allowed by law.

VII. PRAYER FOR RELIEF.

WHEREFORE, Plaintiff, on behalf of itself and the Class, prays that summons be issued notifying Defendants of this Complaint, and that after all legal delays, Defendants be required to answer same, and after all proceedings and a jury trial, there be a judgment in favor of Plaintiff for all amounts commensurate with Plaintiff's and the Class' damages, including but not limited to:

(1) past, present, and future costs associated with increased educational services, including but not limited to special education needs, services, and programs for children with opioid-related learning disabilities or needs;

(2) past, present, and future costs associated with providing care for children living in households afflicted by opioids;

(3) past, present, and future costs associated with increased school security at Plaintiff's and the Class' public schools;

(4) past, present, and future costs for providing medical care, additional therapeutic and prescription drug purchases, and other treatments for employees and family members suffering from opioid-related addiction or disease, including overdoses and deaths;

(5) past, present, and future costs associated with increased healthcare and healthcare insurance;

(6) past, present, and future costs regarding disability payments;

(7) disgorgement of profits;

(8) all costs and means to abate the effects in Florida public schools caused by the opioid epidemic created by Defendants' wrongful and/or unlawful conduct;

(9) all other costs and damages specified herein;

(10) attorneys' fees, costs, and expenses of suit;

(11) pre- and post- judgment interest; and

(12) such other relief as the Court deems appropriate.

For the RICO violations, an award of trebled damages as consistent with 18 U.S.C. §1964(c) and §895.05, F.S., compensatory and actual damages, reasonable attorney's fees, pre-judgment interest, post-judgement interest, and costs against Defendants, each and every one of them jointly and severally, and any additional amount that this Court deems just and proper.

Plaintiff further requests all injunctive and equitable relief that the Court deems appropriate and may be permitted by law.

Plaintiff demands a jury trial on all issues so triable.

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Dated: May 27, 2022

Respectfully submitted,

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Plaintiff's Attorneys

JS 44 (Rev. 3/22)

CIVIL COVER SHEET

The JS 44 civil cover sheet and the information contained herein neither replace nor supplement the filing and service of pleadings or other papers as required by law, except as provided by local rules of court. This form, approved by the Judicial Conference of the United States in September 1974, is required for the use of the Clerk of Court for the purpose of initiating the civil docket sheet. *(SEE INSTRUCTIONS ON NEXT PAGE OF THIS FORM.)*

I. (a) PLAINTIFFS

Putnam County School Board, and on behalf of All Others Similarly Situated

(b) County of Residence of First Listed Plaintiff Putnam County
(EXCEPT IN U.S. PLAINTIFF CASES)

(c) Attorneys *(Firm Name, Address, and Telephone Number)*

Peter G. Tsarnas, Esq. Gertz & Rosen, Ltd.
11 South Forge Street, Akron, OH 44304 (330) 376-8336

DEFENDANTS

Cephalon, Inc.

County of Residence of First Listed Defendant Chester County
(IN U.S. PLAINTIFF CASES ONLY)

NOTE: IN LAND CONDEMNATION CASES, USE THE LOCATION OF THE TRACT OF LAND INVOLVED.

Attorneys *(If Known)*

II. BASIS OF JURISDICTION *(Place an "X" in One Box Only)*

- ☐ 1 U.S. Government Plaintiff
- ☐ 3 Federal Question *(U.S. Government Not a Party)*
- ☐ 2 U.S. Government Defendant
- ☒ 4 Diversity *(Indicate Citizenship of Parties in Item III)*

III. CITIZENSHIP OF PRINCIPAL PARTIES *(Place an "X" in One Box for Plaintiff and One Box for Defendant)*
(For Diversity Cases Only)

	PTF	DEF		PTF	DEF
Citizen of This State	☐ 1	☐ 1	Incorporated *or* Principal Place of Business In This State	☐ 4	☐ 4
Citizen of Another State	☐ 2	☐ 2	Incorporated *and* Principal Place of Business In Another State	☒ 5	☒ 5
Citizen or Subject of a Foreign Country	☐ 3	☐ 3	Foreign Nation	☐ 6	☐ 6

IV. NATURE OF SUIT *(Place an "X" in One Box Only)*

Click here for: Nature of Suit Code Descriptions.

CONTRACT
- ☐ 110 Insurance
- ☐ 120 Marine
- ☐ 130 Miller Act
- ☐ 140 Negotiable Instrument
- ☐ 150 Recovery of Overpayment & Enforcement of Judgment
- ☐ 151 Medicare Act
- ☐ 152 Recovery of Defaulted Student Loans (Excludes Veterans)
- ☐ 153 Recovery of Overpayment of Veteran's Benefits
- ☐ 160 Stockholders' Suits
- ☐ 190 Other Contract
- ☐ 195 Contract Product Liability
- ☐ 196 Franchise

REAL PROPERTY
- ☐ 210 Land Condemnation
- ☐ 220 Foreclosure
- ☐ 230 Rent Lease & Ejectment
- ☐ 240 Torts to Land
- ☐ 245 Tort Product Liability
- ☐ 290 All Other Real Property

TORTS

PERSONAL INJURY
- ☐ 310 Airplane
- ☐ 315 Airplane Product Liability
- ☐ 320 Assault, Libel & Slander
- ☐ 330 Federal Employers' Liability
- ☐ 340 Marine
- ☐ 345 Marine Product Liability
- ☐ 350 Motor Vehicle
- ☐ 355 Motor Vehicle Product Liability
- ☐ 360 Other Personal Injury
- ☐ 362 Personal Injury - Medical Malpractice

PERSONAL INJURY
- ☐ 365 Personal Injury - Product Liability
- ☒ 367 Health Care/ Pharmaceutical Personal Injury Product Liability
- ☐ 368 Asbestos Personal Injury Product Liability

PERSONAL PROPERTY
- ☐ 370 Other Fraud
- ☐ 371 Truth in Lending
- ☐ 380 Other Personal Property Damage
- ☐ 385 Property Damage Product Liability

CIVIL RIGHTS
- ☐ 440 Other Civil Rights
- ☐ 441 Voting
- ☐ 442 Employment
- ☐ 443 Housing/ Accommodations
- ☐ 445 Amer. w/Disabilities - Employment
- ☐ 446 Amer. w/Disabilities - Other
- ☐ 448 Education

PRISONER PETITIONS

Habeas Corpus:
- ☐ 463 Alien Detainee
- ☐ 510 Motions to Vacate Sentence
- ☐ 530 General
- ☐ 535 Death Penalty

Other:
- ☐ 540 Mandamus & Other
- ☐ 550 Civil Rights
- ☐ 555 Prison Condition
- ☐ 560 Civil Detainee - Conditions of Confinement

FORFEITURE/PENALTY
- ☐ 625 Drug Related Seizure of Property 21 USC 881
- ☐ 690 Other

LABOR
- ☐ 710 Fair Labor Standards Act
- ☐ 720 Labor/Management Relations
- ☐ 740 Railway Labor Act
- ☐ 751 Family and Medical Leave Act
- ☐ 790 Other Labor Litigation
- ☐ 791 Employee Retirement Income Security Act

IMMIGRATION
- ☐ 462 Naturalization Application
- ☐ 465 Other Immigration Actions

BANKRUPTCY
- ☐ 422 Appeal 28 USC 158
- ☐ 423 Withdrawal 28 USC 157

INTELLECTUAL PROPERTY RIGHTS
- ☐ 820 Copyrights
- ☐ 830 Patent
- ☐ 835 Patent - Abbreviated New Drug Application
- ☐ 840 Trademark
- ☐ 880 Defend Trade Secrets Act of 2016

SOCIAL SECURITY
- ☐ 861 HIA (1395ff)
- ☐ 862 Black Lung (923)
- ☐ 863 DIWC/DIWW (405(g))
- ☐ 864 SSID Title XVI
- ☐ 865 RSI (405(g))

FEDERAL TAX SUITS
- ☐ 870 Taxes (U.S. Plaintiff or Defendant)
- ☐ 871 IRS—Third Party 26 USC 7609

OTHER STATUTES
- ☐ 375 False Claims Act
- ☐ 376 Qui Tam (31 USC 3729(a))
- ☐ 400 State Reapportionment
- ☐ 410 Antitrust
- ☐ 430 Banks and Banking
- ☐ 450 Commerce
- ☐ 460 Deportation
- ☐ 470 Racketeer Influenced and Corrupt Organizations
- ☐ 480 Consumer Credit (15 USC 1681 or 1692)
- ☐ 485 Telephone Consumer Protection Act
- ☐ 490 Cable/Sat TV
- ☐ 850 Securities/Commodities/ Exchange
- ☐ 890 Other Statutory Actions
- ☐ 891 Agricultural Acts
- ☐ 893 Environmental Matters
- ☐ 895 Freedom of Information Act
- ☐ 896 Arbitration
- ☐ 899 Administrative Procedure Act/Review or Appeal of Agency Decision
- ☐ 950 Constitutionality of State Statutes

V. ORIGIN *(Place an "X" in One Box Only)*

☐ 1 Original Proceeding ☐ 2 Removed from State Court ☐ 3 Remanded from Appellate Court ☐ 4 Reinstated or Reopened ☐ 5 Transferred from Another District *(specify)* ☐ 6 Multidistrict Litigation - Transfer ☒ 8 Multidistrict Litigation - Direct File

VI. CAUSE OF ACTION

Cite the U.S. Civil Statute under which you are filing *(Do not cite jurisdictional statutes unless diversity)*:
18 U.S.C. 1962, et seq., 21 C.F.R. 202.1(e), 18 U.S.C.2, 21 U.S.C. 846, 21 U.S.C.A. 823, 21 C.F.R. 1301.74, 21 U.S.C. 801, 18 U.S.C. 1964(c)

Brief description of cause:
Class Action Complaint against Defendants for their role in the Opiod Marketing Enterprise

VII. REQUESTED IN COMPLAINT:

☒ CHECK IF THIS IS A **CLASS ACTION** UNDER RULE 23, F.R.Cv.P.

DEMAND $ Unknown

CHECK YES only if demanded in complaint:
JURY DEMAND: ☒ Yes ☐ No

VIII. RELATED CASE(S) IF ANY *(See instructions):*

JUDGE Dan Aaron Polster DOCKET NUMBER 1:17-MD-2804

DATE 05/27/2023

SIGNATURE OF ATTORNEY OF RECORD

FOR OFFICE USE ONLY

RECEIPT # _____ AMOUNT _____ APPLYING IFP _____ JUDGE _____ MAG. JUDGE _____

UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF OHIO

I. Civil Categories: (Please check one category only).

1. ☑ General Civil
2. ☐ Administrative Review/Social Security
3. ☐ Habeas Corpus Death Penalty

*If under Title 28, §2255, name the SENTENCING JUDGE: _____

CASE NUMBER: _____

II. **RELATED OR REFILED CASES** See LR 3.1 which provides in pertinent part: "If an action is filed or removed to this Court and assigned to a District Judge after which it is discontinued, dismissed or remanded to a State court, and subsequently refiled, it shall be assigned to the same Judge who received the initial case assignment without regardfor the place of holding court in which the case was refiled. Counsel or a party without counsel shall be responsible for bringing such cases to the attention of the Court by responding to the questions included on the Civil Cover Sheet."

This action: ☑ is **RELATED** to another **PENDING** civil case ☐ is a **REFILED** case ☐ was **PREVIOUSLY REMANDED**

If applicable, please indicate on page 1 in section VIII, the name of the Judge and case number.

III. In accordance with Local Civil Rule **3.8**, actions involving counties in the Eastern Division shall be filed at any of the divisional offices therein. Actions involving counties in the Western Division shall be filed at the Toledo office. For the purpose of determining the proper division, and for statistical reasons, the following information is requested.

ANSWER ONE PARAGRAPH ONLY. ANSWER PARAGRAPHS 1 THRU 3 IN ORDER. UPON FINDING WHICH PARAGRAPH APPLIES TO YOUR CASE, ANSWER IT AND STOP.

(1) **Resident defendant**. If the defendant resides in a county within this district, please set forth the name of such county

COUNTY:

Corporation **For the purpose of answering the above, a corporation is deemed to be a resident of that county in which it has its principal place of business in that district.**

(2) **Non-Resident defendant**. If no defendant is a resident of a county in this district, please set forth the county wherein the cause of action arose or the event complained of occurred.

COUNTY:

(3) **Other Cases**. If no defendant is a resident of this district, or if the defendant is a corporation not having a principle place of business within the district, and the cause of action arose or the event complained of occurred outside this district, please set forth the county of the plaintiff's residence.

COUNTY: Putnam County, FL

IV. The Counties in the Northern District of Ohio are divided into divisions as shown below. After the county is determined in Section **III**, please check the appropriate division.

EASTERN DIVISION

☐	**AKRON**	**(Counties: Carroll, Holmes, Portage, Stark, Summit, Tuscarawas and Wayne)**
☑	**CLEVELAND**	**(Counties: Ashland, Ashtabula, Crawford, Cuyahoga, Geauga, Lake, Lorain, Medina and Richland)**
☐	**YOUNGSTOWN**	**(Counties: Columbiana, Mahoning and Trumbull)**

WESTERN DIVISION

☐	**TOLEDO**	**(Counties: Allen, Auglaize, Defiance, Erie, Fulton, Hancock, Hardin, Henry, Huron, Lucas, Marion, Mercer, Ottawa, Paulding, Putnam, Sandusky, Seneca VanWert, Williams, Wood and Wyandot)**

INSTRUCTIONS FOR ATTORNEYS COMPLETING CIVIL COVER SHEET FORM JS 44

Authority For Civil Cover Sheet

The JS 44 civil cover sheet and the information contained herein neither replaces nor supplements the filings and service of pleading or other papers as required by law, except as provided by local rules of court. This form, approved by the Judicial Conference of the United States in September 1974, is required for the use of the Clerk of Court for the purpose of initiating the civil docket sheet. Consequently, a civil cover sheet is submitted to the Clerk of Court for each civil complaint filed. The attorney filing a case should complete the form as follows:

I.(a) Plaintiffs-Defendants. Enter names (last, first, middle initial) of plaintiff and defendant. If the plaintiff or defendant is a government agency, use only the full name or standard abbreviations. If the plaintiff or defendant is an official within a government agency, identify first the agency and then the official, giving both name and title.

(b) County of Residence. For each civil case filed, except U.S. plaintiff cases, enter the name of the county where the first listed plaintiff resides at the time of filing. In U.S. plaintiff cases, enter the name of the county in which the first listed defendant resides at the time of filing. (NOTE: In land condemnation cases, the county of residence of the "defendant" is the location of the tract of land involved.)

(c) Attorneys. Enter the firm name, address, telephone number, and attorney of record. If there are several attorneys, list them on an attachment, noting in this section "(see attachment)".

II. Jurisdiction. The basis of jurisdiction is set forth under Rule 8(a), F.R.Cv.P., which requires that jurisdictions be shown in pleadings. Place an "X" in one of the boxes. If there is more than one basis of jurisdiction, precedence is given in the order shown below.
United States plaintiff. (1) Jurisdiction based on 28 U.S.C. 1345 and 1348. Suits by agencies and officers of the United States are included here.
United States defendant. (2) When the plaintiff is suing the United States, its officers or agencies, place an "X" in this box.
Federal question. (3) This refers to suits under 28 U.S.C. 1331, where jurisdiction arises under the Constitution of the United States, an amendment to the Constitution, an act of Congress or a treaty of the United States. In cases where the U.S. is a party, the U.S. plaintiff or defendant code takes precedence, and box 1 or 2 should be marked.
Diversity of citizenship. (4) This refers to suits under 28 U.S.C. 1332, where parties are citizens of different states. When Box 4 is checked, the citizenship of the different parties must be checked. (See Section III below; **NOTE: federal question actions take precedence over diversity cases.**)

III. Residence (citizenship) of Principal Parties. This section of the JS 44 is to be completed if diversity of citizenship was indicated above. Mark this section for each principal party.

IV. Nature of Suit. Place an "X" in the appropriate box. If there are multiple nature of suit codes associated with the case, pick the nature of suit code that is most applicable. Click here for: Nature of Suit Code Descriptions.

V. Origin. Place an "X" in one of the seven boxes.
Original Proceedings. (1) Cases which originate in the United States district courts.
Removed from State Court. (2) Proceedings initiated in state courts may be removed to the district courts under Title 28 U.S.C., Section 1441.
Remanded from Appellate Court. (3) Check this box for cases remanded to the district court for further action. Use the date of remand as the filing date.
Reinstated or Reopened. (4) Check this box for cases reinstated or reopened in the district court. Use the reopening date as the filing date.
Transferred from Another District. (5) For cases transferred under Title 28 U.S.C. Section 1404(a). Do not use this for within district transfers or multidistrict litigation transfers.
Multidistrict Litigation – Transfer. (6) Check this box when a multidistrict case is transferred into the district under authority of Title 28 U.S.C. Section 1407.
Multidistrict Litigation – Direct File. (8) Check this box when a multidistrict case is filed in the same district as the Master MDL docket.
PLEASE NOTE THAT THERE IS NOT AN ORIGIN CODE 7. Origin Code 7 was used for historical records and is no longer relevant due to changes in statute.

VI. Cause of Action. Report the civil statute directly related to the cause of action and give a brief description of the cause. **Do not cite jurisdictional statutes unless diversity.** Example: U.S. Civil Statute: 47 USC 553 Brief Description: Unauthorized reception of cable service.

VII. Requested in Complaint. Class Action. Place an "X" in this box if you are filing a class action under Rule 23, F.R.Cv.P.
Demand. In this space enter the actual dollar amount being demanded or indicate other demand, such as a preliminary injunction.
Jury Demand. Check the appropriate box to indicate whether or not a jury is being demanded.

VIII. Related Cases. This section of the JS 44 is used to reference related pending cases, if any. If there are related pending cases, insert the docket numbers and the corresponding judge names for such cases.

Date and Attorney Signature. Date and sign the civil cover sheet.

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