

IN THE CIRCUIT COURT OF THE SIXTH JUDICIAL CIRCUIT  
IN AND FOR PASCO COUNTY, WEST PASCO DIVISION  
NEW PORT RICHEY, FLORIDA

STATE OF FLORIDA, OFFICE OF THE  
ATTORNEY GENERAL, DEPARTMENT  
OF LEGAL AFFAIRS,

Plaintiff,

v.

PURDUE PHARMA L.P., PURDUE  
PHARMA, INC., THE PURDUE  
FREDERICK COMPANY, INC., ENDO  
HEALTH SOLUTIONS, INC., ENDO  
PHARMACEUTICALS, INC., JANSSEN  
PHARMACEUTICALS, INC., JOHNSON &  
JOHNSON, CEPHALON, INC., TEVA  
PHARMACEUTICALS USA, INC.,  
ALLERGAN FINANCE, LLC, ACTAVIS  
PHARMA, INC., ACTAVIS LLC, INSYS  
THERAPEUTICS, INC.,  
AMERISOURCEBERGEN DRUG  
CORPORATION, CARDINAL HEALTH,  
INC., MCKESSON CORPORATION,  
MALLINCKRODT LLC, WALGREEN CO.,  
CVS HEALTHCARE CORP., and CVS  
PHARMACY, INC.

Defendants.

JURY TRIAL DEMANDED

Case No. 2018-CA-001438

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**AMENDED COMPLAINT**

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Plaintiff, the State of Florida, Office of the Attorney General, Department of Legal Affairs (“Florida” or “the State”), sues Defendants, Purdue Pharma L.P., Purdue Pharma, Inc., The Purdue Frederick Company, Inc., Endo Health Solutions, Inc., Endo Pharmaceuticals, Inc., Janssen Pharmaceuticals, Inc., Johnson & Johnson, Cephalon, Inc., Teva Pharmaceuticals USA, Inc., Allergan Finance, LLC, Actavis Pharma, Inc., Actavis LLC, Insys Therapeutics, Inc., AmerisourceBergen Drug Corporation, Cardinal Health, Inc., McKesson Corporation, Mallinckrodt LLC, Walgreen Co., CVS Health Corporation, and CVS Pharmacy, Inc. (collectively, the “Defendants”), and alleges as follows:

### **Introduction**

1. The State of Florida is suffering from a devastating opioid crisis. Thousands of Floridians have died from opioid overdoses, and many thousands more suffer from opioid use disorders and related health conditions. Opioid use has had tragic consequences for communities across Florida, and the State has been forced to expend enormous sums as a result of the opioid crisis. The crisis has a cause: Defendants cooperated to sell and ship ever-increasing quantities of opioids into Florida. To create newfound demand for opioids, Defendants used unfair and misleading marketing – including the use of front groups, paid “opinion leaders,” and Continuing Medical Education courses (“CMEs”) – to convince both doctors and patients that opioids could safely be prescribed for common ailments that cause chronic pain. To meet the artificially inflated demand, Defendants sold, shipped, and dispensed opioids in quantities that could not possibly have been medically justified and in the face of clear evidence that opioids were being diverted for illegitimate uses. Defendants’ plan succeeded, and they recorded multibillion-dollar profits as a result. The State brings this suit to hold Defendants accountable for having created and exacerbated the opioid crisis, and to require them to remediate and abate the harms that the crisis has inflicted – and continues to inflict – on the State and its citizens.

2. Opioids are powerful narcotics that include non-synthetic, partially synthetic, and fully-synthetic derivatives of the opium poppy. Opioids are highly addictive and their use can result in serious medical complications, including opioid use disorder and fatal overdoses. From 1999 to 2016, more than 200,000 people died in the United States from overdoses related to prescription opioids,<sup>1</sup> and estimates indicate that opioids could kill as many as 500,000 people in the United States over the next ten years.<sup>2</sup> Opioids killed 5,725 Floridians in 2016, and every corner of the State is struggling to deal with the effects. In 2017, the Palm Beach County Medical Examiner estimated that he sometimes dealt with ten overdoses a day. In Manatee County, the medical examiner reported in 2017 that the morgue ran out of space for the bodies of opioid overdose victims. In northern Florida, Jacksonville's Chief Medical Examiner stated in 2016 that she is unable to take a day off because the morgue is so busy with overdose victims; that year, the Jacksonville Fire and Rescue Department responded to 3,411 opioid overdoses. Governor Rick Scott declared a state of emergency in Florida on May 3, 2017, as a result of the opioid epidemic.<sup>3</sup>

3. Pasco County is among the hardest hit areas of the State. From 2004 through 2012, Pasco County experienced Florida's highest drug overdose mortality rate. According to the Florida Department of Law Enforcement, in 2016, District 6 (which consists of Pasco and Pinellas Counties) experienced the highest number of oxycodone deaths per capita in Florida. In 2016, the Pasco County Sheriff's Office administered opioid addiction treatment to nearly 2,000 inmates. In 2017, someone overdosed in Pasco County once every three days. Between 2013

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<sup>1</sup> CDC, *Prescription Opioid Data* (Aug. 30, 2017), at <https://www.cdc.gov/drugoverdose/data/prescribing.html>.

<sup>2</sup> See Max Blau, *STAT forecast: Opioids could kill nearly 500,000 Americans in the next decade*, STAT, June 27, 2017, at <https://www.statnews.com/2017/06/27/opioid-deaths-forecast>.

<sup>3</sup> Fla. Exec. Order No. 17-146 (May 3, 2017), at <https://www.flgov.com/wp-content/uploads/2017/05/17146.pdf>.

and 2016, the number of deaths caused by the opioids oxycodone, hydrocodone, and fentanyl increased by more than 50%. In 2018, the overdose rate in Pasco County was higher than in 2017, and the rate of overdose deaths increased in nearly every other county in the Tampa Bay area during this period.

4. These tragic deaths are only one aspect of Florida's opioid crisis, which has inflicted untold pain and suffering on tens of thousands of Floridians. Other consequences include babies born addicted to opioids, children placed in foster care after losing parents to overdoses, chronic addiction, lost job productivity, unemployment, increased spending on emergency medical services, the costs of deceptively marketed opioids, and many more.

5. The opioid crisis, and its costs, are the direct and foreseeable result of Defendants' unconscionable efforts to increase the demand and supply of opioids into Florida.

6. Defendants deceptively, unfairly, and unconscionably sought to convince prescribers and patients that opioids are safe, rarely addictive, and necessary for treating a wide range of common ailments. Defendants spread these myths knowing that opioids create physical dependency within days or weeks; that withdrawal from prescription opioids can be agonizing; that long-term and high-dose opioid use is particularly likely to lead to addiction; and that high doses of opioids can be fatal. Furthermore, Defendants knew or should have known that there was no legitimate scientific basis for their claims.

7. Defendants at all levels of the supply chain – manufacturers, distributors, and chain pharmacies – continued selling opioids in Florida even though they knew or should have known that the drugs were being diverted and misused for non-medical purposes. Defendants had duties to identify and stop suspicious orders and purchases, and to put in place reasonable policies to safeguard against diversion. For example, Defendants allowed a single pharmacy in



Hudson, Florida – a Pasco County town of 34,000 people – to purchase 2.2 million opioid pills in just one year (2011).

8. Defendants’ organized campaign to increase the demand and supply of opioids worked as planned. Opioid sales – less than \$1 billion in 1992 – ballooned to \$8 billion in 2015. That same year, Florida prescribers wrote more than 60 opioid prescriptions for every 100 Floridians. In total, Defendants have sold and shipped *billions* of opioid pills in Florida since 2006.

9. Because Defendants worked together to deceptively market and unconscionably distribute the pills – indifferent to the human cost – the State of Florida has sustained and continues to suffer massive losses. These losses include medical costs, unemployment costs, drug treatment costs, emergency personnel costs, law enforcement costs, naloxone costs,<sup>4</sup> medical examiner costs, foster care expenses, lost productivity, and lost tax revenues, among many other costs. The State was also damaged by directly paying, through state workers compensation and self-funded insurance, among other programs, for opioids that were deceptively marketed on the false promise of offering safe and effective long-term relief from chronic pain with little or no risk of addiction. The State of Florida likewise directly paid, through state workers compensation, self-funded insurance, and other programs, for opioids that should never have been shipped or sold because Defendants knew, or should reasonably have known, that the orders were likely to be diverted and were in violation of Florida law.

10. The State of Florida brings this civil action to hold Defendants accountable for unconscionably creating the State’s opioid crisis and causing the devastating public health and financial effects that have followed. Defendants reaped billions of dollars in revenues while they

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<sup>4</sup> Naloxone is used to block the effects of opioids in overdose cases.

knew, or should reasonably have known, that they were causing immense harm to the State and its citizens. Defendants must now be held to account and ordered to remediate the devastating effects of the opioid crisis they caused in Florida.

### **Nature of the Action**

11. The State of Florida brings this action against all Defendants asserting claims under the Florida Deceptive and Unfair Trade Practices Act, Fla. Stat. §§ 501.201 *et seq.* (“FDUTPA”), and the Florida Racketeer Influenced and Corrupt Organization Act, Fla. Stat. §§ 895.01 *et seq.* (“Florida RICO”), as well as claims for public nuisance, negligence, gross negligence, civil conspiracy, and all Defendants except Insys for negligence *per se*.

### **Jurisdiction and Venue**

12. This Court has jurisdiction pursuant to FDUTPA, Florida RICO, and common law causes of action.

13. The statutory violations alleged herein occurred in or affected more than one judicial circuit in the State of Florida.

14. Venue is proper in the Sixth Judicial Circuit for West Pasco County, Florida because the causes of action arose at least in part in New Port Richey, Port Richey, and Hudson, Florida; Defendants transacted business in New Port Richey, Port Richey, and Hudson, Florida; and some of the conduct alleged herein occurred in New Port Richey, Port Richey, and Hudson, Florida. Moreover, the West Pasco courthouse is the nearest Pasco County courthouse to the Florida Attorney General’s headquarters in Tallahassee, Florida, and its principal regional office in Tampa, Florida.

15. The Office of the Attorney General is the enforcing authority or the proper party to assert all causes of action alleged herein.

16. The Office of the Attorney General has conducted an investigation and the head

of the enforcing authority, Attorney General Pam Bondi, has determined that an enforcement action serves the public interest pursuant to Chapter 501, Part II, Florida Statutes.

### **Parties**

#### **A. Plaintiff**

17. The Department of Legal Affairs of Florida is the enforcement authority for violations of FDUTPA and has the authority to file Count I seeking the full range of relief afforded by Chapter 501, Florida Statutes.

18. The Attorney General of Florida is the chief legal officer of Florida and the enforcement authority of Florida's RICO statute and is authorized to file Count II seeking the full range of relief afforded by Chapter 895, Florida Statutes.

19. The State of Florida is authorized to file Count III for common law public nuisance and pursuant to Chapters 823, 60, and 16, Florida Statutes.

20. The State of Florida is authorized to file Count IV for negligence, Count V for negligence *per se*, and Count VI for gross negligence under Chapter 16, Florida Statutes.

21. The State of Florida is authorized to file Count VII for civil conspiracy under Chapter 16, Florida Statutes.

22. The State of Florida does not seek to enforce or bring a claim against any Defendant under any federal statute or regulation, and none of the State's claims are premised on the violation of any federal law.

#### **B. Manufacturer Defendants**

23. Mallinckrodt, Purdue, Endo, Janssen, Allergan, Actavis Pharma, Inc., Actavis LLC, Cephalon, and Insys are referred to herein as the "Manufacturer Defendants," because their *primary* line of business is pharmaceutical manufacturing. However, as alleged in detail herein, nearly all of the Manufacturer Defendants were also pharmaceutical distributors and were

licensed to distribute opioids in the State of Florida.

24. During the relevant times, the Manufacturer Defendants promoted, marketed, advertised, and sold opioids in the State of Florida to consumers, physicians, other prescribers, and State governmental agencies.

**1. Mallinckrodt**

25. Defendant Mallinckrodt LLC is a Delaware limited liability company headquartered in Missouri. Mallinckrodt LLC is a subsidiary of Mallinckrodt plc, which is an Irish public limited company with its headquarters in Staines-Upon-Thames, Surrey in the United Kingdom. The pharmaceutical business of drug-maker Covidien plc was transferred to Mallinckrodt plc in January 2013. Mallinckrodt LLC is referred to herein as “Mallinckrodt.” Mallinckrodt maintains an office in Florida.

26. Mallinckrodt manufactures four branded opioids: Exalgo (extended-release hydromorphone), Roxicodone (oxycodone), Xartemis XR (extended-release oxycodone and acetaminophen), and Methadose (methadone hydrochloride). Mallinckrodt is also one of the largest manufacturers of generic opioids, manufacturing extended-release morphine sulfate, oral solution of morphine sulfate, fentanyl transdermal system, oral transmucosal fentanyl citrate, a combination of oxycodone and acetaminophen, hydrocodone bitartrate and acetaminophen, hydromorphone hydrochloride and an extended-release version of the same, oxymorphone hydrochloride, methadone hydrochloride, oxycodone hydrochloride, and buprenorphine and naloxone.

27. Mallinckrodt promoted, advertised, and sold branded and generic opioids in Florida.

28. Mallinckrodt held an out-of-state prescription drug wholesale distributor license under Florida law during the relevant times. Mallinckrodt described itself as a “manufacturer

*and distributor of oxycodone and hydrocodone products*” in a 2017 settlement with the Drug Enforcement Administration (“DEA”) (emphasis added).

## **2. Purdue**

29. Defendant Purdue Pharma L.P. is a limited partnership organized under the laws of the State of Delaware with its principal place of business in Connecticut. Defendant Purdue Pharma, Inc. is a New York corporation with its principal place of business in Connecticut. Defendant The Purdue Frederick Company, Inc. is a New York corporation with its principal place of business in Connecticut. These Defendants are collectively referred to herein as “Purdue.”

30. Purdue manufactures the opioids OxyContin (extended-release oxycodone hydrochloride), MS Contin (extended-release morphine sulfate), Butrans (buprenorphine), Hysingla ER (hydrocodone bitartrate), Dilaudid (hydromorphone hydrochloride), Dilaudid-HP (same), and Targiniq ER (extended-release oxycodone hydrochloride and naloxone hydrochloride). Purdue promotes, markets, advertises, and sells these opioids in Florida.

31. Purdue and/or its affiliates held an out-of-state prescription drug wholesale distributor license under Florida law during the relevant times.

## **3. Endo**

32. Defendants Endo Health Solutions, Inc. and Endo Pharmaceuticals, Inc. are both Delaware corporations with their principal places of business in Pennsylvania. Endo Pharmaceuticals, Inc. is a wholly owned subsidiary of Endo Health Solutions, Inc. These Defendants are collectively referred to herein as “Endo.”

33. Endo manufactures the opioids Percocet (oxycodone and acetaminophen), Opana (oxymorphone hydrochloride), and Percodan (oxycodone and aspirin). Endo previously also manufactured Opana ER (extended-release oxymorphone hydrochloride). Endo also

manufactures and sells generic opioids, including oxycodone, oxymorphone, hydromorphone, and hydrocodone. Endo promotes, markets, advertises, and sells its opioid products in Florida, including Percocet and Opana, and previously Opana ER (extended release).

34. Endo and/or its affiliates held an out-of-state prescription drug wholesale distributor license under Florida law during the relevant times.

#### **4. Janssen**

35. Defendant Janssen Pharmaceuticals, Inc. is a Pennsylvania corporation with its principal place of business in New Jersey. Janssen Pharmaceuticals, Inc. was formerly known as Ortho-McNeil-Janssen Pharmaceuticals and Janssen Pharmaceutica, Inc.

36. Defendant Johnson & Johnson is a New Jersey corporation with its principal place of business in New Jersey.

37. Janssen Pharmaceuticals, Inc., is a wholly-owned subsidiary of Johnson & Johnson. Janssen Pharmaceuticals, Inc.'s profits inure to Johnson & Johnson's benefit. Johnson & Johnson controls the development, sale, and marketing of Janssen Pharmaceuticals, Inc.'s drugs. For example, according to its website, Johnson & Johnson's policies "govern[]" the "sales and marketing practices" for the "Johnson & Johnson family of companies," including Janssen Pharmaceuticals, Inc. Johnson & Johnson also "provides sales representatives with ongoing scientific training and product knowledge," as well as training on Johnson & Johnson policies. Johnson & Johnson employees monitor and enforce Janssen Pharmaceuticals, Inc.'s compliance with Johnson & Johnson's policies. Janssen Pharmaceuticals Inc.'s website provides links to Johnson & Johnson's policies, including its policies regarding sales and marketing. Johnson & Johnson corresponded with the U.S. Food and Drug Administration ("FDA") regarding Janssen's opioids and marketing practices.

38. Janssen Pharmaceuticals, Inc. and Johnson & Johnson are collectively referred to herein as “Janssen.”

39. Janssen manufactures the opioids Duragesic (fentanyl) and Tapentadol IR (immediate-release tapentadol) and previously manufactured the opioids Nucynta (immediate-release tapentadol hydrochloride) and Nucynta ER (extended-release tapentadol hydrochloride).

40. Janssen markets and sells opioids in Florida, including Duragesic and Tapentadol IR. Until 2015, Janssen marketed and sold the opioids Nucynta and Nucynta ER in Florida.

41. Janssen and/or its corporate affiliates held an out-of-state prescription drug wholesale distributor license under Florida law during the relevant times.

## **5. Allergan Entities**

42. Defendant Allergan Finance, LLC is a Nevada limited liability company with its principal place of business in New Jersey. Allergan Finance, LLC was formerly known as Actavis, Inc. and Watson Pharmaceuticals, Inc. Allergan Finance, LLC is referred to herein as “Allergan.”

43. Defendant Actavis Pharma, Inc. is a Delaware corporation with its principal place of business in New Jersey. Defendant Actavis LLC is a Delaware limited liability company with its principal place of business in New Jersey. During the time period described herein and until they were sold to Teva Pharmaceutical Industries Ltd. in August 2016, Actavis Pharma, Inc. and Actavis LLC were part of the same corporate family as Allergan Finance, LLC and sold and marketed opioids as part of a coordinated strategy to sell and market the branded and generic opioids of Allergan Finance, LLC, Actavis Pharma, Inc., and Actavis LLC. Allegations with regard to “Allergan” also refer to activities of Actavis Pharma, Inc. and Actavis LLC prior to their sale to Teva.

44. Allergan, Actavis Pharma, Inc., and Actavis LLC manufacture, promote, market,

advertise, and sell opioids nationwide and in Florida, including Kadian (extended-release morphine sulfate) and Norco (hydrocodone bitartrate and acetaminophen), and generic opioids including oxymorphone, extended-release morphine sulfate, fentanyl, oxymorphone hydrochloride, and an extended-release version of the same, or did so during the relevant times.

45. Allergan and/or its corporate affiliates held an out-of-state prescription drug wholesale distributor license under Florida law during the relevant times.

## **6. Cephalon**

46. Defendant Cephalon, Inc. is a Delaware corporation with its principal place of business in Pennsylvania.

47. Defendant Teva USA is a Delaware corporation with its principal place of business in Pennsylvania. Teva USA is a wholly-owned subsidiary of Teva Pharmaceutical Industries Ltd. (“Teva Ltd.”), an Israeli corporation with its principal place of business in Petah Tikvah, Israel. In 2011, Teva Ltd. acquired Cephalon, Inc.

48. Cephalon promotes, advertises, and sells opioids in Florida and nationwide, including Actiq (fentanyl citrate) and Fentora (fentanyl buccal).

49. Since Teva Ltd. acquired Cephalon, Inc., its sales and marketing activities in the United States have been conducted by Teva USA, which has marketed Cephalon products, including its opioid products Actiq and Fentora, as Teva products. Cephalon’s promotional materials and websites for Actiq and Fentora contain the Teva logo. Teva USA and Cephalon, Inc. are collectively referred to herein as “Cephalon.”

50. Cephalon and/or its corporate affiliates held an out-of-state prescription drug wholesale distributor license under Florida law during the relevant times.

## **7. Insys**

51. Defendant Insys Therapeutics, Inc. is a Delaware corporation with its principal



place of business in Arizona.

52. Insys manufactures Subsys (immediate-release fentanyl).

53. Insys promoted, advertised, and sold opioids in Florida and nationwide, including Subsys.

### **C. Distributor Defendants**

54. Defendants AmerisourceBergen, Cardinal, McKesson, Walgreens, and CVS are collectively referred to herein as the “Distributor Defendants,” even though nearly all Manufacturer Defendants also held distributor licenses in Florida and distributed opioids.

Defendants AmerisourceBergen, Cardinal, and McKesson’s primary business is the distribution of pharmaceuticals. Defendants Walgreens and CVS operate national retail chain pharmacies, including many pharmacies across Florida, and are, along with Defendants AmerisourceBergen, Cardinal, and McKesson, among the biggest distributors of opioids in the State of Florida.

55. The Distributor Defendants are among the largest and most profitable companies in the United States. In 2017, AmerisourceBergen ranked eleventh on the list of Fortune 500 companies, Cardinal ranked fifteenth, McKesson ranked fifth, Walgreens ranked seventeenth, and CVS ranked seventh. Together, the Distributor Defendants generated revenue of more than \$750 billion in 2017.

56. During the relevant times, the Distributor Defendants distributed opioids in the State of Florida to Florida pharmacies, which were then purchased by Florida consumers and Florida governmental agencies. The Distributor Defendants also marketed opioids during the relevant times. Walgreens and CVS also dispensed opioids in Florida during the relevant times.

#### **1. AmerisourceBergen**

57. Defendant AmerisourceBergen Drug Corporation (“AmerisourceBergen”) is a Delaware corporation with its principal place of business in Pennsylvania. AmerisourceBergen

operates distribution centers and/or warehouses in Florida, including Orlando. In addition to distributing opioids, AmerisourceBergen has marketed and promoted opioids, including through its marketing and consulting division, Xcenda, which has offices in Palm Harbor, Florida.

## **2. Cardinal**

58. Defendant Cardinal Health, Inc. (“Cardinal”) is an Ohio corporation with its principal place of business in Ohio. Cardinal operates distribution centers and/or warehouses in Florida, including Lakeland, Jupiter, Pompano Beach, Weston, Tampa, and Jacksonville. In addition to distributing opioids, Cardinal has marketed opioids during the relevant times.

## **3. McKesson**

59. Defendant McKesson Corporation (“McKesson”) is a Delaware corporation with its principal place of business in California. McKesson operates distribution and/or warehouse centers in Florida, including Orlando, Lakeland, and Jacksonville. In addition to distributing opioids, McKesson has marketed opioids during the relevant times.

## **4. Walgreens**

60. Defendant Walgreen Co. (“Walgreens”) is an Illinois corporation with its principal place of business in Illinois. Walgreens operates as a chain of retail pharmacies in Florida, and it also operates as a distributor. Walgreens is one of the top distributors of opioids in Florida. In addition to dispensing and distributing opioids, Walgreens has marketed opioids during the relevant times.

## **5. CVS**

61. Defendant CVS Health Corporation is a Delaware corporation with its principal place of business in Rhode Island. CVS Pharmacy, Inc. is a Rhode Island corporation with a principal place of business in Rhode Island. CVS Health Corporation and CVS Pharmacy, Inc. are collectively referred to herein as “CVS.” CVS, including through its subsidiary and affiliated

entities, operates as a chain of retail pharmacies in Florida, and it also operates as a distributor. CVS is among the top distributors of opioids in Florida. In addition to dispensing and distributing opioids, CVS has marketed opioids during the relevant times.

### **Factual Allegations**

62. Defendants created illegitimate demand for dangerous opioids while unlawfully increasing the supply of opioids to meet that demand. Defendants worked together to inflate the supply and demand for opioids. Use of these drugs had previously been confined to highly specialized hospital and end-of-life cancer care settings, because opioids are highly addictive and their use can and does result in fatal overdoses. Defendants launched a campaign of misleading advertising to inflate the market for these drugs, peddling them as safe and appropriate for use to treat a range of chronic conditions, and severely downplaying how addictive and dangerous they are. Defendants also engaged in a range of successful strategies to overcome barriers to the widespread use of their opioid narcotics. Defendants then poured unreasonable, medically unjustifiable quantities of opioids into the State of Florida, deliberately turning a blind eye to abuse and diversion of the drugs.

#### **A. Defendants Created Illegitimate Demand for Dangerous Opioids**

##### **1. Opioids are Dangerous and Highly Addictive Narcotics**

63. Prescription opioids are highly addictive narcotics. Their powerfully addictive properties come from two basic qualities inherent to opioids.

64. First, the use of opioids leads to physical dependency, which is a condition characterized by withdrawal symptoms when the user stops taking opioids. Patients going through withdrawal suffer symptoms including anxiety, nausea, headaches, vomiting, insomnia, hallucinations, and other painful effects. People who have taken opioids for less than a week can suffer withdrawal symptoms when they stop taking opioids.

65. According to medical literature, withdrawal from opioid addiction is agonizing, frequently causing enormous pain and other symptoms.

66. Second, opioid use leads to tolerance. Tolerance refers to a condition where the brain adapts to the presence of opioids, and demands a greater and greater dose over time to achieve the same effects. Tolerance is extremely common in patients who take opioids for any length of time.

67. Tolerance and physical dependence can develop in as little as a few days. High-dose and long-term prescription of opioids for chronic pain present particular dangers. According to the National Institute on Drug Abuse (“NIDA”), roughly a quarter of patients who are prescribed opioids will misuse them. According to the U.S. Centers for Disease Control and Prevention (“CDC”), “as many as 1 in 4 people receiving prescription opioids long term in a primary care setting struggles with addiction.”

68. As a result of these physiological properties, millions of people have been prescribed opioids, became dependent, and suffered the effects of addiction. In 2015, approximately two million Americans “suffered from substance use disorders related to prescription opioid[s].”

69. As their tolerance grows and addiction deepens, many opioid users seek prescriptions from multiple doctors, buy black-market prescription opioids on the street, or turn to opium-derived street drugs like heroin and illicitly-produced fentanyl. Nearly 80% of heroin users reported using a prescription opioid prior to using heroin. Fentanyl and heroin carry extremely high risks of fatal overdose, and deaths caused by fentanyl and fentanyl analogs have skyrocketed in recent years, including in Florida, where deaths involving fentanyl increased by 80% between 2015 and 2016, and deaths involving heroin increased by more than 30%.

70. To meet the growing demand for drugs by people addicted to opioids, prescription opioids have frequently been diverted from lawful, controlled medical uses into the illegal drug market.

71. Opioid use comes with a number of risks in addition to tolerance, dependency, and addiction, including respiratory depression, hyperalgesia (where use of opioids actually leads patients to feel *more* pain), hormonal dysfunction, neonatal abstinence syndrome, declines in immune function, confusion, dizziness (and increased falls and fractures in the elderly). The risk of death is particularly high when opioids are used with other drugs, like alcohol or benzodiazepines, such as Valium (diazepam) or Xanax (alprazolam), which are common treatments for veterans with Post-Traumatic Stress Disorder (“PTSD”).

72. Overdoses of opioids can be fatal and have become increasingly common as prescriptions and addiction has skyrocketed. The number of opioid overdose deaths quadrupled between 2004 and 2017. Patients may even die when taking opioids at a prescribed dose. Because a person’s tolerance to the analgesic or euphoria-producing effects of opioids may develop more quickly than his or her body’s tolerance to other effects on critical functions, many patients who become addicted to opioids seek higher and higher doses, until they eventually take a dose that kills them. More than 40% of all drug overdose deaths in 2016 involved a prescription opioid, and more than 200,000 Americans have died of an opioid overdose from 1999 to 2016.

73. Because of these well-known risks, the consensus in the medical community, prior to Defendants’ concerted campaign of deception, was that opioids were not safe for long-term use or for the treatment of chronic pain. Rather, opioids were reserved for specialized uses, such as treatment of cancer pain. But Defendants realized that they could reap billions of dollars

in profit if they could convince providers to prescribe, and patients to consume, opioids for common ailments.

## **2. Defendants Created a Campaign of Misinformation About Opioids**

74. Defendants were aware that opioids pose significant risks and that the long-term safety and efficacy of opioids for chronic pain has never been established in medical literature. As late as 2013, the FDA indicated it was not aware of any “adequate and well-controlled studies of opioid use longer than 12 weeks.”

75. Nevertheless, in a deliberate plot to counter doctors’ and patients’ legitimate fears of opioids, Defendants developed a campaign of deceptive, unfair, and unconscionable misinformation about the risks and effects of opioid use. They did so to convince prescribers and the public that opioids are appropriate – or even necessary – to treat common conditions that can last months or years, such as back pain, headaches, and fibromyalgia.

76. The following are examples of the deceptive, unfair, and/or unconscionable messages spread by some or all Defendants to prescribers and patients, nationwide and within Florida, as further alleged in the sections detailing each Defendant’s activities.

### **a. The Risk of Addiction to Opioids Is Low**

77. Defendants were aware that opioids are highly addictive, that tolerance and physical dependency develop rapidly, and that prescription opioids confer an increased risk of addiction and overdose even in patients who take their medication as prescribed. By the mid-1990s, a number of studies already demonstrated a high incidence of prescription drug abuse among chronic pain patients, and substantial rates of addiction.

78. Defendants nevertheless portrayed opioids as addictive only in limited circumstances that providers could easily identify, and only for a subset of patients that providers could effectively screen out.

**b. It Is Easy To Identify People at High Risk for Addiction**

79. Defendants created and disseminated screening tools to perpetuate the myth that doctors can easily identify patients who are at a high risk of addiction because, for example, they have a history of substance abuse issues – and that, by implication, opioids are safe for everyone else.

80. Defendants recommended the use of screening tools whose effectiveness had not been established by reliable scientific evidence. Many patients without a history of substance abuse become addicted to prescription opioids.

**c. Signs of Addiction Are Merely “Pseudoaddiction”**

81. Defendants claimed that the signs of opioid addiction were merely symptoms of “pseudoaddiction,” meaning “behaviors (that mimic addictive behaviors) exhibited by patients with inadequately treated pain.” Moreover, Defendants claimed that pseudoaddiction should be treated by giving patients higher doses of opioids. In other words, Defendants led doctors and patients to believe that the cure for signs of addiction was to prescribe ever-higher doses of opioids – despite the life-threatening risks of doing so.

82. In reality, addictive behaviors and signs of addiction are frequently – if not usually – indications of addiction. Defendants knew there was no legitimate evidence to support their claims that doctors should treat signs of addiction as “pseudoaddiction.” As late as 2015, an investigative review of medical studies concluded that empirical evidence supporting pseudoaddiction as a diagnosis distinct from addiction had still not emerged. Similarly, the CDC’s opioid prescribing guidelines do not recommend treating addictive behaviors as “pseudoaddiction.”

83. Likewise, there is no basis for recommending that addiction should be treated by giving patients higher and higher doses of opioids, which comes with significant addiction risks and dramatically increasing risk of overdose.

**d. Defendants' Abuse-Resistant Formulations Are Safer**

84. As the opioid crisis intensified in Florida and elsewhere, Defendants capitalized on the problem they created – the widespread diversion and misuse of opioids – by creating and marketing formulations purported to deter abuse and diversion. These purportedly abuse-deterrent formulations make pills harder to use in ways other than swallowing, such as by making them difficult to crush and snort. Defendants knew that these properties did not make their products resistant to the most common way that people abuse opioids: by swallowing them. According to the CDC, as late as 2016, there were no studies assessing the effectiveness of purportedly abuse-deterrent formulations “on outcomes related to overdose, addiction, abuse, or misuse.”

85. Defendants also knew that these formulations did nothing to reduce the likelihood that a patient taking a pill orally for medical use would become addicted.

86. In the case of Endo’s Opana ER, the FDA found that those addicted responded to the reformulated version by switching from inhalation to injection.

87. The new formulations did not prevent diversion.

**e. Opioids Improve Long-Term Functioning for Chronic Pain Patients**

88. Manufacturer Defendants represented that long-term opioid use can improve the quality of life of chronic pain patients. Defendants directed this message of hope at patients suffering from chronic, often life-long conditions, such as back pain or headaches, as well as prescribers.



89. In reality, Defendants knew that these claims were incorrect for at least two reasons. First, Defendants knew that there were no long-term studies establishing that opioids improve the quality of life in chronic pain patients – or even that they are effective in controlling chronic pain over the long term. Indeed, decades after Defendants began marketing opioids for chronic pain, there is still – as the CDC put it – “insufficient evidence that prescription opioids control chronic pain effectively over the long term.”<sup>5</sup> Second, Defendants knew that patients using opioids for chronic pain were at heightened risk of addiction and that long-term opioid use can cause debilitating deterioration in a patient’s quality of life.

**f. Short-Acting Opioids May Be Used Safely To Treat “Breakthrough Pain” For a Range of Chronic Conditions**

90. Defendants disseminated the idea that short-acting or immediate-release opioids containing fentanyl should be taken in conjunction with long-acting or extended-release opioids to treat “breakthrough pain” for a variety of common chronic conditions. Defendants defined breakthrough pain as a transitory flare of moderate-to-severe pain that occurs in patients with otherwise persistent pain.

91. Fentanyl is a synthetic opioid 80 to 100 times stronger than morphine that can lead to overdoses. More than 29,000 overdose deaths in the United States involved fentanyl and synthetic fentanyl analogs in 2017. Fentanyl and fentanyl analogs caused 2,355 deaths in Florida in 2016. Occurrences of fentanyl increased by 80% just from 2015 to 2016 in Florida, and deaths caused by fentanyl shot up 97% in Florida in that period.

92. In the context of end-stage cancer treatment, patients taking long-acting opioids may need a supplemental short-acting opioid to relieve their pain until they can take their next

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<sup>5</sup> CDC, *Promoting Safer and More Effective Pain Management*, at [https://www.cdc.gov/drugoverdose/pdf/Guidelines\\_Factsheet-Patients-a.pdf](https://www.cdc.gov/drugoverdose/pdf/Guidelines_Factsheet-Patients-a.pdf).

scheduled dose of long-acting medication. Some short-acting opioids contain fentanyl. These drugs can treat transient, intense pain – breakthrough cancer pain – in cancer patients who are already on long-acting opioids for their persistent pain, and who are frequently in a carefully controlled setting like a hospital or treatment center. However, fentanyl-based short-acting opioids are extremely dangerous drugs. They are deadly for people who are not already tolerant of opioids. They have never been accepted as safe treatment for non-cancer chronic pain, partly because evidence shows that people who take these drugs for common chronic ailments are at a higher risk of abusing the drugs, which can lead to overdoses.

93. Because of the tolerance that patients on opioids develop, and because opioids marketed to provide extended-duration pain relief notoriously wear off towards the end of the dose, patients who begin taking opioids for chronic conditions frequently feel that they need more relief before it is time for their next dose.

94. As part of their campaign to expand the market for their opioid products, Defendants marketed high-risk fentanyl-based opioids to fill that “need” in patients taking opioids for chronic conditions, even though Defendants knew that the safety of such use had never been established, and that fentanyl-based opioids come with a high risk of addiction, overdose, and death. Defendants created and disseminated the idea that short-acting, fentanyl-based opioids should be used, in addition to long-acting opioids, to treat “breakthrough pain” in patients using opioids for common ailments like back pain, with catastrophic results.

**g. The Agonizing Effects of Opioid Withdrawal Can Be Managed or Even Avoided By “Tapering” the Dose**

95. Withdrawal from opioids for those who have become addicted can be agonizing. Withdrawal can be more severe for people on higher doses of opioids. Stopping opioid use after

even a short course often causes symptoms of withdrawal, which can include headaches, vomiting, tremors, anxiety, sleep problems, flu-like symptoms, difficulty breathing, and others.

96. Defendants also knew, or should have known, that opioid use leads to physical dependency and painful withdrawal symptoms upon discontinuation, but deceptively represented that withdrawal is easily managed by tapering a patient's dose of opioids. These claims minimized how long the effects of withdrawal could last and trivialized how difficult it can be for people to wean themselves off a dependence to opioids.

#### **h. Opioids Are Safer Than “Traditional” Pain Medicines**

97. Defendants misleadingly claimed that opioids are safer than traditional painkillers like acetaminophen and Nonsteroidal Anti-inflammatory Drugs (“NSAIDs”), like ibuprofen. They presented seemingly objective comparisons of the risks and benefits of opioids and NSAIDs, like ibuprofen, but these comparisons were deceptive because they exaggerated the risks of NSAIDs and trivialized, or simply omitted, the risks of opioids.

98. Defendants claimed that although traditional pain medicines are unsafe at high doses, opioids can be taken at higher and higher doses, with no ceiling on the amount that can be taken safely. This claim is highly misleading. With higher doses, and particularly with the addition of short-acting or immediate-release opioids, the risk of fatal overdose grows. In fact, because of the risks of overdose and addiction, it is highly misleading to represent pain treatment with opioids as a safer alternative to drugs like ibuprofen. In 2010, for example, the numbers of fatal overdoses associated with non-opioid medications (1,109 deaths from acetaminophen and NSAIDs) were a fraction of those associated with opioid medications: 16,651 deaths in the same year.

**i. The Elderly and Veterans Can Safely Use Opioids, While Downplaying or Ignoring Heightened Risk Factors**

99. Defendants aggressively marketed opioids to the elderly and veterans.

100. Defendants aggressively marketed opioids as safe and effective for veterans, even though opioids can cause fatal interactions with benzodiazepines – a common treatment for PTSD – and without addressing these risks.

101. Defendants also aggressively marketed opioids to elderly patients, even though the elderly suffer the same risk of dependence and tolerance that other opioid users experience. In fact, opioid use by older adults comes with additional risks, such as mental confusion and falls, leading to bone fractures. One study of more than 12,000 Medicare patients taking either opioids or other kinds of painkillers found that elderly patients using opioids were four times more likely to suffer a fracture; cardiovascular events were 77% higher in opioid users; and such patients were 87% more likely to die (of any cause). The elderly also face a significant risk of overdose. Older adults take multiple medications at a higher rate, which can lead to dangerous interactions between opioids and other drugs, including anti-anxiety medications. And as people age, medications affect them more strongly and are slower to leave their system. In District 6 (which includes Pasco County and Pinellas County), the age group with the highest number of deaths from hydrocodone and oxycodone was individuals over the age of 50.

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102. Through these and other misrepresentations, Defendants misinformed and continue to misinform prescribers, the public, and the State about the risks of opioid use.

### **3. The Defendants Used a Campaign of Misinformation To Increase Opioid Prescriptions for Common Chronic Ailments**

103. Defendants spread their deceptive, unfair, and unconscionable messages to physicians, other prescribers, and consumers nationwide and in Florida.

104. Defendants did not merely spread their misinformation through their own employees and publications. Defendants recognized that their messages would more strongly influence doctors if those messages appeared to come from, or were reinforced by, purportedly independent sources like doctors, advocacy groups, or scientific studies. Defendants therefore used multiple, mutually reinforcing channels to spread their deceptive claims.

#### **a. Defendants Spread Misinformation Directly**

105. Manufacturer Defendants employed sales representatives to call and visit doctors' offices to deliver deceptive messages about opioids to prescribers, including medical doctors, nurse practitioners, and physician assistants. These in-person sales calls are called "detailing." Sales representatives use meals and other perks to gain access to prescribers. Defendants gave their sales representatives funds, which sometimes totaled tens of thousands of dollars each year for a single representative, to buy "access" to prescribers' offices.

106. Defendants trained these representatives to deliver carefully tailored messages to prescribers across the nation, including in Florida. For example, an article in the *American Journal of Public Health* noted that "Purdue trained its sales representatives to carry the message that the risk of addiction was 'less than one percent.'" Defendants prepared, or hired public relations consultants to prepare, brochures, videos, and other marketing materials for its representatives to distribute to providers during in-person visits. Defendants also engaged in other direct marketing activities such as e-mail advertising, letters, purchasing advertisements in

medical journals, and more. Defendants' sales representatives delivered misinformation about both branded and generic opioids.

107. The Manufacturer Defendants also spread misinformation by working with the Distributor Defendants, who conducted a wide range of marketing activities, as alleged further below.

108. Defendants identified barriers to the dissemination of their myths and used more misrepresentations to overcome those barriers. For example, when insurers refused to cover opioids for uses for which they had not been approved, the Manufacturer Defendants fought back, supplying health care providers with template letters containing misrepresentations. The Distributor Defendants worked with health care providers to get opioid prescriptions to be paid for by insurers and also operated toll-free hotlines to help patients negotiate with their health plans to cover their opioid prescriptions.

**b. Defendants Used Front Organizations To Spread Misinformation**

109. The Defendants, led by the Manufacturer Defendants, spread misinformation through front groups that were created to appear to be neutral, third-party patient advocacy groups and professional associations, but that were in fact funded and influenced by Defendants, including, in some cases, the Distributor Defendants. The Defendants used these organizations to perpetuate the messages that chronic pain is undertreated and that opioids are as safe, effective, and extremely low-risk for most patients with chronic or "breakthrough" pain. The front organizations published "educational" literature for patients on pain management and pain treatment, as well as for doctors and other prescribers. The Defendants funded, influenced, and/or controlled the content of these ostensibly-neutral publications. Defendants then used these publications as supposedly independent support for their marketing claims. These front

organizations purposely appeared as though they were acting independently of Defendants. Defendants funded and used these front organizations as mouthpieces to promote the widespread use of opioids for chronic pain, which increased the sales of the Manufacturer Defendants' branded and generic opioid products.

110. These front organizations include the American Pain Foundation, the Pain Care Forum (a forum of the American Pain Foundation) ("PCF"), the American Academy of Pain Medicine, the American Geriatrics Society, the American Pain Society, among others. While the Manufacturer Defendants dominated these organizations, as explained in more detail below, the Distributor Defendants participated in at least the American Pain Foundation's PCF through their own trade group.

111. **The American Pain Foundation ("APF")**, founded in 1997 and dissolved in 2012, described itself as "the largest advocacy organization for people with pain." It claimed to be devoted to "breaking down the barriers that are preventing people with pain from receiving the necessary pain care they rightfully deserve and need." Although it described itself as an "independent 501(c)(3) organization," APF was funded almost entirely by the pharmaceutical industry. In 2010, for example, 88% of its funds were from the drug manufacturers. Endo paid APF more than \$1 million in 2010 – more than half of the APF's funding that year. Purdue, Cephalon, and Janssen also contributed substantially to the APF in 2010. APF received more than \$10 million of funding from the Manufacturer Defendants and other opioid manufacturers from 2007 to 2012.

112. APF published misrepresentations about opioids aimed at providers and physicians, as described herein.

113. APF also developed materials and initiatives intended to influence prescribers and patients through the media. For example, APF published “A Reporter’s Guide: Covering Pain and Its Management,” which promotes the false concept of pseudoaddiction and claims that “the potential for addiction is low for the vast majority of patients using opioids for the long-term management of chronic pain.” The document argues that under-treatment of pain is a greater concern than addiction and asserts that, “[u]nless a patient has a past or current history of substance abuse, the potential for addiction is low.” It warns reporters that “misunderstandings” about physical dependence and tolerance “reinforce the stigma surrounding legitimate medical use of these medicines” and “fuel fears of addiction” that “may impinge on patient access to these medications.” “The Reporter’s Guide” also claims that dependence is “not related to addiction” – an absurd statement given that physical dependence is both a major reason people become addicted and a hallmark of addiction. APF spread other messages to promote Defendants’ agenda as well, such developing campaigns to present ibuprofen and acetaminophen as unsafe, and media releases criticizing “unbalanced” media coverage of opioids.

114. APF’s messages regarding pain treatment have reached millions of people, nationwide and in Florida. Many remain available online to this day.

115. **The American Geriatrics Society (“AGS”)** is a trade association of geriatrics healthcare professionals. It operated as a front group with close connections and financial support from the Manufacturer Defendants, and in turn advocated for increased use of opioids by the elderly.

116. The Manufacturer Defendants, through AGS targeted the elderly by making false representations to prescribers and consumers. Purdue, Janssen, and Endo participated in the production and dissemination of two AGS “Guidelines”: *The Management of Persistent Pain in*



*Older Persons* (2002) and *Pharmacological Management of Persistent Pain in Older Persons* (2009). For example, this latter AGS publication represented that the risk of addiction was “exceedingly low in older patients with no current or past history of substance abuse.” The authors of the AGS guidelines included a number of paid consultants to Endo, Janssen, Purdue and Cephalon. Purdue sponsored CMEs based on these publications. These publications were extremely influential and widely disseminated, remain available, and continue to influence prescribing decisions.

117. **The American Academy of Pain Medicine (“AAPM”)** is a trade association for physicians with an interest in pain management. AAPM maintained a corporate relations council whose members paid \$25,000 per year, in addition to other funding. Purdue, Endo, Cephalon, and Allergan served as members of the AAPM corporate relations council and paid the yearly fee. In 2011 alone, AAPM received \$1.3 million from pharmaceutical companies.

118. In 2009, AAPM – along with the American Pain Society (“APS”), another front group – funded a “multidisciplinary expert panel” to “formulate recommendations” about the use of opioids in treating chronic non-cancer pain. The AAPM/APS Guidelines were issued in 2009, and remain widely available today. The AAPM/APS Guidelines recommended the use of opioids to treat chronic pain despite the lack of evidence that long-term use was safe, and recommended the use of screening tools to identify patients at a purportedly high risk of addiction. The panel made these recommendations despite the fact that *none* of its recommendations were “supported by high quality evidence,” and only four of its 25 recommendations were supported “by even moderate quality evidence.” Fourteen of the 21 panel members who drafted the AAPM/APS Guidelines, including key opinion leaders

(“KOLs”) Dr. Russell Portenoy and Dr. Perry Fine (discussed in detail below), received support from one or more of Janssen, Cephalon, Purdue, and Endo.

119. The Manufacturer Defendants used the AAPM/APS Guidelines as support for their claims that opioids should be widely prescribed for chronic pain.

120. **The U.S. Pain Foundation** describes itself as an educational and advocacy organization for people with chronic pain. The U.S. Pain Foundation has engaged in advocacy efforts nationwide, including through its participation in 62 advocacy coalitions and active engagement on 80 legislative bills. The U.S. Pain Foundation has close financial connections with the Manufacturer Defendants. For example, between 2012 and 2017, Insys contributed \$2.5 million; Purdue contributed over \$350,000; and Janssen contributed over \$40,000. Teva is still listed as a sponsor on the U.S. Pain Foundation’s website, as are other front groups like AAPM and APS.

121. As described further below, the Manufacturer Defendants sponsored and participated in developing a large number of front group publications and marketing materials that spread the campaign of misinformation about opioids and supported Defendants’ efforts to sell both branded and generic opioids. These publications include *Treatment Options: A Guide for People Living with Pain*, which was sponsored by Purdue, Cephalon, and others and published by APF; *Finding Relief: Pain Management for Older Adults* (2009), which was sponsored by Janssen, with AGS and AAPM as “partners”; *Exit Wounds*, which was sponsored by Purdue and others and published by APF; and others described herein. The marketing materials that appeared to be neutral resources about chronic pain or responsible opioid use include websites such as [www.PainKnowledge.com](http://www.PainKnowledge.com); and [www.LetsTalkPain.org](http://www.LetsTalkPain.org), which contain the misrepresentations described herein.

122. Defendants gave, and continue to give, millions of dollars to front groups. For example, Purdue donated more than \$4 million to front groups between 2012 and 2017.

123. The front groups succeeded in spreading Defendants' misinformation about opioids, nationwide and in Florida. Their publications and messages were widely available, caused inappropriate opioid prescribing, and many remain available online today. The Manufacturer Defendants' false messages through the front organizations have continued to this day.

**c. The Manufacturer Defendants Funded Key Opinion Leaders To Develop and Spread Misinformation About Opioids**

124. The Manufacturer Defendants also spread misinformation through medical experts whom the Manufacturer Defendants paid to deliver deceptive messages because of their ability to influence their peer prescribers, known as KOLs. The Manufacturer Defendants intentionally positioned KOLs to appear to be independent, neutral actors in order to lend legitimacy to their opinions, making doctors and their patients more likely to accept their claims. However, the Manufacturer Defendants paid KOLs to present misrepresentations about opioids by paying them to speak at conferences, paying them consulting fees, hiring them to create promotional videos for opioids, paying them travel and lodging expenses, and paying them food and beverage expenses. The Manufacturer Defendants funded KOLs to create studies to support Defendants' claims. Defendants also trained KOLs and selected them for their ability to stay on message.

125. Defendants employed and sponsored KOLs to tout the benefits of opioid treatment for chronic pain in books, medical literature, pamphlets, research studies, and treatment guidelines. KOLs gave speeches and presented CMEs that misleadingly represented

the purported benefits of opioids for chronic pain. KOLs also advocated for the benefits of so-called abuse and tamper-resistant opioid formulations sold by the Manufacturer Defendants.

126. Some of the most prominent KOLs, paid by a number of Manufacturer Defendants, included **Dr. Lynn Webster, Dr. Russell Portenoy, Dr. Perry Fine, Dr. Scott Fishman**, and others, as discussed in more detail below. Dr. Lynn Webster developed the Opioid Risk Tool (“ORT”) screening test, which the Manufacturer Defendants deceptively represented could accurately predict the risk of opioid dependence.

127. Each of the Manufacturer Defendants hired KOLs as paid consultants, advisory board members, and members of the Manufacturer Defendants’ speakers’ bureaus.

128. The Manufacturer Defendants trained their sales representatives to use the work of KOLs – such as Dr. Russell Portenoy and Dr. Perry Fine – to persuade doctors to prescribe opioids liberally even where the safety of such uses had not been established. The Manufacturer Defendants instructed their sales forces to rely on studies by KOLs that were, in turn, funded by the Manufacturer Defendants.

129. The KOLs furthered Defendants’ scheme to increase the number of opioid prescriptions and opioid use by consumers in Florida and elsewhere.

**d. The Defendants Used Medical Education Programs, Commissioned Studies, and Other Mechanisms To Disseminate Misleading Messages**

130. Defendants funded CMEs, including CMEs in Florida, to spread misinformation. In some cases, Defendants created educational organizations to develop the CMEs; in other cases, Defendants supported front groups and KOLs to develop and provide CMEs. Defendants controlled the content of these presentations. CMEs spread Defendants’ false messages to doctors under the guise of neutral educational programs. Defendants deliberately maintained the illusion that these groups and programs were neutral, rather than heavily influenced by them.

131. Defendants also planned and funded purportedly scientific studies designed to produce results that would promote opioid prescribing. Defendants designed these studies to produce misleading results that they then quoted in marketing materials, speaker presentations, and other public representations about opioids. Some studies promoting myths about opioids were published by Defendants' in-house scientists, including scientists working for Distributor AmerisourceBergen's Xcenda consulting and marketing division, who have co-authored such studies with scientists working for Teva.

132. The Manufacturer Defendants hired or funded the KOLs through educational grants – sometimes under the rubric of the front groups – to conduct the purportedly scientific studies. Many of the key studies cited repeatedly in Defendants' marketing materials and on industry websites were performed by the very KOLs and top opioids consultants cultivated and paid by Defendants to stay on-message, as alleged in more detail below. Defendants then cited and relied upon these studies in their own publications, sales materials, and other publications and websites as described below.

**B. Defendants Illegitimately Inflated the Supply of Opioids by Causing a Flood of Opioids To Engulf Florida**

133. All Defendants worked – with great success – towards their shared goal of creating a market for, and then selling, far more opioids in Florida and nationwide than were medically appropriate or safe.

134. The Manufacturer and Distributor Defendants structured their contracts to give the Distributors strong financial incentives to sell as many opioids as possible. The Distributors benefitted from rebates or “chargebacks” that increased as the sales of pharmaceuticals increased. Joined by this powerful joint incentive to sell as many opioids as possible, the Distributors and Manufacturers cooperated to increase opioid sales in Florida.

135. This cooperation included the Distributor Defendants' active role in marketing and promoting the use of opioids to treat chronic pain. It also included creating the illusion that the Distributor Defendants had erected effective firewalls against the diversion of opioids. The Distributor Defendants created this illusion by repeatedly misleading the public and regulators into thinking that they had enacted safeguards, as they were required to do. For example, the Distributors made public statements that they were cracking down on diversion, setting thresholds to limit the amount of opioids that their pharmacy customers could purchase at a time, and purporting to enforce effective monitoring and "know your customer" procedures to identify pill mills and suspicious orders. In reality, the Distributor Defendants failed to take reasonable precautions or establish effective policies to prevent or reduce the risk of diversion and opioid abuse. The absence of effective safeguards foreseeably resulted in widespread diversion and abuse, imposing enormous costs on the State and its citizens while Defendants earned record profits.

136. Walgreens and CVS violated their duties under state law not only in their capacities as Distributors, but in their capacities as dispensing pharmacies. Pharmacists serve as the last line of defense between dangerous opioids and the public. For this reason, they are subject to duties under the common law and duties under Chapter 465, Florida Statutes, to take special care before dispensing these addictive and dangerous drugs. Walgreens and CVS violated these duties of care by dispensing extremely large amounts of opioids from their retail pharmacy stores in Florida as described in more detail below, all while claiming misleadingly to the public that they were fulfilling their duties as pharmacists.

137. Each of the Distributors, with the exception of Walgreens, belongs to a trade association known until 2016 as the Healthcare Distribution Management Association

(“HDMA”), and now known as the Healthcare Distribution Alliance (“HDA”).<sup>6</sup> With the exception of Insys, the Manufacturer Defendants or their corporate affiliates or parents are also members of the HDA.

138. The HDA published guidelines acknowledging that “distributors are uniquely situated to perform due diligence in order to help support the security of the controlled substances they deliver to their customers” and “[s]uch due diligence can reduce the possibility that controlled substances within the supply chain will reach locations they are not intended to reach.” The HDA is also a member of the front group PCF, a forum of the APF.

139. Individually and through the HDA, Defendants misrepresented their efforts to secure the opioids supply chain and control diversion.

140. All Defendants took actions that caused an unconscionable quantity of opioids to flow into Florida. These actions include selling, distributing, and dispensing unreasonable quantities to pharmacies in the State, in abrogation of their duties under Florida law. They also include turning a blind eye to obvious red flags indicating diversion, while misleading the public and regulators by saying that they were cracking down on such abuse. Not surprisingly, many Defendants have been investigated for their egregious failures to secure the opioid supply chain, and they have paid hundreds of millions of dollars to date in fines and settlements.

**1. Defendants Sold, Shipped, and Dispensed Unreasonable Quantities of Opioids into and in Florida and Thus Opioids Were Being Diverted**

141. Defendants have a duty under Florida law to prevent the diversion of opioids for non-legitimate, non-medical purposes. Given their role in selling, distributing, and/or dispensing

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<sup>6</sup> In 2016, the HDMA changed its name to the Healthcare Distribution Alliance. *See* HDA, *HDMA Launches New Identity as the Healthcare Distribution Alliance* (June 13, 2016), at <https://www.hda.org/news/2016-06-13-hdma-launches-new-identity-as-hda>.

opioids in Florida, Defendants, and particularly the Distributor Defendants, serve as a vital safeguard against the diversion of opioids into illegal, non-medical channels.

142. Defendants have unconscionably violated their duty by selling and shipping *billions* of opioids into Florida without sounding the alarm, stopping the shipments, or taking reasonable steps to prevent diversion.

143. The number of dosages that Defendants sold, distributed, and/or dispensed in Florida are far greater than could be medically justified.

144. Defendants purchased highly detailed data on opioid prescribing, sales, and distribution from sources such as IMS Health (now called IQVIA) and other data-mining firms. Defendants' information on opioid distribution patterns was not limited to their own sales or shipments.

145. Walgreens and CVS are two of the largest pharmacy chains in Florida. Walgreens operates 820 stores across Florida, and CVS operates 754 stores across Florida. Walgreens and CVS tracked which of their stores were top sellers of particular drugs. But instead of using that information and data to prevent shipments of suspicious quantities or filling of suspicious prescriptions, Walgreens and CVS joined the race to sell as many opioids as possible, including by failing to institute safeguards and by marketing opioids to their vast networks of retail pharmacy stores and in-store pharmacists.

146. Armed with knowledge of their own sales and shipments and industry-wide data, Defendants knew or should have known that the quantity of opioids being distributed in Florida far exceeds the medical need of Florida residents. Defendants knew or should have known that they were shipping more opioids than could possibly be medically appropriate, and that a



significant number of opioids in Florida were being diverted from legitimate medical uses.

Opioid shipments continue to be far greater than medically justified.

**2. Defendants Ignored Red Flags of Opioid Diversion and Failed to Implement Reasonable Safeguards To Prevent Diversion**

147. All Defendants failed to fulfill their statutory and common-law duties to secure their link in the opioid supply chain and prevent diversion.

148. Section 499.0121(15), Florida Statutes, imposes legal duties on the Distributor Defendants, and indeed on all Defendants holding distributor licenses in Florida, which they breached. Among other things, this statute requires Defendants to “take reasonable measures to identify its customers”; “understand the normal and expected transactions conducted by those customers”; and “identify those transactions that are suspicious in nature.” Furthermore, they “must establish internal policies and procedures for identifying suspicious orders and preventing suspicious transactions.” “A [Distributor] must assess orders for more than 7,500 unit doses of any one controlled substance in any one month to determine whether the purchase is reasonable,” and in doing so it “may consider the purchasing entity’s clinical business needs, location, and population served, in addition to other factors established in the distributor’s policies and procedures.” Defendants did not fulfill these duties.

149. Apart from Florida’s statutes, all Defendants have a duty to exercise reasonable care when selling, distributing, and dispensing opioids, which Defendants knew or should have known were being diverted. Defendants violated these common-law duties.

150. Manufacturer Defendants purportedly maintained suspicious order monitoring, Know Your Customer, and anti-diversion programs.

151. Nonetheless, the Manufacturers' anti-diversion programs were not sufficient to meet the Manufacturers' duty under Florida law to take reasonable steps to prevent vast quantities of opioids from flowing into Florida and becoming diverted.

152. The Manufacturers also had a duty to ensure that the Distributors distributing their opioids had effective anti-diversion programs in place. Instead, with rare exceptions, they continued doing business with distributors knowing that a significant volume of opioids would be diverted – and in fact offering volume incentives to encourage ever greater numbers of opioids to be sold in Florida. Additionally, as noted above, each Manufacturer (or a corporate affiliate) except Insys was registered as a distributor under Florida law and reported opioid shipments. This underscores their familiarity with the duties of distributors and the importance of securing the entire opioid supply chain.

153. Furthermore, the Manufacturers could and should have suspended sales to specific pharmacies, to specific distributors, and of certain opioids in order to quell diversion. With rare exceptions, they chose instead to continue selling opioids that they knew or should have known would be diverted.

154. The Manufacturers knew their anti-diversion protocols were inadequate.

155. The Distributor Defendants repeatedly turned a blind eye to red flags and signs of diversion and abuse among their customers in Florida and around the country. They failed to put controls in place to identify suspicious pharmacies and ensure that the Distributors were not facilitating those pharmacies' unlawful diversion. And the Distributors behaved unreasonably by failing to notify any Florida law enforcement agency or regulatory body about suspicious orders or evidence of diversion.

156. The Distributor Defendants supplied opioids to pharmacies dispensing a high percentage of controlled substances, pharmacies that dispensed opioid cocktails (dangerous combinations of drugs such as opiates, benzodiazepine, and muscle relaxants), and pharmacies that did not have adequate controls in place to prevent diversion and abuse. The Distributor Defendants served pharmacies that filled prescriptions from far-off and out-of-state doctors and pain clinics, as well as pharmacies that supplied more than one opioid to a single patient – a pattern of prescribing that is unlikely to be medically justified and thus carries a high risk of diversion. The Distributors supplied opioids to pharmacies that admitted to servicing pill mills, high-prescribing doctors, and pharmacies that reported early refills, doctor shopping, and other suspicious practices indicative of abuse or diversion. The Distributor Defendants refused to stop shipments of opioids to such pharmacies.

157. The Distributor Defendants increased the supply of opioids, despite red flags, by approving incremental threshold increases, even where the requests raised the pharmacy's level of oxycodone to suspiciously high levels.

158. Walgreens and CVS also breached their duties and violated Florida law in their capacities as dispensing pharmacies. Both the Florida common law and Chapters 465<sup>7</sup> and 499, Florida Statutes, impose obligations on these dispensing pharmacies, and required Walgreens and CVS to review each controlled substance prescription prior to dispensing an opioid medication and make a determination that the prescription is both effective and valid; ensure that each prescription for an opioid is valid and issued for a legitimate medical purpose by an individual practitioner acting in the usual course of his or her professional practice; refuse to

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<sup>7</sup> Chapter 465, Florida Statutes, governs pharmacies and requires them to verify the validity of prescriptions, the identity of patients receiving controlled substances, adopt procedures to prevent the dispensing of controlled substances based on misrepresentations and invalid physician relationships, and ensure the security of the prescriptions, among other obligations. *See* Fla. Stat. §§ 465.015, 465.0155, 465.022, 465.023, 465.024.

dispense medication if there is reason to believe that the prescription was not issued for a legitimate medical purpose; and provide effective systems, controls, and procedures to prevent theft and diversion of opioids. Under Florida law, a pharmacist's duty to use due care when filling prescriptions goes beyond simply following the prescription's directions – pharmacies that are on notice of red flags and signs of diversion or abuse may not simply robotically fill prescriptions, particularly where those prescriptions are unreasonable on their face because they are written in a quantity, frequency, or other manner that a reasonable pharmacist would do additional investigation and due diligence. Walgreens and CVS did not fulfill these duties.

159. As distributors that also operated many pharmacies, Walgreens and CVS were aware of red flags that should have caused their pharmacies to investigate a prescription before filling it. Examples of such red flags include doctors who write unusually large amounts of opioid prescriptions when compared with similar practitioners in the area; early refills for opioids prescriptions, prescriptions with unusual quantities or dosages; patients seeking to fill a prescription written for someone else; multiple consumers appearing at or near the same time with opioid prescriptions from the same physician; patients who drive long distances to have a prescription filled; consumers who seek large volumes of controlled substances in the highest strength for each prescription type; patients who appear to be creating cocktails with muscle relaxants or tranquilizers, consumers who pay large amounts of cash for opioid prescriptions rather than using some form of insurance.

160. Walgreens and CVS filled opioid prescriptions in Florida under circumstances showing red flags for opioid diversion, in violation of their common law and statutory duties under Florida law.

161. Walgreens and CVS failed to train or instruct their employees with respect to proper policies and protocols to follow to prevent diversion of opioids. This has the direct, readily foreseeable and intended result of employees continuing to fill prescriptions despite clear red flags.

162. Defendants' failure to identify, monitor, detect, investigate, report, and refuse to sell, fill, or dispense suspicious orders and prescriptions of opioids also violated Defendants' duty to act reasonably in light of the serious and foreseeable harms associated with opioid diversion and abuse. All Defendants' failure to take reasonable steps to prevent opioid abuse and diversion is a direct and proximate cause of, and/or substantial factor contributing to, the diversion of prescription opioids into Florida for consumption for non-medical, non-scientific purposes.

163. Defendants knew that widespread diversion of opioids was occurring in Florida, but turned a blind eye in order to earn higher profits. The foreseeable result of Defendants' decision to continue selling, distributing, and dispensing vast quantities of opioids that were deceptively marketed and had no medical justification was widespread addiction, overdoses, death, harms to the State of Florida, and the societal and economic harms that flow from prescription opioid abuse.

164. Defendants' conduct led to precisely the harm that Florida law was designed to prevent. Florida's law is designed to, among other things, protect consumers from harmful distribution practices. Defendants' unlawful practices leading to the diversion of opioids is a direct and proximate cause of and/or a substantial factor leading to opioid abuse, addiction, morbidity, and mortality in Florida. Defendants' unlawful practices leading to the diversion of

opioids is a direct and proximate cause of – and a substantial factor leading to – the opioid epidemic and the past and ongoing damages incurred by the State of Florida.

**3. The Distributor Defendants Have Been Investigated and Fined Repeatedly for Failing to Secure Their Supply Chains, but Refuse To Change Their Ways**

165. The Distributor Defendants’ failure to secure their opioid supply chain and prevent drug diversion has resulted in over a decade of governmental investigations, which the Distributor Defendants have settled for hundreds of millions of dollars. Notwithstanding these settlements and the egregious wrongdoing they uncovered – much of which occurred in Florida – the Distributors continued to violate their duties under Florida law.<sup>8</sup> They did so even though the Distributors publicly represented in connection with their settlements that they would secure their supply chains and prevent future diversion.

166. The details of each Distributor Defendants’ failure to take adequate action to prevent abuse and diversion of opioids are described in the sections on each Defendant herein.

**4. The Distributor Defendants Misrepresented That They Were Complying with Their Duties To Prevent Diversion of Opioids**

167. Defendants, individually and through the HDA, misrepresented to the public and to regulators that they were complying with their duties, including their common law and statutory Florida law duties to identify and prevent suspicious orders of opioids. In so doing, they deceptively concealed their role in creating and perpetuating the opioids crisis that has inflicted devastating harm on Florida.

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<sup>8</sup> The State references actions taken by federal and other state agencies solely because the underlying conduct by Defendants that was the subject of the federal and state investigations and enforcement actions *also* violates Florida law, and because Defendants made public misrepresentations in connection with settlements about their conduct that is subject to Florida law. Florida is not asserting any federal claims; it is not alleging any violation of federal law or any violation of any settlement with any federal authority; it is not alleging any fraud on any federal agency; and it does not seek to enforce or recover for any violation of federal law by Defendants.

168. These misrepresentations included statements that they were implementing suspicious order monitoring programs reasonably designed to identify and prevent opioid shipments that were at high risk of diversion. Defendants made these statements as part of settlements with government entities, among other places. The statements misled the public and officials of the State of Florida to believe that the Distributors were taking effective steps to fight the opioid epidemic. The details of each Defendant's misleading statements are described in the section on each Defendant's specific actions to inflate the demand and supply of opioids.

169. The chain pharmacies also committed to strict anti-diversion systems. Walgreens and CVS acknowledged and represented to the public that they have unique duties and obligations with respect to dispensing opioids and other controlled substances.

170. The Distributor Defendants omitted any mention to the public of the deliberate actions they were taking to exacerbate the opioid epidemic, including ignoring red flags among their pharmacy customers, bouncing problematic customers from one distributor to another, turning up the overall volume of opioids flowing to Florida pharmacies through "threshold creep" as described herein, and actively marketing opioid products to patients and pharmacies.

171. Defendants also made these statements and material omissions through their trade organizations, including the HDA, as well as the National Association of Chain Drugstores ("NACDS"). In an amicus brief in *Masters Pharmaceuticals* filed by the HDA and the NACDS, Defendants represented that they were complying with their duties to identify suspicious orders by utilizing both computer algorithms and human review to detect suspicious orders based on the generalized information that is available to them in the ordering process, taking action when particular orders or series of orders raised red flags because of size, frequency, or departure from patterns, and monitoring for unusual behavior by pharmacies. These statements were designed

to give the false impression that Defendants were not deliberately turning a blind eye to egregious signs of diversion among their pharmacy customers.

172. Through the HDA and directly, the Distributor Defendants participated in the organization of the PCF, a front group in which the Manufacturer Defendants also participated.

173. Despite representing publicly that they would secure the opioids supply chain as described herein, Defendants failed to take reasonable steps to prevent opioid diversion in Florida.

**5. The Distributor Defendants Marketed the Manufacturer Defendants' Opioid Products Even Though the Distributors Knew That Unjustifiably High Quantities of Opioids Were Being Distributed in Florida**

174. The Distributor Defendants marketed and promoted both branded and generic opioids to pharmacies and, in some cases, health care providers and patients. These Distributor marketing activities were an integral part of the Manufacturer Defendants' deceptive scheme to spread misrepresentations about opioids and increase opioid prescribing. Manufacturer Defendants worked with Distributor Defendants to develop marketing activities and paid Distributor Defendants for their efforts. As these marketing activities drove dramatic increases in opioid prescriptions, Distributor Defendants continued to market opioids and continued to distribute unconscionable quantities of opioids, ignoring their obligations to monitor, report, and stop suspicious orders.

175. McKesson and Cardinal promoted opioids for Allergan.

176. McKesson, Cardinal, and AmerisourceBergen all helped market Janssen's opioids.



177. Sometimes, several distributors marketed a single opioid product. McKesson, Cardinal, and AmerisourceBergen marketed Endo's Opana ER through at least email and direct mail.

178. Distributors acted as more than middlemen or mere delivery services; on the contrary, they inserted themselves directly into doctor-patient relationships. The Distributor Defendants marketed opioids directly to patients, including for off-label and unsafe uses, and they also consulted with patients about using opioids. The Defendants worked to overcome insurers' resistance to covering opioids outside of the uses for which they had been approved. Distributors including AmerisourceBergen and its Xcenda division paid in-house scientists to publish articles downplaying the risks of opioids.

179. The national retail pharmacies Walgreens and CVS marketed and distributed opioids and served as a conduit between the manufacturers of opioids and customers.

180. The Distributor Defendants also provided discount cards to induce consumers to purchase the Manufacturer Defendants' opioids.

181. The Distributor Defendants engaged in marketing efforts for the Manufacturer Defendants despite knowing about high order histories and widespread diversion of these same opioids by their customers in Florida and elsewhere. Additional details concerning each Distributor Defendant's marketing activities are described in the sections detailing particular actions by each Defendant.

182. Defendants invested in overcoming resistance on the part of insurance and health plans to pay for opioids prescribed for chronic, non-cancer conditions. Strategies to overcome insurers' refusal to cover opioids included call centers to help patients navigate the insurance and insurance appeals process, as well as working with doctors on the same issues.

183. The Distributor Defendants continually engaged in marketing efforts for the Manufacturer Defendants for at least the past ten years. They and the Manufacturer Defendants did this with the purpose of selling more opioids than were medically justified and, in that way, depriving the purchasers of property.

**C. Specific Actions Taken by Each Defendant to Unlawfully Over-Inflate the Demand and Supply of Prescription Opioids**

**1. Mallinckrodt**

184. Mallinckrodt promulgated and spread misinformation about opioids to prescribers and consumers, nationwide and in Florida, to convince doctors to prescribe and consumers to purchase and consume branded and generic opioid products.

185. Mallinckrodt is one of the largest manufacturers of opioids in the world.

186. Mallinckrodt's 30 mg oxycodone pills were so widely abused in Florida that they were called "M's" by drug users, in reference to the Mallinckrodt logo engraved into the pills. Interstate 75, from Florida to Appalachia, was known as the Blue Highway, a reference to the blue coating on Mallinckrodt's 30 mg pills.

187. Mallinckrodt advertised Exalgo and Xartemis XR as abuse-resistant. For example, one Mallinckrodt press release stated that "the physical properties of EXALGO may make it difficult to extract the active ingredient using common forms of physical and chemical tampering, including chewing, crushing and dissolving." But Mallinckrodt knew, and has known for years, that its opioids were at high risk of being abused, and that abuse-resistant formulas did not make opioids less addictive. It also knew that its opioids were sought after by drug abusers, and that even its abuse-resistant opioid formulations could deliver a fatal dose if crushed and consumed.

188. Mallinckrodt designed its marketing scripts to overcome doctors' concerns of abuse so they would prescribe more of Mallinckrodt's opioids.

189. As some Manufacturers and Distributors began to raise their standards for selling and distributing oxycodone, Mallinckrodt advertised its opioids as a more accessible alternatives that were ready to fill the void, and as a replacement for OxyContin.

190. Mallinckrodt instructed physicians that opioid doses can be safely increased with no ceiling dose, and encouraged doctors to dramatically increase patients' dosages. In doing so, it misrepresented the risks associated with taking increasingly high doses of opioids – risks that include addiction and fatal overdose.

191. Mallinckrodt frequently promoted the concept of pseudoaddiction to patients and doctors, including through its sales force.

192. Mallinckrodt also worked closely with numerous front organizations. In 2010, Mallinckrodt created the Collaborating and Acting Responsibly to Ensure Safety ("C.A.R.E.S.") Alliance, which it described as a "patient safety initiative which provides education and tools to healthcare professionals and patients to support responsible opioid prescribing and safe use." The C.A.R.E.S. Alliance used unbranded marketing to promote opioid use to treat non-cancer chronic pain.

193. For example, by 2012 the C.A.R.E.S. Alliance was promoting the book *Defeat Chronic Pain Now!* to doctors and patients. *Defeat Chronic Pain Now!* includes numerous misleading or false statements that promoted the widespread use of opioids. For example, the book argues that "[w]hen chronic pain patients take opioids to treat their pain, they rarely develop a true addiction and drug craving." "[I]n our opinion," the book's authors explained, "many of these folks on TV [shows about opioid addiction] appeared not to be addicted, but

rather had developed a physical dependence, which is a normal bodily reaction that happens with lots of different types of medication, including medications not used for pain, and is easily remedied.” *Defeat Chronic Pain Now!* also represented that “[o]pioids, even if taken chronically, can be safely and comfortably stopped by gradually reducing the dosage, usually by 10 percent every five to seven days.” In a mock Q&A, a patient with chronic pain expresses concern that opioid treatment might result in addiction, but the authors respond, “We definitely would try [opioid] treatment for our patients in your situation” because “[i]t is very uncommon for a person with chronic pain to become ‘addicted’ to narcotics IF (1) he doesn’t have a prior history of any addiction and (2) he only takes the medication to treat pain.” The authors also argue that, like addiction, “the issue of tolerance is overblown.” “The bottom line,” according to *Defeat Chronic Pain Now!*, is that “[o]nly rarely does opioid medication cause a true addiction when prescribed appropriately to a chronic pain patient who does not have a prior history of addiction.” *Defeat Chronic Pain Now!* remains available for purchase online today.

194. The C.A.R.E.S. Alliance worked closely with other front groups. For example, the Alliance offered to send doctors (for free) *Clinical Guidelines for the Use of Opioid Therapy in Chronic Noncancerous Pain*, written by APS and the AAPM. In addition, a portion of the sales of *Defeat Chronic Pain Now!* were donated to the American Pain Foundation.

195. Mallinckrodt also had direct relationships with front groups. For example, Mallinckrodt was a member of the U.S. Pain Foundation.

196. Mallinckrodt had close relationships with numerous KOLs. For example, Dr. Lynn Webster served on the company’s Advisory Board and performed a study about the anti-deterrent effects of Mallinckrodt’s drugs that the company relied on in its marketing materials. Dr. Scott Fishman’s book, *Responsible Opioid Prescribing*, was given away for free by

Mallinckrodt's C.A.R.E.S. Alliance. The book argues in favor of opioid-use for non-cancer pain, and its distribution was funded by opioid manufacturers such as Endo and Purdue. Dr. Fishman served as president of both APF and the AAPM and received funding from Manufacturer Defendants including Janssen, Endo, Cephalon, and Purdue. Dr. Fishman published a glowing review of *Defeat Chronic Pain Now!*

197. Mallinckrodt's sales team marketed its generic opioids as well as its branded opioids.

198. Mallinckrodt and its representatives made, and continue to make, these and other misrepresentations in order to increase opioid prescriptions.

199. Mallinckrodt delivered its false and misleading misrepresentations to Florida doctors.

200. Mallinckrodt also actively marketed its own opioid products.

201. Mallinckrodt knew its anti-diversion program was inadequate. The *Washington Post* has reported that in 2009 a law enforcement task force informed Mallinckrodt of a bust in which Mallinckrodt's pills were recovered. Mallinckrodt identified the Florida-based distributor responsible for the diverted drugs (which had a long history of egregious opioid purchases). Yet in the six weeks after the bust, Mallinckrodt reportedly shipped an additional 2.1 million oxycodone tablets to the same distributor.

202. On July 11, 2017, Mallinckrodt agreed to pay \$35 million to resolve a federal investigation that had been underway since at least 2011. The settlement arose from the DEA's allegations regarding Mallinckrodt's "distribution of oxycodone and hydrocodone products," including its alleged failure to "conduct adequate due diligence of its customers" and "detect and report . . . orders of unusual size and frequency." Additionally, the DEA alleged that, as a

distributor, Mallinckrodt failed to “use ‘chargeback’ information from its distributors to evaluate suspicious orders” and “take sufficient action to prevent recurrence of diversion by downstream customers after receiving concrete information of diversion of Mallinckrodt product by those downstream customers.” As part of this settlement, Mallinckrodt agreed that at certain times from 2008 through 2011, aspects of Mallinckrodt’s system to monitor and detect suspicious orders were inadequate to prevent diversion. Mallinckrodt publicly stated that it would improve its internal controls.

203. Despite representing publicly that it would secure its supply chain, Mallinckrodt failed to take reasonable steps to prevent opioid diversion in Florida. Mallinckrodt claimed that it was taking action, pointing to its participation in the “Anti-Diversion Industry Working Group, a collective of leading manufacturers and distributors of pharmaceutical controlled substances coming together to collaborate and share best practices . . . for opioid anti-diversion programs.”

204. On August 8, 2018, the U.S. House of Representatives Energy & Commerce Committee sent Mallinckrodt a letter requesting information about the company’s suspicious-order monitoring programs. The request for information is part of the Committee’s investigation into “potential breakdowns in the controlled substances supply chain which may have contributed to the nation’s opioid epidemic.” Mallinckrodt has yet to publicly respond.

205. Mallinckrodt sold medically unjustifiable quantities of opioids in Florida, and knew or should have known that its opioids were being diverted.

206. Mallinckrodt’s deceptive, unfair, and unconscionable actions led Florida prescribers to prescribe and consumers to consume opioid products. The opioid crisis described herein is a direct and foreseeable result of Mallinckrodt’s actions. The State of Florida was damaged by Mallinckrodt’s actions.

207. Mallinckrodt's deceptive, unfair, and unconscionable actions are continuing and continue to harm the State of Florida.

208. Mallinckrodt's deceptive, unfair, and unconscionable statements about opioids and other actions were material, were false, were made with intent to deceive, were made with the intent that the recipient of the information or another party reasonably rely upon it, and were made to further a scheme to defraud consumers and prescribers in violation of the Florida Communications Fraud Act, Fla. Stat. § 817.034.

## **2. Purdue**

209. Purdue promulgated and spread misinformation about opioids to prescribers and consumers, nationwide and in Florida, to convince doctors to prescribe and consumers to purchase and consume branded and generic opioid products.

210. Purdue trained its sales representatives to deliver a wide range of misinformation about opioids, such as the incorrect and unfounded claim that the risk of opioid addiction is less than 1%. Purdue knew that there was no legitimate scientific basis for this claim, which came from an anecdote in a one-paragraph letter to the editor. Rather, as early as the 1990s, studies at the time demonstrated rates of prescription drug abuse among chronic pain patients as high as 34%. Purdue's representatives made hundreds of thousands of sales calls in Florida between 2006 and 2016.

211. Purdue widely promoted the false notion that patients who take opioids for chronic pain face little to no risk of addiction. For example, Purdue claimed in a company press release that fear of addiction to opioids was "exaggerated" and that "there is very little risk of addiction from the proper uses of" opioids. Purdue trivialized the risk of addiction in many documents over many years.

212. Purdue's educational brochure, *Providing Relief, Preventing Abuse*, claimed that addiction is only triggered in susceptible individuals.

213. Purdue misrepresented that certain telltale signs of addiction were not signs of opioid addiction. Through its sponsorship and distribution of the publication *Responsible Opioid Prescribing*, Purdue falsely stated that certain behaviors, such as demanding or manipulative behavior to obtain opioids, visiting multiple doctors to obtain multiple prescriptions, requesting drugs by name, and hoarding opioids, were not signs of opioid addiction.

214. Purdue misrepresented that doctors and patients could effectively screen for addiction risk using the ORT test – a five question, one-minute screening questionnaire developed by KOL Dr. Lynn Webster. Purdue represented that the ORT could predict the risk of opioid addiction, but the ORT test cannot accurately predict a patient's risk of opioid addiction.

215. Purdue spread the false message of “pseudoaddiction” to physicians and consumers. Purdue's Vice President of Health Policy, Dr. J. David Haddox, coined the term “pseudoaddiction,” which he defined as a “syndrome of abnormal behavior” resulting from “inadequate pain management.” Dr. Haddox opined that pseudoaddiction is caused by the “undermedication of pain.” In presentations to prescribers, Purdue cited Dr. Haddox's research to support the false and perverse proposition that the proper response to signs of addiction is *more* opioids.

216. Purdue's educational pamphlet, *Providing Relief, Preventing Abuse*, represented that “pseudoaddiction has emerged in the literature to describe the inaccurate interpretation of behaviors in patients who have pain that has not been effectively treated.” Addictive behavior, according to Purdue, did not preclude “successful opioid therapy.”



217. Purdue falsely represented that taking opioids improved a person's quality of life. Purdue sponsored APF's publication of *A Policymaker's Guide to Understanding Pain & Its Management*. This publication inaccurately claimed that "[m]ultiple clinical studies" showed that opioids improved daily function, psychological health, and overall quality of life for those suffering from chronic pain.

218. Purdue sponsored the APF publication, *Treatment Options: A Guide for People Living with Pain* ("*Treatment Options*"), which represented the risk of death as a reason to avoid NSAIDs. Under a heading asking "[s]hould I take these pain medicines?", the publication claimed that "NSAIDs can cause life-threatening side effects in some persons" and that "[t]here are 10,000 to 20,000 deaths each year because of the side effects of this class of medicines." In contrast, *Treatment Options* posed no such question about the appropriateness of opioids. Rather, the publication stated that opioids could be "increased over time" and that there was "no ceiling dose as there is with the NSAIDs." This comparison is deceptive because opioids also pose severe and life-threatening effects, particularly at higher doses, and more people die each year from opioid use than from NSAID use.

219. *Treatment Options* also trivialized the risk of addiction. It stated that law enforcement officers' use of the phrase "'narcotics'" to describe opioids "reinforces myths and misunderstandings as it places emphasis on potential abuse rather than on the importance of their use as pain medicines." The publication dismissed the concern that an "average person" could become addicted to opioids and blamed this concern for doctors' hesitation to write opioid prescriptions and for the fact that opioids were, as a result, "under-used." It also claimed that withdrawal can be prevented by slowly reducing the dose, without addressing that many people

have an extremely difficult time weaning themselves off opioids once they become physically dependent.

220. Purdue sponsored the APF publication *Exit Wounds*, which targeted veterans with misinformation about opioids. Presented as the personal narrative of a single veteran, *Exit Wounds* described opioids as the “gold standard” of pain medications, as “often underused,” and as drugs that can “increase [your] level of functioning.” The publication further stated, “[l]ong experience with opioids shows that people who are not predisposed to addiction are unlikely to become addicted to opioid pain medications.” It also did not address the significant dangers of taking benzodiazepines, commonly prescribed for PTSD, with opioids. The book encouraged veterans that they “may need to push” doctors “hard” to get their preferred pain treatment. The publication further suggested that patients should plan for a “recurrence of pain” by “having a supply of a pain medication on hand.”

221. Purdue also targeted the elderly through misrepresentations to prescribers and consumers. Purdue supported AGS’s *Guidelines for the Pharmacological Management of Persistent Pain in Older Persons* (2009). The AGS Guidelines misrepresented that the risk of addiction was “exceedingly low in older patients with no current or past history of substance abuse.”

222. Purdue engaged KOLs to make misrepresentations regarding the length of time opioids would be effective against pain to physicians and the public. The KOLs used presentation slides created by Purdue while serving as faculty or speakers at meetings attended by Florida prescribers to make these misrepresentations. Purdue also instructed its sales representatives to make these same misrepresentations to prescribers.

223. Purdue and its representatives made, and continue to make, these and other misrepresentations about opioids.

224. Purdue knew by the mid-1990s that OxyContin was being abused, and that OxyContin was being mentioned “on websites and in chat rooms frequented by drug abusers”, and that “[m]onitoring that traffic” was “enough to keep a person busy all day.” By 1999, Purdue had received a tremendous amount of information indicating that OxyContin was being diverted and abused to a great extent in many states, including Florida. Yet Purdue never adequately addressed the diversion and abuse of its opioid products.

225. Purdue sold medically unjustifiable quantities of opioids in Florida, and knew or should have known that its opioids were being diverted.

226. Purdue’s deceptive, unfair, and unconscionable actions led Florida prescribers to prescribe and consumers to consume opioid products. The opioid crisis described herein is a direct and foreseeable result of Purdue’s actions. The State of Florida was damaged by Purdue’s actions.

227. Purdue’s deceptive, unfair, and unconscionable actions are continuing and continue to harm the State of Florida.

228. Purdue’s deceptive, unfair, and unconscionable actions and statements about opioids were material, were false, were made with intent to deceive, were made with the intent that the recipient of the information or another party reasonably rely upon it, and were made to further a scheme to defraud consumers and prescribers in violation of § 817.034, Florida Statutes.

### 3. Endo

229. Endo promulgated and spread misinformation about opioids to prescribers and consumers, nationwide and in Florida, to convince doctors to prescribe and consumers to purchase and consume branded and generic opioid products.

230. Endo misrepresented the risk of addiction to opioids on a number of websites. On [www.opana.com](http://www.opana.com), Endo stated that “[m]ost doctors who treat patients with pain agree that patients treated with prolonged opioid medicines usually do not become addicted.” On another of its websites, [www.PainAction.com](http://www.PainAction.com), Endo misleadingly represented that “[m]ost chronic pain patients do not become addicted to the opioid medications that are prescribed for them,” downplaying the significant risk of addiction that opioids present.

231. Endo communicated similar misrepresentations to patients and the public through brochures and pamphlets. One brochure, *Understanding Your Pain: Taking Oral Opioid Analgesics*, stated that “[t]aking opioids as prescribed for pain relief is not addiction” and “[a]ddiction 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.” In the same publication, Endo stated that the following test should guide patients in determining whether they are addicted to opioids: “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 pain and improve your function. You are not addicted.” The same brochure promoted the concept that “you may also need to take a short-acting opioid in between” doses of a long-acting opioid “for any increase in pain.” In another pamphlet for patients, called *Information on Taking a Long-Acting Opioid: What Does It Mean to Me?*, Endo misrepresented the distinctions between physical dependence, tolerance, and addiction to downplay the risk that patients would become addicted to opioids.

232. Endo promoted the deceptive and discredited concept of pseudoaddiction directly and through KOLs and front groups. It sponsored, distributed, and funded the distribution of *Responsible Opioid Prescribing*, by KOL Dr. Scott Fishman, which incorrectly claimed that signs of addiction in patients, such as “[r]equesting analgesics by name,” “[d]emanding or manipulative behavior,” seeing more than one doctor to obtain opioids, and hoarding are all mere signs of pseudoaddiction and not addiction.

233. Endo instructed its sales representatives to tell prescribers that opioids would improve patients’ ability to function, allowing them to return to work and increase physical activity. For example, Endo distributed a flyer to doctors claiming that use of Opana ER would allow a patient with chronic pain to work as a chef. The Endo-sponsored *Responsible Opioid Prescribing* likewise stated that patients improved their function with opioids and that functional improvement is the goal of a “long-term therapeutic treatment course.” Endo knew that no studies had established that opioids improved long-term functioning.

234. Endo reinforced its misleading messages about pseudoaddiction through multiple channels. It sponsored a CME through the American Association of Family Physicians (“AAPF”), entitled “Managing Pain: Dispelling the Myths.” This CME was also published as a monograph and distributed to all AAPF members. Endo represented that symptoms of addiction could be remedied by prescribing more opioids. Endo distributed *Avoiding Opioid Abuse While Managing Pain* by KOL Dr. Lynn Webster, which claims a doctor should regard aberrant patient behavior as pseudoaddiction and increase the patient’s opioid dose to remedy the situation. An American Pharmacists Association publication, supported by Endo and promoting Endo’s opioid product Opana ER, claimed that fears of addiction and abuse were “based largely on misunderstanding and misuse of terminology” and that addiction was distinct from

“pseudoaddiction.” The AAPM offered a CME on “The Truth About Pain Management” in conjunction with one of its annual meetings, and the chief lecturer promoting pseudoaddiction had financial ties to Endo, as well as Cephalon and Purdue Pharma.

235. Through front groups the APF and the Endo-funded and controlled National Initiative on Pain Control (“NIPC”), Endo sponsored the website PainKnowledge.com until 2012. This website proclaimed that “[p]eople who take opioids as prescribed usually do not become addicted” and that opioid dosages should be raised until “you are on the right dose of medication for your pain,” without addressing the dangers that high doses of opioids present to patients. The website listed certain adverse effects from opioids but omitted the severe adverse effects of hyperalgesia, immune system and hormone dysfunction, cognitive impairment, tolerance, dependence, addiction, and death. PainKnowledge.com represented that, with 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.”

236. Endo funded and promoted the Screener and Opioid Assessment for Patients with Pain (“SOAPP”) as another tool to determine whether a person is likely to become addicted to opioids. For example, the Endo-supported website painEDU.org claimed, among other misrepresentations, that the SOAPP screening tool could effectively manage addiction risk. The SOAPP is unable to accurately predict a patient’s risk of opioid addiction.

237. Endo made the deceptive claim that there is no maximum dosage of opioids that can be safely prescribed, and that as a result opioids are safer than NSAIDs. Endo promoted the idea that “side effects” – not risk of overdose – are the only “ceiling” on opioids prescriptions.

This misrepresentation is dangerous, because patients develop tolerance to opioids that requires higher doses to achieve pain relief, and higher doses carry a much higher risk of overdose.

238. Endo substantially funded and controlled the NIPC to promote its misleading messages, including the concept of pseudoaddiction. Endo commissioned the NIPC Education Council, which it called an “educational advisory group of thought leaders in the area of pain management and opioid pharmacotherapy,” to develop the program. CMEs offered include “Opioid Analgesia: Practical Treatment of the Patient with Chronic Pain,” and “Advances in Opioid Analgesia: Maximizing Benefit; Minimizing Harm.” The programs promoted the use of opioids for pain from osteoarthritis, neuropathy, and back pain, promoted use of a screening tool to identify patients at higher risk for opioid addiction, and claimed that patients needing more and more opioids is merely a sign of pseudoaddiction.

239. Endo supported the publication *A Clinical Guide to Opioid Analgesia* by KOLs Dr. Russell Portenoy and Dr. Perry Fine, which was distributed through national and regional professional societies and was available online. It promoted the discredited idea of pseudoaddiction and the myth that “long-term opioid therapy of an older population with no history of substance abuse is rarely associated with de novo development of abuse or addiction.”

240. Endo also targeted elderly patients through misrepresentations to prescribers and consumers. Endo supported the 2009 *Guidelines for the Pharmacological Management of Persistent Pain in Older Persons*, which misrepresented that the risk of addiction was “exceedingly low in older patients with no current or past history of substance abuse.” The Chairman of the task force that wrote the guidelines, KOL Dr. Bruce Ferrell, had promoted opioids in 2007 as part of an Endo-funded CME on treating pain in older patients, and by 2010 Ferrell was one of Endo’s paid speakers.

241. Endo's misrepresentations reached Florida prescribers. CMEs developed by Endo's consultants and sponsored by the front organizations were presented to doctors in Florida. For example, CMEs and webcasts called *Opioid REMS: Achieving Safe Use While Improving Patient Care* were sponsored by the APS, the AAPM, and other organizations.

242. One of the REMS-related organizations is called the ER/LA Opioid Analgesics REMS Program Companies, a consortium that includes Purdue, Allergan, Endo, Janssen, Mallinckrodt, and Teva. This entity funded the creation of the *Opioid REMS* CME with a grant. The second is called CO\*RE (Collaborative for Opioids REMS Education), which is essentially a front group of front groups – its “partners” include APS as well as standard professional organizations such as the American Academy of Physician Assistants and the American Association of Nurse Practitioners, but the “Funder Information” indicates that the project is funded by the Manufacturer Defendants, including Allergan, Endo, Janssen, Purdue, and Teva.

243. The *Opioid REMS* CMEs were created by Endo consultants, including Dr. Charles Argoff (who co-authored the book *Defeat Chronic Pain Now!* and also consulted for Teva and Janssen), Dr. Steven Stanos (who also consulted for Janssen), and one non-Endo consultant, Dr. Paul Arnstein, who consulted for Janssen and Mallinckrodt. These presentations were given in Florida, including in Tallahassee in 2013 and 2014, and in Orlando in 2014. The CME continued to promote discredited and false ideas.

244. Endo targeted physicians, including in Florida, with the goal of getting them to prescribe opioids for chronic pain. It paid Florida doctors to speak, and it targeted doctors for marketing of Opana ER. It marketed opioids at Florida conferences, including an APS convention in Tampa, and sponsored presentations by KOLs on opioids at Florida events.



245. Endo paid various consultants and speakers to promote opioids, including in Florida. Endo distributed *Understanding Your Pain: Taking Oral Opioid Analgesics*, a patient-education pamphlet edited by KOL Dr. Russell Portenoy. In the Q&A Section, the pamphlet indicated that, if a patient develops “tolerance” to opioids, “it does not mean you will ‘run out’ of pain relief,” because “[y]our dose can be adjusted or another medicine can be prescribed.” In recommending increasing opioid dosage as a response to tolerance, Endo did not address the risks that accompany high-dose opioid use. Endo paid KOLs directly. For example, Endo retained KOL Dr. Perry Fine as a paid consultant, along with other physicians who spoke at opioids conferences.

246. In 2012, Endo began touting its reformulated Opana ER as resistant to crushing and less likely to be misused. However, the reformulated drug was no less addictive. In any event, Endo’s claim was untrue – as the FDA explained when it ultimately pulled Opana ER from the shelves, the route of abuse for reformulated Opana ER simply changed from nasal inhalation to injection.

247. Endo misrepresented the risks and benefits of non-opioid pain relief treatments. For example, Endo supported the case study *Case Challenges in Pain Management: Opioid Therapy for Chronic Pain* to prescribers. It described a patient who was using NSAIDs for pain management as having “a massive upper gastrointestinal bleed believed to be related to his protracted use of NSAIDs” over eight years, and used this information as a reason to recommend opioid-based pain treatments without disclosing the serious risks of opioid treatments.

248. Endo also sponsored *Treatment Options*, whose many misrepresentations are alleged herein.

249. Endo made misrepresentations – including pseudoaddiction, the risk of addiction, and the efficacy of screening tools to predict addiction – about not only its branded opioids, but also to the generic opioid products Endo sold.

250. Endo and its representatives made, and continue to make, these and other misrepresentations about opioids.

251. Endo was also well aware that its opioid products were being abused and diverted. In 2016, Endo settled allegations brought by the State of New York that focused on improper marketing, abuse, and diversion of Opana ER. The investigation found that Endo had no meaningful program in place to ensure that its sales representatives were not encouraging healthcare providers who are engaged in abuse and diversion to write more prescriptions for Opana ER. As part of the settlement, Endo agreed to create an Abuse and Diversion Detection Program, but this program was inadequate and the abuse and diversion continued.

252. Endo sold medically unjustifiable quantities of opioids in Florida, and knew or should have known that its opioids were being diverted.

253. Endo's deceptive, unfair, and unconscionable actions led Florida prescribers to prescribe and consumers to consume opioid products. The opioid crisis described herein is a direct and foreseeable result of Endo's actions. The State of Florida was damaged by Endo's actions.

254. Endo's deceptive, unfair, and unconscionable actions are continuing and continue to harm the State of Florida.

255. Endo's deceptive, unfair, and unconscionable actions and statements about opioids were material, were false, were made with intent to deceive, were made with the intent that the recipient of the information or another party reasonably rely upon it and were made to

further a scheme to defraud consumers and prescribers in violation of § 817.034, Florida Statutes.

#### **4. Janssen**

256. Janssen promulgated and spread misinformation about opioids to prescribers and consumers, nationwide and in Florida, to convince doctors to prescribe and consumers to purchase and consume branded and generic opioid products.

257. Janssen spread these misrepresentations through its own sales representatives, collaborations with front groups, regional speaker programs, KOLs, and other practices.

258. Janssen misrepresented that most opioid patients are at little risk of addiction. Janssen stated to prescribers that their reluctance to prescribe opioids was unfounded because the risks were lower than generally believed.

259. On its website [www.PrescribeResponsibly.com](http://www.PrescribeResponsibly.com), Janssen represented that the risks of becoming addicted to opioids are overstated. Furthermore, Janssen stated that “true addiction occurs only in a small percentage of patients with chronic pain who receive chronic opioid . . . therapy.”

260. Janssen misrepresented that the potential for addiction can be easily controlled. Janssen misrepresented to prescribers that most patients will not experience withdrawal after ending Nucynta treatment. Janssen promoted the discredited ORT as a valid method to determine whether a patient is likely to become addicted to opioids.

261. Janssen stated publicly that the risk of addiction to opioids “can usually be managed” by opioid agreements between doctors and patients, which purported to set forth opioid usage plans for patients.

262. Janssen promoted Nucynta as crush and breakage resistant to persuade prescribers that Nucynta was less likely to be abused. Through its sales representatives, Janssen represented

to prescribers that Nucynta's formulation had properties that curtailed addiction risks relative to other opioids.

263. Janssen, through publications, speaker presentations, and sales personnel falsely represented that high doses of opioids posed little danger to patients and encouraged doctors to increase patients' doses.

264. Janssen funded studies to address marketing needs and placed them in medical literature to support its marketing efforts.

265. Janssen funded, edited, participated in the development of, and controlled the content of misleading materials published by front groups, including the unbranded APF initiative "Let's Talk Pain," which included a website and other promotional materials and activities.

266. The "Let's Talk Pain" website included misinformation about opioids, such as by stating that "pseudoaddiction . . . refers to patient behaviors that may occur when pain is under-treated" and that "[p]seudoaddiction is different from true addiction because such behaviors can be resolved with effective pain management."

267. Janssen also used front groups to spread the misrepresentation that opioids create positive long-term outcomes for users with chronic pain.

268. Janssen sponsored and controlled the content of a patient education guide and video titled *Finding Relief: Pain Management for Older Adults*, which was distributed by Janssen's sales force. *Finding Relief* described the addictive qualities of opioids as a myth, claiming that "[m]any studies show that opioids are rarely addictive when used properly for the management of chronic pain." It featured a man playing golf on the cover and listed examples of expected functional improvement from opioids, including sleeping through the night, returning

to work, recreation, sex, walking, and climbing stairs. It stated that “opioids may make it easier for people to live normally,” without addressing the life-altering effects of addiction, did not address the material risks of abuse and addiction when discussing side effects of opioids. It also mischaracterized dose limitations as “disadvantages” of alternative pain management medications, without discussing the risks associated with increasing opioid dosages.

269. The *Finding Relief* video includes deceptive statements such as that fears of opioids are overemphasized and that there’s no relationship between addiction and dependence.

270. Janssen co-sponsored the APF publication *Special Considerations: Pain in Specific Populations*. This publication sought to normalize opioid use as a treatment option among the elderly.

271. Janssen paid for APF to distribute *Exit Wounds*, which contained misrepresentations including those alleged herein, to veterans and others.

272. Janssen funded and exercised influence and control over other front groups.

273. Janssen spread misrepresentations through KOLs and speakers’ bureaus.

274. In addition to controlling the activities of Janssen Pharmaceuticals, Inc., Johnson & Johnson directly participated in the deceptive, unfair, and unconscionable acts and practices described herein. Johnson & Johnson paid physicians involved in disseminating misleading information about opioids. Authors of the *Clinical Guidelines for the Use of Chronic Opioid Therapy in Chronic Noncancer Pain* and *Pharmacological Management of Persistent Pain in Older Persons*, described herein, disclosed financial ties to Johnson & Johnson. Likewise, Johnson & Johnson is a “participating organization” of the PCF, and Johnson & Johnson employees are listed in a directory of PCF contacts.

275. Janssen delivered its false and misleading misrepresentations to thousands of Florida doctors, who wrote prescriptions as a result of Janssen's deceptive actions.

276. Janssen and its representatives made, and continue to make, these and other misrepresentations about opioids.

277. Janssen sold medically unjustifiable quantities of opioids in Florida, and knew or should have known that its opioids were being diverted.

278. Janssen's deceptive, unfair, and unconscionable actions led Florida prescribers to prescribe and consumers to consume opioid products. The opioid crisis described herein is a direct and foreseeable result of Janssen's actions. The State of Florida was damaged by Janssen's actions.

279. Janssen's deceptive, unfair, and unconscionable actions are continuing and continue to harm the State of Florida.

280. Janssen's deceptive, unfair, and unconscionable actions and statements about opioids were material, were false, were made with intent to deceive, were made with the intent that the recipient of the information or another party reasonably rely upon it, and were made to further a scheme to defraud consumers and prescribers in violation of § 817.034, Florida Statutes.

## **5. Allergan Entities**

281. Allergan, Actavis Pharma, Inc., and Actavis LLC promulgated and spread misinformation about opioids to prescribers and consumers, nationwide and in Florida, to convince doctors to prescribe and consumers to purchase and consume branded and generic opioid products. These products include the branded drugs Kadian and Norco, as well as generic opioids including oxymorphone.

282. Like the other Defendants, Allergan aimed to sell more opioids by convincing patients and providers that opioids are not merely appropriate, but *necessary*, for a wide range of conditions that cause chronic pain. Further, Allergan misrepresented that opioids can be taken with little risk of addiction in most patients, even though it knew that opioid use leads to tolerance and physical dependence, and that anyone who takes opioids is at risk of addiction.

283. For example, Allergan trained sales representatives to tell providers that opioid patients have a low risk of addiction, many opioid patients are merely experiencing pseudoaddiction, and opioid withdrawal is a minor concern. It trained sales representatives to tell prescribers that patients taking opioids for chronic pain have improved functionality if they continue taking opioids.

284. Allergan and its speakers told prescribers that opioids pose little addiction risk when taken by patients who have no history of addiction or abuse.

285. Allergan deceptively promoted opioids as helping to maintain quality of life, an elevated mood, and improved social functioning.

286. Allergan misrepresented the risks and benefits of other pain medications like NSAIDs. Allergan falsely represented that opioids were safer than NSAIDs.

287. Allergan presented its messages as supported by scientific literature, but represented the results of studies in misleading ways.

288. Allergan distributed a brochure that stated that the risk of opioid addiction was “less likely if you never had an addiction problem,” implying that the risk of addiction was low.

289. Allergan misrepresented that doctors and patients could effectively screen for addiction by using the invalid ORT.

290. Allergan instructed doctors to set dosage levels based on the needs of the patient with no maximum dose in mind. Allergan misrepresented that opioids were safer than other drugs, such as NSAIDs and acetaminophen, because opioids do not have dose ceilings.

291. Allergan misrepresented the dangers of high-dose opioid treatment. Allergan told prescribers that pain patients would not develop opioid tolerance and that opioid prescriptions had no dosage ceiling and were therefore safe.

292. Allergan also misrepresented that opioids create positive long-term outcomes for users with chronic pain even though no studies exist to support those claims.

293. Allergan also relied on KOLs to deliver Allergan-approved messages.

294. Allergan widely distributed gift cards that cover the co-pay on branded and generic opioid prescriptions, including in Florida.

295. Allergan developed its training materials for a national audience, and delivered its messages to a large number of prescribers in Florida, who wrote prescriptions filled by Florida patients.

296. Allergan's marketing efforts and sales force promoted both branded and generic opioids.

297. Actavis Pharma, Inc. and Actavis LLC marketed opioids and participated in the misleading marketing of both branded and generic opioids alleged herein, including by developing training and promotional materials.

298. Allergan, Actavis Pharma, Inc., and Actavis LLC and their representatives made, and continue to make, these and other misrepresentations about opioids, nationwide and in Florida.



299. Allergan, Actavis Pharma, Inc., and Actavis LLC sold medically unjustifiable quantities of opioids in Florida, and knew or should have known that their opioids were being diverted.

300. Allergan, Actavis Pharma, Inc., and Actavis LLC's deceptive, unfair, and unconscionable marketing led Florida prescribers to prescribe and consumers to consume opioid products. The opioid crisis described herein is a direct and foreseeable result of Allergan's, Actavis Pharma, Inc.'s, and Actavis LLC's actions. The State of Florida was damaged by Allergan's, Actavis Pharma, Inc.'s, and Actavis LLC's actions.

301. Allergan's, Actavis Pharma, Inc.'s, and Actavis LLC's deceptive, unfair, and unconscionable actions are continuing and continue to harm the State of Florida.

302. Allergan's, Actavis Pharma, Inc.'s and Actavis LLC's deceptive, unfair, and unconscionable actions and statements about opioids were material, were false, were made with intent to deceive, were made with the intent that the recipient of the information or another party reasonably rely upon it, and were made to further a scheme to defraud consumers and prescribers in violation of § 817.034, Florida Statutes.

## **6. Cephalon**

303. Cephalon promulgated and spread misinformation about opioids to prescribers and consumers, nationwide and in Florida, to convince doctors to prescribe and consumers to purchase and consume branded and generic opioid products.

304. Many of Cephalon's misrepresentations were aimed at convincing doctors to prescribe and consumers to purchase its short-acting opioid products, Actiq and Fentora, for chronic pain and other uses well beyond the limited contexts for which these products can be safely used. To do this, Cephalon developed and promoted the idea that "breakthrough pain"

experienced by patients taking long-acting opioids for chronic conditions required “rescue” treatment with short-acting opioids containing fentanyl.

305. These products have been demonstrated to be medically safe and appropriate for use in treating breakthrough *cancer* pain for those patients who are already opioid tolerant. Breakthrough cancer pain is an acute, short-term onset of pain, of moderate-to-severe intensity, affecting patients whose pain is otherwise stable.

306. Fentanyl, an ingredient in Actiq and Fentora, is linked to fatal respiratory complications in patients. Because it is 80 to 100 times more potent than morphine, and because it poses a high risk of addiction, drugs containing fentanyl are particularly likely to cause overdoses and death. Because of the dangers of Actiq and Fentora, objective studies established that these products should only be used by patients who are opioid-tolerant, because life-threatening respiratory depression and death could occur at any dose in patients not on a chronic regimen of opioids. For this reason, Actiq and Fentora are contraindicated in the management of acute or postoperative pain. Because of the high risk of addiction leading to overdose, these drugs have not been established as safe for use outside of end-stage cancer contexts.

307. To overcome doctors’ and patients’ reluctance to use these powerful drugs more widely, Cephalon aggressively marketed its opioid products for “breakthrough pain,” a term used by Cephalon to encourage improper prescriptions and use of the products. Cephalon marketed and promoted Actiq for treatment of chronic, non-cancer pain, including non-cancer breakthrough pain. Cephalon, through its sales force, paid KOLs, sponsored articles, and more represented that Actiq (and later Fentora) was appropriate for a variety of non-cancer conditions, including sports injuries, headaches including migraines, and back pain. It deliberately sought to

create a new market by marketing the drug far beyond oncologists and promoting Actiq (and later Fentora) for “nonmalignant pain,” or pain not caused by cancer.

308. Cephalon executive Bob Roche boasted in 2007 that the launch of Fentora had been aggressive and the company sought to expand the use of Fentora to broader indications, including lower-back pain and neuropathic pain.

309. On September 10, 2007, Cephalon sent letters to doctors informing them that Fentora may lead to death and other “serious adverse events.” Cephalon stated, “[t]hese deaths occurred as a result of improper patient selection (*e.g.*, use in opioid non-tolerant patients), improper dosing, and/or improper product substitution.’” Cephalon nonetheless continued to promote Fentora for use by all cancer patients, regardless of whether the patient was opioid tolerant.

310. Cephalon created a marketing plan to spread its misinformation. This campaign was intended to, and did, reach a nationwide audience of prescribers, including those in Florida. Cephalon spent millions of dollars to promote its opioid products.

311. In a number of cases, Cephalon paid for the studies on which it relied, and some of the key studies were conducted by its own consultants and employees. For example, Cephalon paid for a study by KOL Dr. Lynn Webster about how Actiq would help non-cancer “breakthrough pain.” Cephalon sponsored another study by KOLs Dr. Perry Fine and Dr. Russell Portenoy, also aimed at providing a basis for promoting Cephalon’s opioid products for non-cancer “breakthrough pain.” Cephalon relied on these KOL studies – sometimes co-authored by Cephalon’s own in-house employees, such as Dr. John Messina – to support its marketing claims that Fentora could be used safely for “breakthrough pain” outside the cancer

context, including for lower-back pain and chronic neuropathic pain. It also relied on these studies in its materials aimed at getting health insurance plans to cover its opioid products.

312. Cephalon misrepresented the risk of addiction to opioids in its publications. In materials promoting Actiq for “nonmalignant pain,” Cephalon called concerns about patients becoming addicted to opioids “a widespread misunderstanding” and claimed that the effects of opioid dependence was “usually not problematic for patients who are on chronic opioid therapy.”

313. Cephalon also advanced the phony concept of pseudoaddiction. Its brochure, *Making Pain Talk Painless: A Guide To Help You Talk with Your Doctor About Pain Management* stated that medicine-seeking behavior is not addiction and encouraged patients to talk to their doctor about obtaining more pain medicine.

314. Cephalon sponsored and developed *Opioid Medications and REMS: A Patient’s Guide*, a guidebook for patients that misrepresented the risks of addiction to opioids. The guidebook stated that patients without a history of addiction “do not commonly become addicted to opioids.” Cephalon circulated the guidebook nationally, and it was available to and intended to reach prescribers in Florida.

315. Cephalon sponsored a CME titled *Optimizing Opioid Treatment for Breakthrough Pain*, which promoted opioids for unsafe uses and misleadingly portrayed the risks and benefits of using opioids for the treatment of chronic pain. The CME misrepresented that Actiq and Fentora, taken in conjunction with long-acting opioids, would help patients regain functionality, improve patients’ quality of life, and allow for a more active lifestyle. *Optimizing Opioid Treatment for Breakthrough Pain* was available online and reached Florida prescribers.

316. Cephalon made similar misrepresentations through front groups that it funded. Cephalon co-sponsored the APF publication *Treatment Options*, which contains the many misrepresentations alleged herein.

317. The same publication claimed that opioid drugs could give them “a quality of life [they] deserve.” The publication further represented that despite the “great benefits of opioids, they are often under-used” because providers and patients may be fearful of them.

318. Cephalon’s campaign to create a new market for its short-acting opioids also relied on the front organizations. One of the key studies on which it relied, *Prevalence and Characteristics of Breakthrough Pain in Opioid-Treated Patients with Chronic Non-Cancer Pain*, was copyrighted by APS, authored by KOL Dr. Russell Portenoy and co-authored by a series of Cephalon consultants who were on Cephalon’s speaker’s bureau. The study promoted the idea of using “rescue dosing” of short-acting opioids for patients with chronic pain unrelated to cancer. Cephalon cited these studies in branded and unbranded marketing.

319. Cephalon relied on at least one APF publication it funded in marketing opioids.

320. Cephalon was aware that physicians were prescribing Fentora for uses that were not medically supported as safe and appropriate. Cephalon was also aware that its deceptive marketing practices caused prescribers to write inappropriate prescriptions.

321. In 2011, Cephalon wrote and copyrighted an article titled “2011 Special Report: An Integrated Risk Evaluation and Risk Mitigation Strategy for Fentanyl Buccal Tablet (FENTORA®) and Oral Transmucosal Fentanyl Citrate (ACTIQ®)” that was published in Pain Medicine News. The article promoted use of Cephalon’s drugs by representing that Fentora had “been shown to be effective in treatment of [breakthrough pain] associated with multiple causes of pain.”

322. Cephalon sponsored a CME, *Opioid-Based Management of Persistent and Breakthrough Pain*, which was authored by KOL Dr. Perry Fine and distributed by Pain Medicine News in 2009. The CME concluded, “[a]ll individuals with chronic, moderate to severe pain associated with functional impairment should be considered for a trial of opioid therapy.”

323. Cephalon sponsored a CME entitled “Practical Issues in Prescribing Opioids: Maximizing Pain Relief and Minimizing Risk,” in 2006, at a symposium in conjunction with APS’s annual meeting. The faculty included Dr. Perry Fine, who had financial relationships with Cephalon and Endo, Dr. Steven D. Passik, who had financial relationships with Cephalon, Purdue, and Endo, and other doctors with financial and other relationships with opioid manufacturers. The CME promoted the use of fentanyl tablets for chronic non-cancer pain and cited KOL-led and Cephalon-funded studies. The CME also promoted the SOAPP and ORT screening tools. It promoted the deceptive claim that “aberrant behaviors” may emerge when opioids are prescribed “too stingily because of old-fashioned views, addiction fears, and legal / regulatory concerns” arguing that “while not empirically validated, undertreatment may predispose to pseudoaddiction and aberrant drug-related behavior.” In other words, the solution to “addiction fears” is more opioids.

324. Cephalon used KOLs to promote its messages about opioids, and directed the content of that messaging. Dr. Perry Fine and other KOLs did other work for Cephalon, including serving on speakers’ bureaus to promote marketing.

325. Cephalon and Teva continued to make these misrepresentations. In 2014 and thereafter, Cephalon and its paid consultants continued to promote Fentora for common, non-cancer conditions such as lower-back pain, arthritis, and diabetic neuropathy. One 2015 article

authored by a Teva consultant stated that the “good news” about non-cancer breakthrough pain is the availability of rapid-onset fentanyl-based opioids, including Fentora. As late as 2018, Teva scientists, writing with authors working at AmerisourceBergen’s Xcenda division, published a study promoting the notion that risk of opioid abuse is limited to a “sub-population” of those taking opioids long-term for chronic non-cancer pain.

326. Marketing Fentora and Actiq for chronic, non-cancer pain and to cancer patients who were not already opioid-tolerant was deceptive, unfair, and unconscionable. Cephalon aimed to dramatically increase the use – and therefore distribution and availability for diversion – of opioids so potent that they can cause a fatal overdose on the very first use. As a result of these representations, fentanyl deaths have shot up as described herein, including in Florida.

327. Cephalon also worked through front groups to promote other myths about opioids. For example, it supported an APF publication called Pain Notebook, which promoted misrepresentations about pain. Pain Notebook was cited in later KOL materials, such as “Consensus Panel Recommendations” regarding breakthrough pain (which was based on a meeting held in Orlando, Florida and was also supported by Cephalon), which promoted the idea of using immediate-release opioids to treat “breakthrough” pain in patients without cancer.

328. At a 2004 Orlando, Florida meeting of the AAPM, KOL Dr. Lynn Webster presented a Cephalon-sponsored study on the use of fentanyl-based opioids for the treatment of chronic non-cancer pain, which Cephalon then provided in its sales trainings. The study promoted the use of fentanyl-based short-acting opioids to address breakthrough pain in patients with chronic pain, such as back pain and headache.

329. After 2011, Cephalon continued to promote the idea that clinical trials suggested that short-acting opioids were effective for “breakthrough pain” in patients without cancer, and it

promoted APS's and AAPM's Guidelines for use of opioids for non-cancer patients. And Teva marketed its generic version of Actiq directly to consumers.

330. Cephalon and its representatives made, and continue to make, these and other misrepresentations about opioids. In 2018, Teva-funded scientists are still publishing studies downplaying the risks of treating chronic, non-cancer pain with opioids.

331. Cephalon sold medically unjustifiable quantities of opioids in Florida, and knew or should have known that its opioids were being diverted.

332. Cephalon's deceptive, unfair, and unconscionable actions led Florida prescribers to prescribe and consumers to consume opioid products. The opioid crisis described herein is a direct and foreseeable result of Cephalon's actions. The State of Florida was damaged by Cephalon's actions.

333. Cephalon's deceptive, unfair, and unconscionable actions are continuing and continue to harm the State of Florida.

334. Cephalon's deceptive, unfair, and unconscionable actions and statements about opioids were material, were false, were made with intent to deceive, were made with the intent that the recipient of the information or another party reasonably rely upon it, and were made to further a scheme to defraud consumers and prescribers in violation of § 817.034, Florida Statutes.

## **7. Insys**

335. The lengths to which Insys went to sell its opioid product Subsys have recently become well-known. Insys paid millions of dollars in sham "speaker's fees" that were, in reality, kickbacks to doctors in exchange for writing prescriptions of Insys's highly addictive fentanyl spray. According to public records, Insys paid \$18.7 million to doctors between August 2013 and December 2016; one Florida doctor received \$270,000 from Insys. Six of Insys's top



executives are under criminal indictment for their role in the kickback scheme.

336. The Department of Justice has also intervened in a whistleblower lawsuit filed by a Florida-based Insys sales representative alleging that, in addition to kickbacks, Insys gave jobs to doctors' significant others and paid for physicians to visit strip clubs, shooting ranges, and expensive restaurants – all so that they would increase their opioid prescribing. There have already been numerous convictions and plea bargains related to Insys's scheme. For example, in July 2017, the former Insys regional manager for the Southeast – an area which included Florida – pleaded guilty to paying doctors kickbacks. And in June 2018, a Fort Myers doctor pleaded guilty to receiving kickbacks from Insys.

337. Insys deliberately marketed Subsys, which had only been established as safe for opioid-tolerant patients with breakthrough cancer pain, to high-volume opioid prescribers whom Insys knew was prescribed primarily to patients without cancer. A former Insys employee estimated that only about 10% of Subsys prescriptions at a prominent pain clinic had cancer.

338. The leadership of Insys knew that certain doctors diverted the movement of Subsys from legitimate medical distribution to illicit commercial distribution.

339. Insys also deliberately implemented a strategy, including misrepresentations, to overcome the need for insurers and pharmacy benefits managers to grant prior authorizations for new Subsys prescriptions.

340. Insys's unfair marketing campaign was especially harmful to Florida. According to data from the Center for Medicaid and Medicare Services, in 2015 more prescriptions for Subsys were written in Florida than any other state.

341. Insys sold medically unjustifiable quantities of opioids in Florida, and knew or should have known that its opioids were being diverted.

342. Insys's deceptive, unfair, and unconscionable actions led Florida prescribers to prescribe and consumers to consume opioid products. The opioid crisis described herein is a direct and foreseeable result of Insys's actions. The State of Florida was damaged by Insys's actions.

343. Insys's deceptive, unfair, and unconscionable actions are continuing and continue to harm the State of Florida.

344. Insys's deceptive, unfair, and unconscionable actions and statements about opioids were material, were false, were made with intent to deceive, were made with the intent that the recipient of the information or another party reasonably rely upon it, and were made to further a scheme to defraud consumers and prescribers in violation of § 817.034, Florida Statutes.

## **8. AmerisourceBergen**

345. AmerisourceBergen, despite being a giant distributor with comprehensive systems for tracking the movement of drugs, failed to prevent abuse and diversion of opioids in Florida.

346. AmerisourceBergen sold and shipped unreasonable quantities of opioids into Florida, including many red-flag pharmacies in Florida, and continued to do so despite extensive and blatant evidence of diversion at many facilities in Florida. AmerisourceBergen has been investigated and fined for some of its many failures to secure its supply chain, but continues to allow inappropriate and harmful distribution of opioids.

347. In 2007, the DEA issued an immediate suspension order against an AmerisourceBergen's distribution center in Orlando, Florida for failing to maintain effective controls against hydrocodone diversion. As part of the agreement to restore the Orlando facility's license to ship controlled substances, AmerisourceBergen publicly stated that it would implement an enhanced and more sophisticated order monitoring program nationwide.

348. In January 2017, AmerisourceBergen agreed to pay \$16 million to settle claims by the West Virginia Attorney General that AmerisourceBergen had shipped increasing amounts of opioids without sufficient anti-diversion procedures in place.

349. Despite representing publicly that it would secure its supply chain, AmerisourceBergen failed to take reasonable steps to prevent opioid diversion in Florida. AmerisourceBergen claims misleadingly, on its web site and in other public statements, that its “diversion control program” is a sophisticated diversion control program through which it provides daily reports to regulators about the quantity, type, and receiving pharmacy of every order of controlled substances it distributes and has an effective diversion control team and protocol. But the implication that AmerisourceBergen has effectively addressed diversion is false, as AmerisourceBergen’s repeated payments to settle diversion-related violations indicate.

350. AmerisourceBergen’s public statements misled the public and officials of the State of Florida to believe that AmerisourceBergen was taking effective steps to fight the opioid epidemic.

351. AmerisourceBergen also participated in inflating the demand for opioids. It broadly advertised its promotional services to the Manufacturer Defendants. If hired by a Manufacturer Defendant, AmerisourceBergen provided targeted communications to customers through a variety of marketing media to distinguish the Manufacturer Defendant’s product. AmerisourceBergen promoted at least three Manufacturer Defendants’ opioid products.

352. AmerisourceBergen’s Xcenda scientists continue to publish articles and materials promoting the use of opioids to treat chronic non-cancer pain and downplaying the risks of abuse.

353. The opioid crisis described herein is a direct and foreseeable result of AmerisourceBergen's actions. The State of Florida was damaged by AmerisourceBergen's actions.

354. AmerisourceBergen's deceptive, unfair, and unconscionable actions are continuing and continue to harm the State of Florida.

355. AmerisourceBergen's deceptive, unfair, and unconscionable actions and statements about opioids and about its efforts to comply with its duties under Florida law to prevent abuse and diversion were material, were false, were made with intent to deceive, were made with the intent that the recipient of the information or another party reasonably rely upon it, and were made to further a scheme to defraud consumers and prescribers in violation of § 817.034, Florida Statutes.

## **9. Cardinal**

356. Cardinal sold and shipped unreasonable quantities of opioids into Florida, including red-flag pharmacies in Florida, and continued to do so despite extensive and blatant evidence of diversion at many facilities in Florida. Cardinal has been investigated and fined for some of its many failures to secure its supply chain, but continues to allow inappropriate and harmful distribution of opioids.

357. Cardinal was on notice that its protocols were inadequate to prevent the diversion and abuse of the opioids within its care.

358. Between November 28 and December 7, 2007, the DEA issued "immediate suspension orders" against three Cardinal distribution centers – including Cardinal's Lakeland, Florida distribution center – because the DEA determined that the facilities' failure to maintain effective anti-diversion controls constituted an "imminent danger to public health or safety." On January 30, 2008, the DEA issued an order to show cause why a fourth Cardinal distribution

center should not have its license revoked. To resolve these administrative actions, Cardinal paid a \$34 million fine – at the time, the largest fine ever levied for anti-diversion violations – and publicly stated that it would maintain effective controls against the diversion of controlled substances.

359. Cardinal did not maintain effective controls. On October 26, 2011, the DEA executed an administrative search warrant at Cardinal’s Lakeland, Florida distribution center. The investigation uncovered that Cardinal’s Lakeland facility had shipped 50 times as much oxycodone to its top four pharmacy customers in Florida as it had to all other Florida pharmacies combined. Additionally, the DEA found that the Lakeland facility’s shipments exceeded Cardinal’s own internal volume thresholds, and that a Cardinal investigator had warned that Lakeland’s oxycodone shipments posed a high risk of diversion – but he had been ignored. The DEA issued its second immediate suspension order against Cardinal’s Lakeland facility on February 2, 2012.

360. Cardinal ultimately agreed to shut down its Lakeland distribution facility for two years. Cardinal later paid \$34 million in civil penalties to resolve the administrative action against its Lakeland facility (plus an additional \$10 million for allowing diversion in other parts of the country).

361. Cardinal agreed to pay \$20 million in January 2017 to settle claims by the West Virginia Attorney General that Cardinal had failed to use proper controls when shipping opioids.

362. Cardinal’s public representations created the appearance that Cardinal would secure its supply chain in Florida. These representations were false. Cardinal failed to take reasonable steps to prevent opioid diversion in Florida.

363. Cardinal touted its anti-diversion practices and purported anti-diversion monitoring programs, and publicly stated in settlements that it would take reasonable measures to prevent diversion. Cardinal states that its “sophisticated, state-of-the-art anti-diversion program includes advanced analytics, technology and on-the-ground deployment of investigators to evaluate pharmacies, scrutinize customers and orders, as well as identify, block and report orders of prescription controlled substances that do not meet our strict anti-diversion criteria.”

364. Cardinal’s public statements misled the public and officials of the State of Florida to believe that Cardinal was taking effective steps to fight the opioid epidemic.

365. Cardinal also marketed opioids and contributed to the improper inflation of demand. Cardinal’s promotional services offered to the Manufacturer Defendants included programs to train KOLs. Cardinal also offered to provide KOLs to deliver web-based conference programs promoting a drug manufacturer’s products. Further, Cardinal offered a proprietary database of providers to whom the Manufacturer Defendants could send email blasts and presentation material to promote its products. Cardinal provided these services to the Manufacturer Defendants to promote opioids sold by the Manufacturer Defendants.

366. Cardinal knew or had reason to know that the materials it distributed for Allergan were misleading.

367. The opioid crisis described herein is a direct and foreseeable result of Cardinal’s actions. The State of Florida was damaged by Cardinal’s actions.

368. Cardinal’s deceptive, unfair, and unconscionable actions are continuing and continue to harm the State of Florida.

369. Cardinal’s deceptive, unfair, and unconscionable actions and statements about opioids and about its efforts to comply with its duties under Florida law to prevent abuse and

diversion were material, were false, were made with intent to deceive, were made with the intent that the recipient of the information or another party reasonably rely upon it, and were made to further a scheme to defraud consumers and prescribers in violation of § 817.034, Florida Statutes.

## **10. McKesson**

370. McKesson sold and shipped unreasonable quantities of opioids into Florida, including many red-flag pharmacies in Florida, and continued to do so despite extensive and blatant evidence of diversion at many facilities in Florida. McKesson has been investigated and fined for some of its many failures to secure its supply chain, but continues to allow inappropriate and harmful distribution of opioids.

371. McKesson, one of the biggest companies in the United States, was aware of its failure to prevent diversion and abuse of opioids in Florida. On May 2, 2008, McKesson agreed to pay more than \$13 million in civil penalties for filling hundreds of suspicious opioid orders. More than half of the settlement amount was attributable to McKesson's Lakeland, Florida distribution center, which was accused of shipping 2.1 million suspicious hydrocodone dosages to Tampa-area pharmacies.

372. McKesson publicly misrepresented that it was complying with its duties under Florida law to stop abuse and diversion of opioids. McKesson publicly stated in the context of its 2008 settlement that it had taken steps, outlined in a Compliance Addendum, to ensure that lapses in diversion prevention would not occur again in distribution facilities like its Lakeland distribution center. McKesson publicly represented as part of the settlement that it would implement a program to detect and prevent diversion.

373. These public statements were false and misleading. McKesson did not implement a program that effectively identified and stopped diversion. In fact, the *Washington Post*

reported that subsequent DEA investigations uncovered that between 2008 and 2013, McKesson had failed to implement adequate anti-diversion protocols at 12 distribution centers, including its facility in Lakeland.

374. On January 5, 2017, McKesson agreed to pay a \$150 million civil penalty – the largest paid to date by a distributor – for its ongoing failure to identify suspicious orders from distribution centers (including Lakeland) or otherwise create an effective anti-diversion program. A DEA memorandum concluded that McKesson had “[i]gnored blatant diversion” (including by pharmacies served by McKesson that resold opioids to criminal drug rings), “[i]gnored [its] own procedures designed to prevent diversion,” evidenced a “[p]attern of raising thresholds arbitrarily,” and “[s]upplied controlled substances in support of criminal diversion activities.”

375. McKesson continues to make similar deceptive public statements about its anti-diversion activity. It claims to have “teams, processes and technologies dedicated to preventing diversion” and to be “committed to maintaining . . . strong programs designed to detect and prevent opioid diversion within the pharmaceutical supply chain.” Any such programs are inadequate to prevent egregious diversion and abuse.

376. McKesson’s public statements misled the public and officials of the State of Florida to believe that McKesson was taking effective steps to fight the opioid epidemic.

377. In addition to inflating the supply of opioids through illegal means, McKesson also worked to expand the demand for opioids by providing a range of marketing services. McKesson offered to provide behavioral coaching services and “behavioral call campaigns” for the Manufacturer Defendants. If a Manufacturer Defendant hired McKesson, then one of McKesson’s call center staff trained in behavioral coaching techniques would contact patients directly by telephone to ensure that patients took their medications. McKesson provided



behavioral coaching and behavioral call services to the Manufacturer Defendants for their opioid products.

378. As part of its promotional program, McKesson studied the impact of its coaching services on the length of time that patients take specific drugs. McKesson boasted that its coaching services caused patients to be 25% more adherent to their medications, which according to McKesson, translated to an additional 31 days of taking specific medications. McKesson's coaching services caused patients to take more of the Manufacturer Defendants' opioid products. Studies indicate that the longer a patient takes opioids, the greater the risk of addiction.

379. McKesson provided coaching services to Purdue.

380. McKesson has administered Purdue's prescription savings card program for OxyContin, Butrans, and Hysingla.

381. The opioid crisis described herein is a direct and foreseeable result of McKesson's actions. The State of Florida was damaged by McKesson's actions.

382. McKesson's deceptive, unfair, and unconscionable actions are continuing and continue to harm the State of Florida.

383. McKesson's deceptive, unfair, and unconscionable actions and statements about opioids and about its efforts to comply with its duties under Florida law to prevent abuse and diversion were material, were false, were made with intent to deceive, were made with the intent that the recipient of the information or another party reasonably rely upon it, and were made to further a scheme to defraud consumers and prescribers in violation of § 817.034, Florida Statutes.

## **11. Walgreens**

384. Walgreens sold and shipped unreasonable quantities of opioids into Florida,

including many red-flag pharmacies in Florida, and continued to do so despite extensive and blatant evidence of diversion at many facilities in Florida. Walgreens further dispensed unreasonable quantities of opioids from its own retail pharmacies in Florida despite being on notice of signs of diversion, in violation of its duties as a pharmacist under Florida law.

Walgreens has been investigated and fined for some of its many failures to secure its supply chain and its own pharmacy stores, including in Florida, but continues to allow inappropriate and harmful distribution of opioids.

385. Walgreens is one of the largest distributors of opioids in Florida, having shipped billions of dosages of opioids into Florida since 2006. Walgreens likewise dispensed billions of opioid dosages from its retail pharmacies in Florida. Walgreens has violated its obligations under Florida law as both a large-scale distributor and a large-scale pharmacy to prevent abuse.

386. Walgreens agreed to pay \$80 million to resolve a DEA investigation into inadequate recordkeeping and diversion related to opioids. The allegations focused on issues surrounding Walgreens' Florida operations, particularly its distribution center in Jupiter and six retail pharmacies in Florida, including one in Port Richey. According to the DEA, "Walgreens' Florida pharmacies each allegedly ordered more than one million dosage units of oxycodone in 2011 – more than ten times the average amount."

387. According to public news reports, in Pasco County, "a Walgreens drug distribution center sold 2.2 million tablets to a single Walgreens' pharmacy in tiny Hudson, a roughly six-month supply for each of its 12,000 residents." North of Jupiter, Florida, it shipped more than 1.1 million pills to each of two Fort Pierce Walgreens pharmacies."

388. In some cases, Walgreens increased orders as much as 600% in the space of just two years, including, for example, supplying a town of 3,000 with 285,800 orders of oxycodone

in a one-month period. The DEA noted that “[p]rescription drug abuse is a tremendous problem in Florida” and that Walgreens’ Florida distribution center had failed, systemically, to report suspicious orders from its Walgreens retail pharmacies across Florida. These retail Walgreens pharmacies, in turn, “filled customer prescriptions that they knew or should have known were not for legitimate medical use.”

389. In connection with the settlement of the DEA allegations, Walgreens publicly stated that it would maintain a compliance program to detect and monitor diversion, including training its pharmacists on red flags for diversion, but it has failed to implement a program to adequately do so.

390. Walgreens’ public statements misled the public and officials of the State of Florida to believe that Walgreens was taking effective steps to fight the opioid epidemic.

391. The opioid crisis described herein is a direct and foreseeable result of Walgreen’s actions. The State of Florida was damaged by Walgreen’s actions.

392. Walgreen’s deceptive, unfair, and unconscionable actions are continuing and continue to harm the State of Florida.

393. Walgreens’ deceptive, unfair, and unconscionable actions and statements about opioids and about its efforts to comply with its duties under Florida law to prevent abuse and diversion were material, were false, were made with intent to deceive, were made with the intent that the recipient of the information or another party reasonably rely upon it, and were made to further a scheme to defraud consumers and prescribers in violation of § 817.034, Florida Statutes.

## **12. CVS**

394. CVS sold and shipped unreasonable quantities of opioids into Florida, including to many red-flag pharmacies in Florida, and continued to do so despite extensive and blatant

evidence of diversion at many facilities in Florida. CVS also dispensed unreasonable quantities of opioids in Florida from its own retail pharmacies in Florida despite being on notice of signs of diversion, in violation of its duties as a pharmacist under Florida law. CVS has been investigated and fined for some of its many failures to secure its supply chain and its own pharmacy stores, but continues to allow inappropriate and harmful distribution of opioids.

395. CVS is one of the top ten distributors of opioids in Florida. It distributed more than 700 million dosages of opioids in Florida between 2006 and 2014. CVS also operates a vast network of Florida pharmacies, which dispense opioids. CVS stores in New Port Richey, Zephyrhills, and Hudson received and dispensed huge quantities of opioids during the same period. CVS violated its obligations under Florida law as both a large-scale distributor and a chain pharmacy to prevent abuse.

396. In 2015, CVS agreed to pay \$22 million to resolve DEA allegations that retail stores in Sanford, Florida distributed controlled substances including opioids based on prescriptions that had not been issued for legitimate medical purposes. The DEA described the settlement as part of a “crackdown on pill mills in Florida,” in which “[p]rescription drug addicts were travelling to Florida for access to physicians who were prescribing pain medication without regard to medical need and to pharmacies that were filling the prescriptions despite red flags that they were illegitimate.”

397. CVS has settled numerous other opioid-related investigations. In 2016, CVS agreed to pay \$3.5 million to settle allegations that its pharmacists were filling fake prescriptions for addictive painkillers in CVS’s stores in Massachusetts and New Hampshire. The same year, CVS agreed to pay \$8 million to settle allegations that its Maryland pharmacies had dispensed controlled substances for prescriptions that did not serve a legitimate medical purpose. In 2017,

CVS agreed to pay \$5 million to settle allegations that it had failed to maintain adequate records regarding controlled substances at its stores in California. And as recently as June 2018, CVS agreed to pay \$1.5 million to resolve allegations that it had failed to timely report loss or theft of substances including the opioid hydrocodone.

398. CVS was aware of its obligations under Florida law to serve as a safeguard against abuse. In 2015, CVS publicly stated that, “the abuse of controlled substance pain medication is a nationwide epidemic that is exacting a devastating toll upon individuals, families and communities. Pharmacists have a legal obligation under state and federal law to determine whether a controlled substance was issued for a legitimate purpose and to decline to fill prescriptions they have reason to believe were issued for a non-legitimate purpose.” However, the implication that CVS was actually complying with its obligations under Florida law was false, and CVS continued to pay fines to resolve numerous diversion-related violations in the ensuing years.

399. Notwithstanding these repeated investigations into its failure to prevent diversion, CVS claims, misleadingly, that its “utilization management program” “ensure[s] that opioids are being prescribed and used appropriately.”

400. CVS’s public statements misled the public and officials of the State of Florida to believe that CVS was taking effective steps to fight the opioid epidemic.

401. The opioid crisis described herein is a direct and foreseeable result of CVS’s actions. The State of Florida was damaged by CVS’s actions.

402. CVS’s deceptive, unfair, and unconscionable actions are continuing and continue to harm the State of Florida.

403. CVS's deceptive, unfair, and unconscionable actions and statements about opioids and about its efforts to comply with its duties under Florida law to prevent abuse and diversion were material, were false, were made with intent to deceive, were made with the intent that the recipient of the information or another party reasonably rely upon it, and were made to further a scheme to defraud consumers and prescribers in violation of § 817.034, Florida Statutes.

**D. The Applicable Statutes of Limitation Are Tolled Because of the Defendants' Deceptive Concealment and Public Misrepresentations**

404. The State of Florida's claims against Defendants are subject to the doctrines of equitable estoppel and equitable tolling. Defendants have knowingly and deceptively concealed the facts supporting the allegations alleged in this Amended Complaint. The State of Florida has been unable to access information sufficient to discover and properly bring claims against Defendants.

405. Consequently, Defendants may not raise statute of limitations defenses. Defendants purposefully concealed their conduct.

406. Among other actions, Defendants made public misrepresentations suggesting that they were taking adequate efforts to comply with their obligations to monitor, report, and prevent suspicious orders, including under Florida Drug and Cosmetic Act, Fla. Stat. §§ 499.001 *et seq.* ("FDCA"), including representations that they were implementing suspicious order monitoring programs in governmental settlements. Thus, any applicable statutes of limitation are tolled. The State did not know, and could not have known, many key facts relevant to bringing this action until shortly before initiating this action.

407. Defendants' misrepresentations led the public, and the State, to believe that Defendants were working to fight the opioid epidemic.

408. Furthermore, through their participation in trade organizations, the HDMA and the NACDS, the Distributor Defendants made the following statements in an amicus brief in *Masters Pharmaceuticals*,<sup>9</sup> which state the Distributor Defendants were acting in accordance with applicable law:

- a. HDMA and NACDS members not only have statutory and regulatory responsibilities to guard against diversion of controlled prescription drugs, but undertake such efforts as responsible members of society.
- b. Distributors take seriously their duty to report suspicious orders, utilizing both computer algorithms and human review to detect suspicious orders based on the generalized information that is available to them in the ordering process.
- c. A particular order or series of orders can raise red flags because of its unusual size, frequency, or departure from typical patterns with a given pharmacy.
- d. Distributors also monitor for and report abnormal behavior by pharmacies placing orders, such as refusing to provide business contact information or insisting on paying in cash.

409. The above statements imply that the Distributor Defendants took responsibility for and acted in complete accordance with Florida law with respect to distributing controlled substances. The Distributor Defendants have demonstrated actual or constructive knowledge that these statements were made to mislead the public that the Distributor Defendants were not in dereliction of their duties.

410. The State of Florida reasonably relied on the Distributor Defendants' statements regarding their supposed compliance with Florida law.

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<sup>9</sup> *Masters Pharm., Inc. v. U.S. Drug Enf't Admin.*, No. 15-1335, 2016 WL 1321983 (D.C. Cir. filed Apr. 4, 2016).

411. Among other actions, the Manufacturer Defendants employed KOLs and funded front organizations to promote falsely the health benefits of opioids and conceal the reality of the harmfulness and highly addictive nature of the opioids the Manufacturer Defendants promoted, advertised, and sold in Florida.

412. Florida otherwise reasonably relied on Defendants' statements that they had acted in full accordance with Florida law.

413. Defendants cannot claim prejudice from the tolling of the State of Florida's claims. The State of Florida filed suit promptly upon discovering facts sufficient to show a cause of action. Defendants knowingly concealed these same facts.

414. Florida's claims were equitably tolled until Florida discovered Defendants' conduct. Defendants are estopped from asserting a statute of limitations defense because they took affirmative steps to deceptively conceal their own conduct.

**E. Defendants' Conduct Has Injured the State of Florida and Its Citizens**

415. Each Defendant's actions dramatically increased inappropriate opioid prescribing and use nationwide and in Florida and injured the State of Florida and its citizens. Each Defendant's actions also caused the illegal diversion of opioids in Florida (and fueled an illegal market for opioids). The failure to prevent suspicious orders caused those orders to reach opioid users, who suffered or died as a result, and imposed significant costs on the State of Florida.

416. Defendants' misrepresentations about the safety of opioids convinced prescribers to prescribe opioids to patients for whom opioids would never previously have been considered. According to an article published in the *American Journal of Public Health*, "it is well documented" pharmaceutical companies' marketing efforts and educational programs targeting providers "influences physicians' prescribing." Another recent study showed that doctors who



had just one meal paid for by an opioid manufacturer were more likely to prescribe opioids than other prescribers.

417. Each Manufacturer Defendant promoted its own branded and generic products, and also, individually and jointly, including through front organizations, promoted unfounded and mutually reinforcing misrepresentations about the safety and efficacy of opioids in general. The Distributor Defendants promoted opioids directly, and promoted unfounded representations about opioids through studies and through their trade organization. These misrepresentations collectively caused the dramatic increase in branded and generic opioid prescribing and use. At the same time, the Distributor Defendants greatly increased the supply of opioids beyond safe levels through a deliberate campaign to ignore their obligations to prevent diversion.

418. As a result of Defendants' actions to inflate the demand for and supply of opioids, between 1999 and 2014, sales of opioids nearly quadrupled, according to the CDC. Nearly 259 million opioid prescriptions were written in the United States in 2012 alone. This equates to more than one opioid prescription for every American adult. At the same time, diagnoses of opioid addiction increased nearly 500% from 2010 to 2016. Many tens of thousands of Floridians are currently addicted to opioids. Defendants' relentless campaign of deceptive, unfair, and unconscionable marketing, along with their concerted effort to overcome every safeguard intended to prevent abuse and diversion, caused this spike in opioid usage rates – and opioid abuse rates – in Florida and in the United States.

419. Opioid users frequently turn to other opioids when they are suffering the symptoms of withdrawal, because opioids work the same way and have many similar properties and effects on those who are addicted. For example, a person who becomes addicted to an opioid prescribed by a doctor may turn to whatever opioids he or she can buy on the street if the

doctor refuses to provide the opioids he or she craves. If the user cannot afford black market prescription opioids, he or she may turn to heroin. According to the National Survey on Drug Use and Health, four out of five current heroin users report that their drug use began with an opioid pain reliever.

420. There were nearly 13,000 deaths due to heroin overdoses in the United States in 2015, and 779 of those occurred in Florida. Pasco County has experienced an uptick in heroin-related deaths, and other counties in Florida have also experienced heroin-related deaths. Florida has expended and continues to expend significant resources dealing with these overdoses and their effects on the drug user's family and community.

421. Florida has also expended and continues to expend significant resources dealing with prescription opioid overdoses.

422. Deaths from opioid overdoses do not fully capture the breadth of the harms suffered by Florida and its citizens. For example, opioid use results in thousands of hospitalizations and emergency room visits. In 2014, there were 21,700 opioid-related emergency department visits. In Miami-Dade County alone, there were 128 hospital admissions for opioid poisoning in 2015. The State of Florida often bears the cost of treatment.

423. Another result of Defendants' actions is the upsurge of the sober home crisis in Florida. The opioid epidemic has created a market of thousands of people with opioid dependence. Instead of helping those with addiction problems recover, many sober homes have become hotbeds of opioid distribution and have distorted the character of once-peaceful neighborhoods.

424. The opioid crisis has affected some of Florida's most vulnerable demographics, such as the elderly. The AARP reports that elderly Americans have faced a 500% increase in

hospitalization rates related to opioids over the last 20 years. In 2015, “physicians prescribed opioid painkillers to almost one third of all Medicare patients, or nearly 12 million people. In the same year, 2.7 million Americans over age 50 took painkillers in amounts – or for reasons – beyond what their physicians prescribed.”

425. Defendants’ actions alleged in this Amended Complaint have caused numerous societal injuries to the State of Florida. Defendants’ conduct has contributed to deaths, drug addiction, personal injuries, child neglect, children placed in foster care, babies born addicted to opioids, crime, poverty, property damage, unemployment, and lost productivity, among others. The State of Florida is expending extraordinary resources to address these and other social problems resulting from the opioid crisis and will continue to expend resources addressing these problems.

426. Defendants’ actions alleged in this Amended Complaint have caused numerous economic injuries to the State of Florida. Defendants’ conduct has caused economic losses for medical treatment, rehabilitation costs, hospital stays, emergency room visits, emergency personnel costs, law enforcement costs, substance abuse prevention costs, costs for displaced children, naloxone costs, medical examiner expenses, and lost tax revenues, among others.

427. The State of Florida was also harmed by its expenditures for deceptively marketed opioids that did not deliver on Defendants’ claims of effective pain relief with a low risk of addiction. Florida paid for opioids under state programs such as worker’s compensation, self-funded state insurance, and others.

428. The societal and economic injuries incurred by the State of Florida were foreseeable by Defendants.

429. Defendants' conduct was the proximate cause of the harm suffered by the State of Florida.

**COUNT I**  
**Violation of the Florida Deceptive and Unfair Trade Practices Act**  
**(All Defendants)**

430. This is an action against all Defendants for violation of the FDUTPA, Fla. Stat. §§ 501.201 *et seq.*

431. Plaintiff State of Florida adopts, realleges, and incorporates by reference paragraphs 1 through 429 above as if fully set forth herein.

432. Defendants' acts or practices alleged herein are unfair, deceptive, and/or unconscionable in violation of FDUTPA.

433. Defendants' sale, promotion, marketing, advertising, distribution, and manufacturing of opioid products in the State of Florida involves trade or commerce within the meaning of FDUTPA.

434. Defendants sold, promoted, marketed, distributed, and advertised opioid products to the State of Florida and its governmental entities, businesses, and consumers within Florida.

435. Defendants' falsehoods, misrepresentations, and omissions of material facts, as detailed above, constitute deceptive, unfair, and unconscionable acts or practices that are prohibited by FDUTPA. These acts or practices offend established public policy and are immoral, unethical, oppressive, unscrupulous, or substantially injurious to Florida governmental entities, businesses, and consumers.

436. Defendants' actions in distributing opioids, as detailed above, constitute unfair, unconscionable, and/or deceptive acts or practices that are prohibited by FDUTPA. These acts or practices offend established public policy and are immoral, unethical, oppressive,

unscrupulous, or substantially injurious to Florida governmental entities, businesses, and consumers.

437. Defendants' unfair, deceptive, and unconscionable acts or practices, or the effects thereof, are continuing, will continue, and are likely to recur unless permanently restrained and enjoined.

438. Further, a FDUTPA violation also occurs when a Defendant violates "any law, statute, rule, regulation, or ordinance which proscribes unfair methods of competition, or unfair, deceptive, or unconscionable acts or practices."

439. The FDCA, Chapter 499, Florida Statutes, regulates the trade practices of wholesale drug distributors. Chapter 465, Florida Statutes, regulates the trade practices of dispensing pharmacies.

440. The FDCA requires each Defendant registered as a distributor to "take reasonable measures to identify its customers, understand the normal and expected transactions conducted by those customers, and identify those transactions that are suspicious in nature" and to "establish internal policies and procedures for identifying suspicious orders and preventing suspicious transactions." Fla. Stat. § 499.0121(15)(b). Chapter 465 imposes similar requirements on dispensing pharmacies. Defendants violated these statutory provisions over a period of at least the past decade while thousands of Florida consumers became addicted to opioids and died. These violations are unfair and unconscionable acts or practices, and offend established public policy and are immoral, unethical, oppressive, unscrupulous, or substantially injurious to Florida governmental entities, businesses, and consumers.

441. The Distributor Defendants and national retail chain pharmacy Defendants continued to fill suspicious orders of opioids by their customers in Florida. This also constitutes

a violation of Chapters 499 and 465, Florida Statutes, and is an unconscionable and/or unfair act or practice. This conduct offends established public policy and is immoral, unethical, oppressive, unscrupulous, or substantially injurious to Florida governmental entities, businesses, and consumers.

442. Defendants' acts caused damage to Florida when Florida purchased deceptively marketed opioids and incurred the many other costs alleged herein.

443. Consequently, the State of Florida seeks all available relief under FDUTPA, including but not limited to damages, disgorgement, restitution, civil penalties, equitable relief, injunctive relief, and attorneys' fees and costs.

**COUNT II**  
**Violation of the Florida Racketeer Influenced and Corrupt Organization Act**  
**(All Defendants)**

444. This is an action against all Defendants for violation of the Florida RICO.

445. Plaintiff State of Florida adopts, realleges, and incorporates by reference paragraphs 1 through 429 above as if fully set forth herein.

446. This is a claim brought by the State of Florida by and through its Department of Legal Affairs against all Defendants for treble damages, forfeiture, equitable relief, penalties, and attorneys' fees and costs under Chapter 895, Florida Statutes.

447. The Department of Legal Affairs is an investigative agency under § 895.02(6), Florida Statutes.

448. The Department of Legal Affairs is authorized to institute a civil action under § 895.05(5), Florida Statutes.

449. Defendants' acts and practices as described above constitute violations of § 895.03(3), Florida Statutes. Defendants are associated with an enterprise (the "Enterprise")

and conducted or participated, directly or indirectly, in such Enterprise through a pattern of racketeering activity. Further, Defendants' acts and practices described above constitute a violation of § 895.03(4), Florida Statutes, because Defendants conspired or endeavored to violate § 895.03(3), Florida Statutes.

450. The Enterprise consists of the Manufacturer Defendants, the front organizations they supported, the Distributor Defendants, the HDA, and the KOLs supported by the Manufacturer Defendants. The Enterprise is ongoing and continuing and has the purpose of ensuring the continuing and improper over-prescription and flow of opioids to Florida residents, by, on one hand, engaging in a campaign of false and misleading marketing to inflate the demand for opioids far beyond their limited safe uses, and by, on the other hand, deliberately turning a blind eye to the diversion of opioids and unlawfully bombarding Florida with an outsized and unreasonably large supply of opioids. The common purpose of the Enterprise as a whole, shared by all Defendants, is to increase greatly the amount of opioids sold in Florida to maximize Defendants' profits by driving up both the demand and the supply, with foreseeable harmful results, using improper means. The Enterprise was ongoing and functions as a continuing unit.

451. The Manufacturer Defendants, front organizations, and KOLs participated in the Enterprise by sharing a common purpose of marketing opioids for chronic pain through numerous violations of the Florida Communications Fraud Act, Fla. Stat. § 817.034. They knowingly made false and misleading statements or knowingly omitted material statements to Florida physicians, other prescribers, consumers, the State of Florida, and the general public in furtherance of the deceptive scheme. They misled these entities by promoting opioids for use in addressing long-term, chronic pain, by promoting certain opioids for use outside of the limited

contexts in which they are safe, and by downplaying and omitting the risks of opioids and misleading these entities into believing these risks could be managed simply.

452. The Manufacturer Defendants participated in the Enterprise through a pattern of racketeering activity. The Manufacturers performed thousands of acts in violation of § 817.034, Florida Statutes. The last act was conducted within five years, and at least one other act was conducted within the last ten years preceding the filing of this Amended Complaint. The Manufacturer Defendants willfully and intentionally disseminated misleading and false statements and willfully and intentionally omitted material statements to Florida physicians, other Florida prescribers, Florida consumers, the State of Florida, and the general public. The Manufacturer Defendants did so individually and through front organizations and KOLs, among other means. Florida physicians, other prescribers, consumers, the State of Florida, and the general public reasonably relied on these representations or omissions of material facts. Acts violating Chapter 817, Florida Statutes, are predicate acts under § 895.02, Florida Statutes.

453. By jointly supporting the same front organizations, providing them with false information regarding the prescribing and use of opioids, and paying or otherwise causing them to develop and disseminate a coordinated campaign of misrepresentations to promote opioids in general (both branded and generic), the Manufacturer Defendants conspired or jointly endeavored to violate § 895.03(3), Florida Statutes, in violation of § 893.03(4), Florida Statutes, with front organizations and KOLs.

454. The Distributor Defendants willfully and knowingly joined this aspect of the conspiracy by agreeing with Manufacturer Defendants to market their branded and generic opioids, and by marketing those opioids, in return for payments from the Manufacturer Defendants. The Manufacturer Defendants and Distributor Defendants came to a mutual



understanding to try to accomplish a common and unlawful plan to engage in a pattern of racketeering activity as described in this Amended Complaint as did the front organizations and the KOLs.

455. The Distributor Defendants also participated in the Enterprise by sharing a common purpose with all Defendants of over-supplying Florida with prescription opioids through numerous violations of § 817.034, Florida Statutes. The Distributor Defendants, individually and through their trade organization the HDA, knowingly made false statements to regulators and the public indicating that they were fulfilling their duties to act as independent watchdogs guarding against suspicious orders of opioids and against diversion of opioids in the supply chain when, in reality, the Distributor Defendants deliberately turned a blind eye to signs of diversion and suspicious orders in Florida and to failures by their customers, the pharmacies, to safeguard adequately against diversion. They did this by refusing to stop supplying red-flag pharmacies, by approving unreasonable threshold increases for opioids despite the presence of what should have been alarm bells, by increasing the amounts of opioids flowing to pharmacies through threshold increases, and by telling the public and regulators that they had fixed the egregious lapses for which they were disciplined, all while continuing to funnel extraordinary quantities of opioids into the State of Florida to meet the inflated demand created by the false marketing that the Distributors helped the Manufacturers to conduct.

456. The Distributor Defendants deliberately failed and refused to report suspicious ordering behavior and other pharmacy red flags. Walgreens and CVS further refused to take reasonable measures to stop their retail stores from dispensing unreasonable amounts of opioids and filling suspicious prescriptions, even while telling the public they were complying with their duties as dispensing pharmacies to prevent diversion. They did so in order to further the shared

goal of selling as many opioids as possible and ensuring that the growing demand for opioids – which the same Distributors had a hand in creating – would be met by skyrocketing supply and an unimpeded flow of drugs into even the most suspicious pharmacies.

457. The Distributor Defendants participated in the Enterprise by engaging in a pattern of racketeering by making numerous false representations, including that they were instituting and maintaining effective anti-diversion programs, and that they were complying with their obligations to stop and report suspicious orders. The Distributor Defendants repeatedly misled the public and regulators, including the State of Florida and Florida consumers, by making numerous misrepresentations, in violation of § 817.034, Florida Statutes, that they were fulfilling the obligations imposed on them by Florida law to monitor and stop abuse and diversion of opioids. Defendants misrepresented that they were complying with their duties as licensed distributors in the State of Florida. The last act was conducted within five years, and at least one other act was conducted within the last ten years preceding the filing of this Amended Complaint. The Distributor Defendants exerted control over and directed this aspect of the Enterprise by claiming, individually and through their trade organization, that they were complying with their duties to identify and stop suspicious orders of opioids, while at the same time subverting these duties by distributing large amounts of opioids in Florida and ignoring signs of abuse and diversion.

458. The Manufacturer Defendants and the Distributor Defendants each led a crucial aspect of the overall Enterprise, whose goal was to sell unreasonable amounts of opioids through unlawful means. The false marketing led primarily by the Manufacturers, with the participation of the KOLs, the front organizations, and the Distributors, sought to, and did, cause a sustained spike in demand for opioids in Florida by creating the misimpression that opioids were a safe and

appropriate treatment for chronic pain (and that certain other opioids were appropriately taken for pain outside a limited cancer context). In response to and in conjunction with this increased demand, the Distributor Defendants led a campaign to relentlessly increase the supply of opioids into the State by ignoring all red flags, knocking down safeguards, and giving the false impression that they were complying with their state common law and statutory duties to serve as a line of defense against abuse and diversion of the opioid supply, when in fact they were knowingly violating these duties.

459. Without the misrepresentations made by all Defendants under the leadership of the Manufacturer Defendants, the Distributor Defendants would not have been able to supply the increasing numbers of orders of prescription opioids for non-medical purposes throughout Florida. Without the efforts led by the Distributor Defendants to subvert anti-diversion safeguards, increase thresholds for opioids at pharmacies with indicators of diversion, ship unreasonable quantities, and mislead the public and regulators about compliance efforts, the Manufacturer Defendants would not have been able to profit so significantly on the inflated demand they worked so hard to generate. Without the refusal of the national chain retail pharmacy Distributor Defendants to act as the final safeguards preventing suspicious prescriptions from being filled, they, the Manufacturer Defendants, and the other Distributor Defendants would not have profited so greatly from the total breakdown of controls on the supply chain.

460. As a result of the concerted action between and among the Manufacturer and Distributor Defendants, with the shared purpose of selling amounts of opioids in Florida vastly exceeding the medically appropriate amounts through a pattern of violations of § 817.034,

Florida Statutes, Florida statutory and common law was violated on a regular basis and in an ongoing way.

461. The impact of Defendants' deceptive scheme to market opioids falsely in Florida and to meet the resulting increased demand by ignoring diversion and shipping unreasonable quantities while suggesting that they were guarding against those very practices is still in place as opioids are still being prescribed and consumed for improper uses. The opioid epidemic continues to devastate Florida's health care and law enforcement systems.

462. Upon information and belief, all Defendants, in the course of participating in the Enterprise through a pattern of violations of § 817.034, Florida Statutes, utilized property, both real and personal, both tangible and intangible, including money, that was used in the course of, intended for use in the course of, derived from, or realized through conduct in violation of §§ 895.01-895.05, Florida Statutes, while conducting business in Florida. That property is subject to civil forfeiture to the State of Florida. A more particular description of the property to be forfeited is unavailable to the State of Florida at this time.

463. The State of Florida and its agencies and instrumentalities have suffered damages from and as a direct result of Defendants' violations of the Florida RICO. Accordingly, the State of Florida seeks damages from Defendants, including treble damages as allowed by law.

**COUNT III**  
**Public Nuisance**  
**(All Defendants)**

464. This is an action against all Defendants under Florida common law for damages and abatement of the ongoing public nuisance created by Defendants.

465. Plaintiff adopts, realleges, and incorporates by reference paragraphs 1 through 429 above as if fully set forth herein.

466. The State of Florida alleges violations of Florida common law and §§ 823.01 *et seq.*, Florida Statutes, and, acting on its own behalf and on behalf of its residents, seeks monetary relief and abatement of the ongoing public nuisance created by Defendants.

467. A public nuisance is defined as any annoyance to the community or harm to public health.

468. Defendants have created an opioid epidemic – which constitutes a public nuisance – that has caused enormous public harm in Florida and continues to jeopardize the health and safety of Florida residents.

469. The public nuisance created by Defendants’ conduct violates rights common to the Florida public; subverts public order, decency or morals; and causes inconvenience or damage to the public in general. Defendants’ conduct has harmed public health in Florida and is an annoyance to Florida communities.

470. Throughout the State of Florida, Defendants’ conduct has affected, and continues to affect, communities and a considerable number of people. Defendants have caused widespread opioid abuse, addiction, overdoses, injury, crime, and mortality in Florida.

471. Defendants’ conduct has injuriously affected public rights, including the right to public health, safety, peace, comfort, and convenience, in communities throughout Florida.

472. The public nuisance created by Defendants has imposed severe economic costs on the State of Florida, its residents, and its communities. The State of Florida, acting on its own behalf and on behalf of its residents, therefore seeks monetary relief from Defendants.

473. Each Defendant created or assisted in the creation of the epidemic of opioid use and injury, and each Defendant is jointly and severally liable for abating it. Left unabated, the opioid epidemic will continue to threaten the health and safety of Florida residents. The State of

Florida, acting on its own behalf and on behalf of its residents, therefore seeks monetary and injunctive relief to abate the public nuisance and halt the threat of future harm.

**COUNT IV**  
**Negligence**  
**(All Defendants)**

474. This is an action against Defendants under Florida common law for negligence.

475. Plaintiff State of Florida adopts, realleges, and incorporates by reference paragraphs 1 through 429 above as if fully set forth herein.

476. The Office of the Attorney General is entitled to bring claims at common law as the public interest requires and retains wide discretion in making the determination as to the public interest.

477. Each Defendant had duties to exercise appropriate care when marketing, selling, distributing, and/or dispensing opioid drugs in Florida, including to take reasonable precautions to identify, monitor, detect, investigate, report, and refuse to sell, fill, or dispense suspicious orders and prescriptions of opioids. Reasonable and responsible drug manufacturers, distributors, and pharmacies would have anticipated that misleading marketing and excessive diversion of opioids, over a period of years, would lead to devastation across Florida communities and inflict serious harm on the State. But Defendants pocketed millions of dollars in profit from selling and distributing opioids in Florida, while ignoring their duties to protect against diversion and the resulting harm to the State.

478. Defendants' duties were assumed voluntarily, as a condition for the privilege of selling, distributing, and in the case of Walgreens and CVS dispensing, controlled substances in Florida.

479. Further, Defendants were warned repeatedly by governmental agencies and publicly available sources that diversion was occurring and that the opioids supply chain fell beneath the applicable duty of reasonable care.

480. The sheer volume of opioids sold, distributed, and dispensed in Florida has been, by itself, sufficient to alert Defendants that opioids were necessarily being diverted into unlawful channels.

481. Defendants breached their duties to maintain effective controls against diversion of opioids, and the foreseeable result is that widespread diversion occurred.

482. Defendants' breach of duty is the proximate cause and a substantial factor contributing to the damages suffered by the State of Florida and its citizens alleged in this Amended Complaint, including but not limited to medical costs, unemployment costs, drug treatment costs, emergency personnel costs, law enforcement costs, naloxone costs, medical examiner costs, foster care expenses, lost productivity, and lost tax revenues.

483. The harms to the State of Florida and its citizens were foreseeable in light of the Defendants' breach of their duties.

484. The State of Florida seeks damages resulting from Defendants' negligence.

**COUNT V**  
**Negligence *Per Se***  
**(All Defendants except Insys)**

485. This is an action against all Defendants except Insys under Florida common law for negligence *per se*.

486. Plaintiff State of Florida adopts, realleges, and incorporates by reference paragraphs 1 through 429 above as if fully set forth herein.

487. The Office of the Attorney General is entitled to bring claims at common law as the public interest requires and retains wide discretion in making the determination as to the public interest.

488. In addition to failing to abide by their general common-law duties, Defendants also violated statutory duties embodied in the FDCA, Fla. Stat. §§ 499.001 *et seq.* The Florida legislature has stated that careful distribution of controlled substances is “necessary to protect the public health, safety and welfare.” *Id.* § 499.0121. The FDCA was passed with the intention of protecting consumers by “[s]afeguard[ing] the public health and promote the public welfare by protecting the public from injury.” *Id.* § 499.002(1)(a). As a consumer protection and public safety statute, the class of people the FDCA seeks to protect includes the public and those entities which serve the public, including the State of Florida.

489. The FDCA is intended to prevent harms of the kind caused by Defendants’ violations, and their failure to abide by these laws proximately caused, and was a substantial factor contributing to, the State’s injuries.

490. Defendants Walgreens and CVS further violated statutory duties embodied in the Florida Pharmacy Act, Chapter 465, Florida Statutes, regulating Florida pharmacists. *See Fla. Stat. §§ 465.001 et seq.* The Florida Legislature determined that every pharmacy in the State “meet minimum requirements for safe practice” in order to protect against “danger to the public.” *Id.* § 465.002. As a statute aimed at protecting consumers and the safety of the public in Florida, the class of people the Florida Pharmacy Act seeks to protect includes the public and the entities that serve the public, including the State of Florida.



491. The Florida Pharmacy Act is intended to prevent harms of the kind caused by Defendants Walgreens and CVS's violations, and their failure to abide by these laws proximately caused, and was a substantial factor contributing to, the State's injuries.

492. The injuries suffered by the State of Florida and its citizens, including but not limited to medical costs, unemployment costs, drug treatment costs, emergency personnel costs, law enforcement costs, naloxone costs, medical examiner costs, foster care expenses, lost productivity, and lost tax revenues, are the type of injuries the FDCA and Florida Pharmacy Act were designed to prevent.

493. Defendants' repeated violations of the FDCA and Florida Pharmacy Act described above constitute negligence *per se*.

494. The State of Florida seeks damages resulting from the Defendants' negligence *per se*.

**COUNT VI**  
**Gross Negligence**  
**(All Defendants)**

495. This is an action against Defendants under Florida common law for gross negligence.

496. Plaintiff State of Florida adopts, realleges, and incorporates by reference paragraphs 1 through 429 above as if fully set forth herein.

497. The Office of the Attorney General is entitled to bring claims at common law as the public interest requires and retains wide discretion in making the determination as to the public interest.

498. Defendants owed the State a duty to exercise reasonable care in the marketing, manufacture, sale, distribution, and dispensing of opioids.

499. Defendants owed a heightened duty of care to the State because of the great danger of addiction, death, and related harms resulting from their marketing, manufacture, sale, distribution, and dispensing of opioids.

500. Defendants were aware (or should have been aware) of the great danger posed by opioid use and diversion. Yet, in pursuit of profit, they continued to act as alleged herein, in reckless disregard of the injuries inflicted on the State of Florida and its citizens. For example, Defendants failed to take reasonable precautions to identify, monitor, detect, investigate, report, and refuse to sell, fill, or dispense suspicious orders and prescriptions of opioids, despite their awareness (or circumstances that should have made them aware) of the high risk of diversion.

501. Defendants' conduct alleged herein imposed an exceptional risk of injury and constituted a clear and present danger of harm to the State of Florida and its citizens. Defendants' conduct alleged herein was so reckless or wanting in care that it constituted a conscious disregard or indifference to the life, safety, or rights of those exposed to Defendants' conduct in Florida.

502. Defendants' marketing, manufacture, sale, distribution, and dispensing of opioids displayed a conscious disregard for the consequences of their acts and omissions, including widespread addiction and death, as well as related costs incurred by the State.

503. Defendants' breach of their duties constituted a proximate cause and a substantial factor contributing to the damages suffered by the State of Florida and its citizens as alleged in this Amended Complaint.

504. The harms suffered by the State of Florida, including but not limited to increased medical costs, unemployment costs, drug treatment costs, emergency personnel costs, law enforcement costs, naloxone costs, medical examiner costs, foster care expenses, lost

productivity, and lost tax revenues, were foreseeable in light of Defendants' breach of their duties.

505. The State of Florida seeks damages resulting from Defendants' gross negligence and reserves the right to seek punitive damages.

**COUNT VII**  
**Civil Conspiracy**  
**(All Defendants)**

506. This is an action against all Defendants under Florida common law for civil conspiracy.

507. Plaintiff adopts, realleges, and incorporates by reference paragraphs 1 through 429 above as if fully set forth herein.

508. Defendants engaged in a civil conspiracy to create a public nuisance in conjunction with their unlawful marketing, sale, distribution, and diversion of opioids into Florida.

509. The Manufacturer and Distributor Defendants purposefully failed to act to prevent diversion and failed to monitor for, report, and prevent suspicious orders of opioids.

510. Defendants acted tortiously in concert with each other and in pursuit of a common design – the sale and distribution of far more opioids within Florida than were medically justified – and Defendants knew each other's conduct constituted a breach of their legal duties. Each Defendant provided substantial assistance and encouragement in the tortious conduct designed to increase opioid sales within Florida.

511. Defendants' conspiracy is continuing, and the overt acts performed in compliance with the conspiracy's objectives are ongoing and have occurred within the last year.

512. Defendants' conspiracy and acts in furtherance thereof include the Florida RICO

allegations set forth in Count II above.

513. Defendants acted with a common understanding or design to commit unlawful acts, as alleged herein, and acted purposely, without a reasonable or lawful excuse, to create the injuries alleged herein.

514. Defendants acted with malice, purposely, intentionally, unlawfully and without a reasonable or lawful excuse.

515. Defendants' conspiracy and Defendants' actions and omissions in furtherance thereof proximately caused and/or substantially contributed to the direct and foreseeable losses alleged herein.

**Prayer for Relief**

WHEREFORE, Plaintiff State of Florida prays for the following relief:

- a. The acts described herein be adjudged unlawful under statutory and common law;
- b. Defendants be enjoined from, either directly or indirectly through third parties, continuing to misrepresent or omit the relative risks and benefits of opioids;
- c. Distributor Defendants be enjoined from failing to implement effective anti-diversion procedures;
- d. Plaintiff recover all measure of damages allowable under statutory and common law, including treble damages;
- e. Plaintiff recover restitution on behalf of Florida agencies and consumers;
- f. Defendants disgorge their ill-gotten proceeds;
- g. Defendants divest themselves of any interest in any enterprise, including real property under Florida RICO;

- h. Defendants forfeit any property used in the course of, intended for use in the course of, derived from, or realized through conduct in violation of Florida RICO;
- i. Reasonable restrictions be imposed upon the future activities or investments of any Defendant under Florida RICO;
- j. The enterprise be dissolved under Florida RICO;
- k. An order be issued suspending or revoking any license, permit, or prior approval granted to the enterprise by any agency of the State under Florida RICO;
- l. Plaintiff be awarded civil penalties against Defendants under the FDUTPA and Florida RICO;
- m. Plaintiff recover its attorneys' fees, costs of investigation, and other costs as provided by law;
- n. An order abating the public nuisance and ordering any injunctive relief that the Court finds appropriate under law; and
- o. An order ordering such other and further relief as the Court deems appropriate.

#### **Jury Trial Demand**

Plaintiff hereby demands a trial by jury on all issues so triable.

Respectfully submitted, this 16 day of November 2018.

**PAMELA JO BONDI**  
**Attorney General**

*/s/ Gregory S. Slemp*

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**CERTIFICATE OF SERVICE**

I HEREBY CERTIFY that on November 16, 2018, a true and correct copy of the foregoing was filed with the Clerk of Court using the Florida Courts e-Filing Portal, which will send a notice of electronic filing to all registered to receive such notifications and that copies were served via email to the following counsel of record on the service list.

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