IN THE SUPERIOR COURT
OF GWINNETT COUNTY, GEORGIA

STATE OF GEORGIA,	
Plaintiff,	
v.	
PURDUE PHARMA L.P.; PURDUE PHARMA INC.; THE PURDUE FREDERICK COMPANY INC.; TEVA PHARMACEUTICAL INDUSTRIES LTD.; TEVA PHARMACEUTICALS USA, INC.; CEPHALON, INC.; ENDO INTERNATIONAL PLC; ENDO HEALTH SOLUTIONS, INC.; ENDO PHARMACEUTICALS INC.; PAR PHARMACEUTICAL, INC.; PAR PHARMACEUTICAL COMPANIES, INC., F/K/A PAR PHARMACEUTICAL HOLDINGS, INC.; QUALITEST PHARMACEUTICALS, INC.; ALLERGAN PLC; ACTAVIS, PLC; ACTAVIS LLC; ACTAVIS PHARMA, INC.; ACTAVIS, INC.; WATSON PHARMACEUTICALS, INC.; WATSON PHARMA, INC.; WATSON LABORATORIES, INC.; MALLINCKRODT PLC; MALLINCKRODT LLC; SPECGX LLC; MCKESSON CORPORATION; CARDINAL HEALTH, INC.; AMERISOURCEBERGEN DRUG CORPORATION; J M SMITH CORPORATION; and JOHN DOE DEFENDANTS 1 through 80,	**CIVIL ACTION NO.: 19-A-00060-8** ***TRIAL BY JURY REQUESTED*** ***TRANSFER TO BUSINESS COURT REQUESTED*** ***MATTER OF SPECIAL PUBLIC IMPORTANCE PURSUANT TO O.C.G.A. § 16-14-12***
Defendants.	

COMPLAINT

The sovereign State of Georgia ("the State") hereby files this Complaint against Defendants Purdue Pharma L.P., Purdue Pharma Inc.; The Purdue Frederick Company Inc.;

Cephalon, Inc.; Teva Pharmaceutical Industries Ltd.; Teva Pharmaceuticals USA, Inc.; Endo Health Solutions, Inc.; Endo International plc; Endo Pharmaceuticals Inc.; Par Pharmaceutical, Inc.; Par Pharmaceutical Companies, Inc. f/k/a Par Pharmaceutical Holdings, Inc.; Qualitest Pharmaceuticals, Inc.; Mallinckrodt plc; Mallinckrodt LLC; SpecGx LLC; Allergan plc; Actavis plc; Watson Pharmaceuticals, Inc.; Watson Laboratories, Inc.; Actavis, Inc.; Actavis LLC; Actavis Pharma, Inc.; Watson Pharma, Inc.; AmerisourceBergen Drug Corporation; Cardinal Health, Inc.; McKesson Corporation; J M Smith Corporation; and John Doe Defendants 1 through 80 (collectively "Defendants").

Based upon personal knowledge, information, belief, and investigation of counsel, the State alleges the following:

PRELIMINARY STATEMENT

1. "It is accurate to describe the opioid epidemic as a man-made plague, twenty years in the making. The pain, death, and heartache it has wrought cannot be overstated."[1] As the Director of the Centers for Disease Control and Prevention ("CDC") has noted: "We know of no other medication routinely used for a nonfatal condition that kills patients so frequently."[2]

2. Georgia has an opioid crisis. The sovereign State of Georgia, through its Attorney General, Christopher M. Carr, brings this civil action to seek justice for the catastrophic effects of that crisis on the State and its citizens.

3. The opioid crisis does not exist as a matter of coincidence. Instead, it has been, and is still being, fueled by the unlawful actions of Defendants, who have generated billions of dollars in drug sales through their deceptive and illegal marketing of opioids, and who have

[1] *In re: National Prescription Opiate Litigation*, No. 1:17-md-02804-DAH, Doc. 1203, at *38 (N.D. Ohio Dec. 19, 2018).
[2] Thomas R. Frieden and Debra Houry, *Reducing the Risks of Relief—The CDC Opioid-Prescribing Guideline*, 372 New Eng. J. Med 1501, 1503 (2016).

failed to prevent the diversion of opioids in the State of Georgia. Defendants' actions have not only created short-term losses to the State, but long-term, costly problems that Georgia must grapple with for generations to come.

4. The State of Georgia and its citizens have borne the costs, both in money and heartache, of Defendants' unlawful actions, which combined and concurred in causing injury and damage to the State. Accordingly, the State brings this action to protect the families of Georgia and to recover taxpayer money and resources spent to combat the opioid epidemic. In particular, the State seeks all available: (a) injunctive relief to stop the deceptive marketing; (b) damages for the loss of tax revenue for the State; (c) damages for, and abatement of, the public health epidemic that Defendants have created; (d) damages for any and all of the State's increased costs associated with Defendants' unlawful conduct; (e) other damages sustained by the State as a result of Defendants' conduct; (f) treble damages; (h) disgorgement of Defendants' unjust profit; (i) punitive damages; and (j) any other injunctive and equitable relief within this Court's powers to redress and halt Defendants' unlawful practices.

PARTIES

PLAINTIFF

THE SOVEREIGN STATE OF GEORGIA

5. The State of Georgia brings this action by and through its Attorney General, Christopher M. Carr, in its sovereign capacity to protect the interests of the State of Georgia and its citizens as *parens patriae*. The Attorney General brings this action pursuant to his constitutional, statutory, and common law authority, including the authority granted to him by O.C.G.A. § 45-15-3(6).

6. The State has standing to recover damages incurred as a result of Defendants' actions and omissions. The State has standing to bring all claims pled herein.

DEFENDANTS

MANUFACTURER DEFENDANTS

Purdue and Associated Companies

7. Defendant Purdue Pharma L.P. is a limited partnership organized under the laws of Delaware with its principal place of business in Stamford, Connecticut.

8. Defendant Purdue Pharma Inc. is a New York corporation with its principal place of business in Stamford, Connecticut.

9. Defendant The Purdue Frederick Company Inc. is a New York corporation with its principal place of business in Stamford, Connecticut.

10. At all relevant times, Purdue Pharma L.P., Purdue Pharma Inc., The Purdue Frederick Company Inc., and their U.S. Drug Enforcement Administration ("DEA") registrant subsidiaries and affiliates (collectively, "Purdue") are or have been in the business of manufacturing, selling, promoting, and/or distributing opioids throughout the United States, including the State of Georgia. These opioids include, but are not limited to, OxyContin (oxycodone hydrochloride, extended release formulation); MS Contin, (morphine sulfate, extended release formulation); Dilaudid/Dilaudid HP (hydromorphone hydrochloride); Butrans (buprenorphine); Hysingla ER (hydrocodone bitartrate); and Targiniq ER (oxycodone hydrochloride with naloxone hydrochloride).

11. The Purdue Defendants may be served with process through their corporate headquarters at: One Stamford Forum, 201 Tresser Boulevard, Stamford, CT 06901-3431.

Teva and Associated Companies

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

13. Defendant Teva Pharmaceutical Industries Ltd. is an Israeli corporation with its principal place of business in Petah Tikva, Israel. Cephalon, Inc. became a wholly owned subsidiary of Teva Pharmaceutical Industries Ltd. when it was acquired in October, 2011.

14. Defendant Teva Pharmaceuticals USA, Inc. is a Delaware corporation with its principal place of business in North Wales, Pennsylvania and is a wholly owned subsidiary of Teva Pharmaceutical Industries Ltd.

15. Cephalon, Inc., Teva Pharmaceutical Industries Ltd., Teva Pharmaceuticals USA, Inc., and their DEA registrant subsidiaries and affiliates (collectively, "Cephalon/Teva") are in the business of manufacturing, selling, promoting, and/or distributing both brand name and generic opioids throughout the United States, including in Georgia. These opioids include, but are not limited to, Actiq and Fentora. Actiq and Fentora are both formulations of fentanyl citrate, a very potent opioid.

16. The Cephalon/Teva Defendants may be served with process through their registered agent at the following address: Corporate Creations Network Inc., 2985 Gordy Parkway, 1st Floor, Marietta, GA 30066.

Endo and Associated Companies

17. Defendant Endo Health Solutions, Inc. is a Delaware corporation with its principal place of business in Malvern, Pennsylvania.

18. Defendant Endo Pharmaceuticals Inc. is a Delaware corporation with its principal place of business in Malvern, Pennsylvania, and is a wholly owned subsidiary of Endo Health Solutions, Inc.

19. Endo International plc has two principal places of business: one in Dublin, Ireland and the other in Malvern, Pennsylvania.

20. Defendant Par Pharmaceutical, Inc. is a Delaware corporation with its principal place of business in Chestnut Ridge, New York and is a wholly owned subsidiary of Par Pharmaceutical Companies, Inc. f/k/a Par Pharmaceutical Holdings, Inc. Defendant Par Pharmaceutical Companies, Inc. is a Delaware corporation with its principal place of business in Chestnut Ridge, New York. Par Pharmaceutical, Inc. and Par Pharmaceutical Companies, Inc. (collectively "Par Pharmaceuticals") were acquired by Endo International plc in September 2015 and serve as operating companies of Endo International plc.

21. Defendant Qualitest Pharmaceuticals, Inc. is an Alabama corporation with its principal office located in Huntsville, Alabama. Qualitest Pharmaceuticals, Inc. was acquired by Endo International plc in 2010 and merged with Par Pharmaceuticals in 2010.

22. Endo Health Solutions, Inc. Endo International plc, Endo Pharmaceuticals Inc., Par Pharmaceuticals, Qualitest Pharmaceuticals, Inc., and their DEA registrant subsidiaries and affiliates (collectively, "Endo") are or have been in the business of manufacturing, selling, promoting, and/or distributing both brand name and generic opioids throughout the United States, including in Georgia. These include generic oxycodone, oxymorphone, hydromorphone, and hydrocodone products and the branded opioids Opana (oxymorphone hydrochloride); Opana ER (extended release Opana); Percodan (oxycodone and aspirin); Percocet (oxycodone and acetaminophen); and Zydone (hydrocodone and acetaminophen).

23. The Endo Defendants may be served with process through their registered agent at the following address: CT Corporation System, 289 South Culver Street, Lawrenceville, GA 30046-4805.

Mallinckrodt and Associated Companies

24. Defendant Mallinckrodt plc is an Irish public limited company headquartered in Staines-upon-Thames, United Kingdom and maintains a U.S. headquarters in St. Louis, Missouri.

25. Defendant Mallinckrodt LLC, a wholly owned subsidiary of Mallinckrodt plc, is a Delaware limited liability company with its principal place of business in St. Louis, Missouri.

26. Defendant SpecGx, LLC is a Delaware limited liability company with its headquarters in Clayton, Missouri, and is a wholly owned subsidiary of Mallinckrodt plc.

27. Mallinckrodt plc, Mallinckrodt LLC, SpecGx LLC, and their DEA registrant subsidiaries and affiliates (collectively, "Mallinckrodt") are or have been in the business of manufacturing, marketing, selling and distributing opioids throughout the United States, including the State of Georgia, including generic formulations of morphine sulfate, extended release, morphine sulfate, fentanyl transdermal, oral transmucosal fentanyl citrate, oxycodone with acetaminophen, hydrocodone bitartrate and acetaminophen, hydromorphone hydrochloride, hydromorphone hydrochloride, extended release, naltrexone hydrochloride, oxymorphone hydrochloride, methadone hydrochloride, oxycodone hydrochloride, buprenorphine, and naloxone.

28. Mallinckrodt is the largest supplier of opioid pain medications and among the top ten generic pharmaceutical manufacturers in the United States, based on prescriptions.

29. The Mallinckrodt Defendants may be served with process through their registered agent at the following address: CT Corporation System, 289 South Culver Street, Lawrenceville, GA 30046-4805.

Allergan and Associated Companies

30. Defendant Allergan plc is an Irish public limited company with its principal place of business in Dublin, Ireland.

31. Defendant Actavis, Inc. is a corporation with its principal office in Parsippany, New Jersey. Defendant Watson Pharmaceuticals, Inc. acquired Actavis, Inc. in October, 2012. The combined company changed its name to Actavis plc in October, 2013.

32. Defendant Actavis plc acquired Allergan plc in March 2015. The combined company changed its name to Allergan plc in June 2015.

33. Defendant Watson Laboratories, Inc. is a Nevada corporation with its principal place of business in Corona, California, and is a wholly-owned subsidiary of Allergan plc.

34. Defendant Actavis Pharma, Inc. (f/k/a Actavis, Inc., f/k/a Watson Pharma, Inc.) is a Delaware corporation with its principal place of business in New Jersey.

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

36. Each of these defendants is owned by Defendant Allergan plc, which uses them to market and sell its drugs in the United States. Allergan plc exercises control over the marketing and sales efforts and profits from the sale of Allergan/Actavis products.

37. Allergan plc, Actavis plc, Actavis, Inc., Actavis LLC, Actavis Pharma, Inc., Watson Pharmaceuticals, Inc., Watson Pharma, Inc., and Watson Laboratories, Inc. (collectively, "Allergan") are or have been in the business of manufacturing, selling, promoting, and/or distributing both brand name and generic opioids throughout the United States, including Georgia. These opioids include, but are not limited to, the branded drugs Kadian and Norco, a generic version of Kadian, and generic versions of Duragesic and Opana. Allergan also

manufactured promethazine with codeine, which, when mixed with citrus flavored soda, is a commonly abused opioid "cocktail," until it stopped manufacture in 2014 due to negative associations of this drug.

38. The Allergan Defendants may be served with process through their registered agent at the following address: CT Corporation System, 289 South Culver Street, Lawrenceville, GA 30046-4805. Alternatively, they may be served at the following address: Corporate Creations Network, 2985 Gordy Parkway, 1st Floor, Marietta, GA 30006.

DISTRIBUTOR DEFENDANTS

39. At all relevant times, Distributor Defendants were engaged in "wholesale distribution" as defined under state and federal law. Distributor Defendants distributed, supplied, sold, and placed into the stream of commerce prescription opioids, without fulfilling their legal obligations to monitor, detect, report, investigate, or otherwise prevent the fulfillment of suspicious orders[3], thereby leading to the foreseeable diversion of these dangerous drugs for illegitimate and/or non-medical purposes.

40. Distributor Defendants' failure to meet their obligations is the reason for the substantial volume of prescription opioids plaguing Georgia.

AmerisourceBergen Drug Corporation

41. Defendant AmerisourceBergen Drug Corporation ("AmerisourceBergen") is a Delaware corporation with its principal place of business in Chesterbrook, Pennsylvania. AmerisourceBergen is the second largest pharmaceutical distributor in North America.

[3] For purposes of this Complaint, this duty to monitor, detect, report, investigate, or otherwise prevent the fulfillment of suspicious orders, is referred to as "obligations." For purposes of this Complaint, the term "suspicious orders" shall mean any orders of prescription opioids that are required to be investigated and/or reported under Georgia and/or federal law.

42. According to its 2016 Annual Report, AmerisourceBergen is "one of the largest global pharmaceutical sourcing and distribution services companies, helping both healthcare providers and pharmaceutical and biotech manufacturers improve patient access to products and enhance patient care."

43. At all relevant times, AmerisourceBergen operated as a licensed pharmacy wholesaler in Georgia and delivered substantial amounts of opioid drugs to buyers in this state. AmerisourceBergen is registered with the Georgia Secretary of State as a Delaware corporation.

44. Defendant AmerisourceBergen may be served with process through its registered agent at the following address: CT Corporation System, 289 South Culver Street, Lawrenceville, GA 30046-4805.

Cardinal Health, Inc.

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

46. At all relevant times, Cardinal Health operated as a licensed pharmacy wholesaler in Georgia and distributed substantial amounts of opioid drugs to buyers in this State. Cardinal Health is a global distributor of pharmaceutical drugs and medical products, and is one of the largest distributors of opioids in the United States. In December 2013, Cardinal Health entered a ten-year agreement with CVS Caremark to form the largest generic drug sourcing operation in the United States. In 2016, Cardinal Health generated $121 billion in revenue.

47. Defendant Cardinal Health may be served with process through its registered agent at the following address: CT Corporation System, 289 South Culver Street, Lawrenceville, GA 30046-4805.

McKesson Corporation

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

49. At all relevant times, McKesson operated as a licensed pharmacy wholesaler in Georgia and delivered substantial amounts of opioid drugs to buyers in this State. Moreover, McKesson operates a distribution center in Duluth, Gwinnet County, Georgia. McKesson is the largest pharmaceutical distributor in North America and delivers approximately one-third of all pharmaceuticals used there. According to McKesson's 2017 Annual Report, the company's "pharmaceutical distribution business operates and serves thousands of customer locations through a network of 27 distribution centers, as well as a primary redistribution center, two strategic redistribution centers and two repackaging facilities, serving all 50 states and Puerto Rico."

50. Defendant McKesson Corporation may be served with process through its registered agent at the following address: Corporation Service Company, 40 Technology Parkway South, #300, Norcross, GA 30092.

J M Smith Corporation

51. J M Smith Corporation is a Delaware corporation with its principal place of business in Spartanburg, South Carolina. Smith Drug Company is a division of J M Smith Corporation responsible for operating J M Smith Corporation's pharmaceutical distribution business. J M Smith Corporation and Smith Drug Company are referred to as "Smith Drug" throughout this Complaint.

52. Smith Drug is a wholesale pharmaceutical distributor primarily serving the eastern United States. At all relevant times, Smith Drug operated as a licensed pharmacy

wholesaler in Georgia and delivered substantial amounts of opioid drugs to buyers in this State. Smith Drug operates a distribution center in Valdosta, Georgia.

53. Defendant Smith Drug may be served with process through its registered agent at the following address: CT Corporation System, 289 South Culver Street, Lawrenceville, GA 30046-4805.

JOHN DOE DEFENDANTS 1 THROUGH 80

54. John Doe Defendants 1 through 10, whether singular or plural, are those entities or persons who marketed and promoted the use of prescription opioid drugs through false, scientifically unsupported or misleading representations: (1) in advertising, medical education presentations, speaking engagements, medical literature, publications, websites, and/or statements to physicians and medical students; (2) through funding or employing "Key Opinion Leaders" as described more fully below; and/or (3) through funding or participating in "Front Groups" as described more fully below.

55. John Doe Defendants 11 through 20, whether singular or plural, are those entities or persons that are wholesale distributors of prescription opioid drugs who: (1) failed to implement an effective system to monitor the distribution of opioid drugs; (2) failed to identify and report suspicious orders of opioid drugs destined to pharmacies and individuals in Georgia to the DEA or Georgia Drugs and Narcotics Agency; (3) failed to maintain effective controls against diversion of opioid drugs for other than legitimate uses in violation of the Georgia Controlled Substances Act and related laws concerning distribution of controlled substances; and/or (4) otherwise failed to comply with the Georgia Controlled Substances Act and related laws concerning distribution of controlled substances.

56. John Doe Defendants 21 through 30 whether singular or plural, are those officers, directors, executives, or agents who were directly and personally involved in developing and executing the marketing efforts of Manufacturer Defendants or of John Doe Defendants 1-10.

57. John Doe Defendants 31 through 40, whether singular or plural, are those entities or persons who had a responsibility to monitor, detect, report, investigate, or otherwise prevent the fulfillment of suspicious orders of controlled substance prescriptions and who failed in their duty to do so.

58. John Doe Defendants 41 through 50, whether singular or plural, are those officers, directors, executives, entities, or agents who participated in the "Opioid Promotion Enterprise" described in Count I of this Complaint or who, through proceeds derived from the "Opioid Promotion Enterprise," including real property or personal property of any nature (including money), acquired or maintained, directly or indirectly, any interest in or control of the enterprise.

59. John Doe Defendants 51 through 60, whether singular or plural, are those officers, directors, executives, entities, or agents who participated in the "Opioid Diversion Enterprise" described in Count I of this Complaint or who, through proceeds derived from the "Opioid Diversion Enterprise," including real property or personal property of any nature (including money), acquired or maintained, directly or indirectly, any interest in or control of the enterprise.

60. John Doe Defendants 61 through 70, whether singular or plural, are those officers, directors, executives, entities, or agents who participated in a RICO Enterprise which caused or contributed to this opioid crisis or who, through proceeds derived from a RICO Enterprise, including real property or personal property of any nature (including money), acquired or maintained, directly or indirectly, any interest in or control of the enterprise.

61. John Doe Defendants 71 through 80, whether singular or plural, are those officers, directors, executives, entities, or agents who, by virtue of their position and the legal duties vested in them, had an obligation to monitor, detect, investigate, refuse, and/or report suspicious orders of prescription opioids.

62. The John Doe Defendants are incorporated where any Defendant is referenced in this civil action.

DEFENDANTS' AGENTS

63. All of the actions described in this Complaint are part of, and in furtherance of, the unlawful conduct alleged herein and were authorized, ordered, and/or done by Defendants' officers, agents, employees, or other representatives who were actively engaged in the management of Defendants' affairs within the course and scope of their duties and employment and/or with Defendants' actual, apparent, and/or ostensible authority.

JURISDICTION AND VENUE

64. The State brings this action exclusively under Georgia law. No independent federal claims are being asserted, and to the extent that any claim or factual assertion set forth herein may be construed to have stated any claim for relief arising under federal law, such claim is expressly and undeniably disavowed.

65. Because the State of Georgia is not a citizen for purposes of diversity jurisdiction, no federal court can exercise subject matter jurisdiction over this case based on diversity of citizenship between the parties.

66. Federal question subject matter jurisdiction pursuant to 28 U.S.C. § 1331 is not invoked by the State or its Complaint, as it exclusively sets forth herein viable state law claims against Defendants. Nowhere herein does the State of Georgia plead, expressly or implicitly, any

cause of action or request any remedy that arises under federal law. The issues presented in the allegations of this Complaint do not implicate any substantial federal issues. No federal issue is important to the federal system as a whole under the criteria set by the Supreme Court in *Gunn v. Minton*, 568 U.S. 251 (2013).

67. Specifically, the causes of action asserted and the remedies sought herein are founded upon the statutory, common, and decisional laws of the State of Georgia. Accordingly, any exercise of federal jurisdiction is without basis in law or fact. Further, the assertion of federal jurisdiction over the claims made herein would improperly disturb the congressionally approved balance of federal and state responsibilities. To be plain, the State cites federal statutes and federal regulations in its Complaint to define the contours of the duty owed by Defendants under Georgia law, not to allege an independent federal cause of action or to create a substantial federal question. Even where a federal regulation informs some part of the case, that does not convert any state legal cause of action into any federal question, substantial or otherwise, because it is Georgia law, and not any federal authority, that establishes the existence of the duties owed.

68. This Court has jurisdiction over this action pursuant to O.C.G.A. § 9-10-91. Defendants regularly transacted business in Georgia, including through manufacturing, marketing, selling, distributing, monitoring, transporting, and/or storing opioids or through opioid transactions in Georgia. All of the Defendants engaged in and/or acted in concert to directly (and unlawfully) manipulate Georgia government regulation and control of the use and distribution of controlled substances. For instance, these Defendants concealed the alarming, suspicious distribution and use of opioids. These acts caused a substantial increase in opioid use and, consequently, diversion of drugs within the State of Georgia, directly leading to Georgia's substantial costs, losses, and necessary additions to its infrastructure to combat this growing

crisis. Through these actions and other actions alleged in the Complaint, Defendants tortiously injured the State of Georgia. Defendants derived substantial revenue from goods used or consumed in Georgia and for services rendered in Georgia.

69. Venue in Gwinnett County is appropriate pursuant to Ga. Const. of 1983, Art. 6, Sec. 2, Para. 4 and O.C.G.A. § 14-2-510 as events giving rise to the causes of action alleged herein occurred in this county, Defendants transact business in this county, Defendants intentionally manufactured prescription opioid medications to send to and/or directed opioid medications to this county, and at least one Defendant maintains an office in this county. Venue is also appropriate in Gwinnett County as most of the Defendants in this matter are subject to service of process in Gwinnett County through their registered agents.

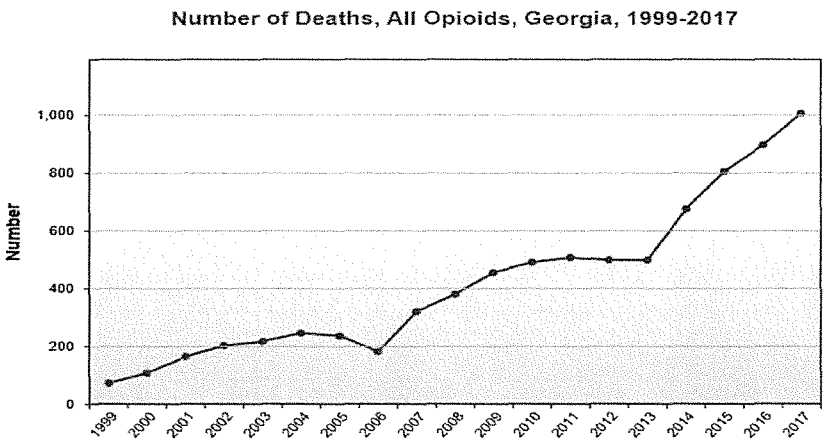
FACTUAL ALLEGATIONS

I. THE OPIOID CRISIS IN GEORGIA

70. Georgia finds itself in the midst of an unprecedented prescription drug crisis, with hundreds of deaths attributable to opioid prescription drug overdoses every year.[4]

71. The State of Georgia had the eleventh highest number of opioid overdoses in the United States between 1999 and 2014.[5] Opioid-involved overdose deaths have not just increased – ***but exploded by an astonishing 1000%*** – since 1999 when these drugs were first meaningfully introduced to the State of Georgia.[6]

[4] The Henry J. Kaiser Family Foundation, *Opioid Overdose Deaths and Opioid Overdose Deaths as a Percent of All Drug Overdose Deaths* (2015), https://www.kff.org/other/state-indicator/opioid-overdose-deaths/?currentTimeframe=12&sortModel=%7B%22colId%22:%22Location%22,%22sort%22:%22asc%22%7D.
[5] Substance Abuse Research Alliance, *Prescription Opioids and Heroin Epidemic in Georgia*, 2017, http://www.senate.ga.gov/sro/Documents/StudyCommRpts/OpioidsAppendix.pdf
[6] https://oasis.state.ga.us/trendingtool/index.html?redirectto=MortalityDrugOverdoses.



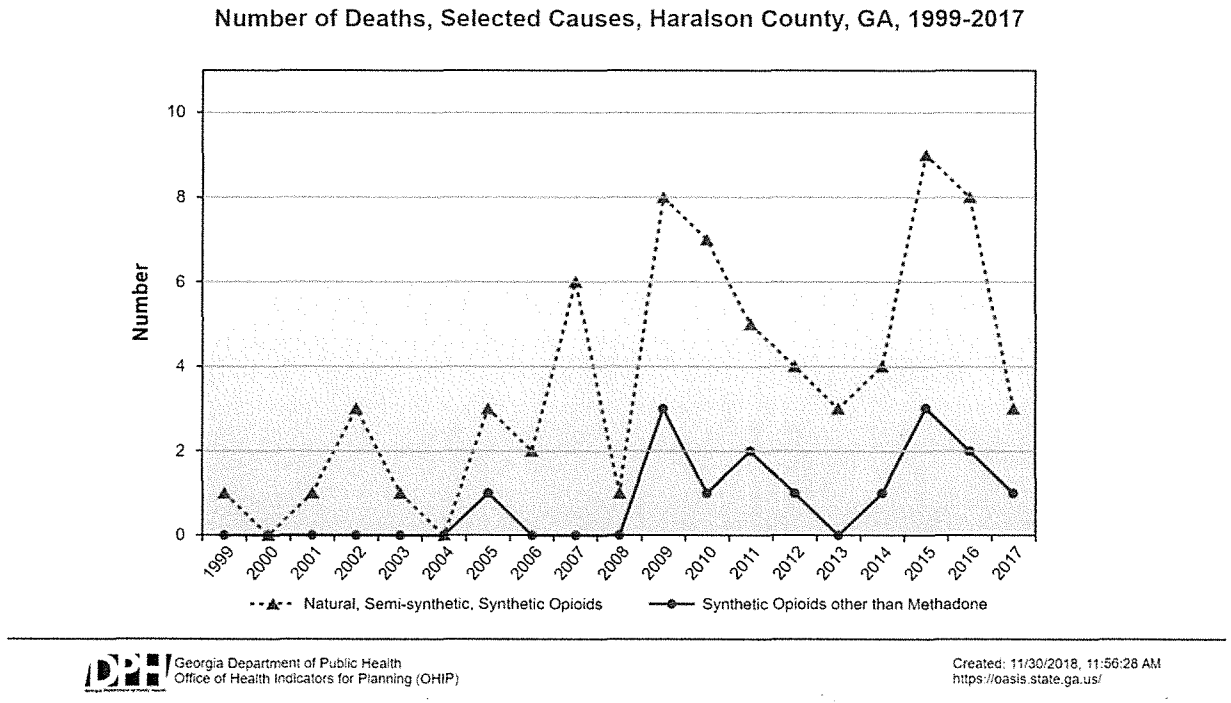
MEASURE	1999	2000	2001	2002	2003	2004	2005	2006	2007	2008	2009	2010	2011	2012	2013	2014	2015	2016	2017	1999-2017 TOTAL
Number of Deaths	73	108	164	203	217	246	237	181	321	380	456	491	508	499	499	675	806	897	1,007	7,968

72. Statistics in recent years show the ever-increasing momentum of this crisis: from 2010 to 2016, the total number of documented opioid-involved overdose deaths in Georgia increased by an astounding 117%, from 426 to 929 deaths, and the death rate increased by 111%, from 4.3 to 9.1 deaths/100,000 persons.[7] In 2016, the State of Georgia experienced at least 897 opioid drug-related deaths[8] and 9,912 hospital admissions for drug-related disorders. Tellingly, the annual number of such hospital admissions had tripled since 2000,[9] with 2,435 documented emergency room visits and 1,709 hospitalizations due to opioid overdoses.[10] In 2017, there were 1,529 deaths attributed to all drugs in the State of Georgia, but an overwhelming number of them (1,007) were the result of opioids.[11] From 1999 to 2017, more people have died from opioid overdoses (7,968) in the State of Georgia than the 2010 total populations of sixteen (16) Georgia

[7] Georgia Department of Public Health, Opioid Overdose Surveillance (Preliminary Report), 2016 dph.georgia.gov/sites/dph.georgia.gov/files/2016%20OPIOID%20PRELIMINARY%20REPORT.FINAL.PDF.
[8] We anticipate this and other death estimates will increase as litigation progresses forward.
[9] https://oasis.state.ga.us/oasis/webquery/qryMorbidity.aspx.
[10] https://dph.georgia.gov/sites/dph.georgia.gov/files/2016%20OPIOID%20PRELIMINARY%20REPORT.FINAL.PDF.
[11] https://oasis.state.ga.us/oasis/webquery/qryDrugOverdose.aspx.

counties: Calhoun, Clay, Clinch, Echols, Glascock, Miller, Quitman, Randolph, Schley, Stewart, Talbot, Taliaferro, Treutlen, Warren, Webster, or Wheeler.[12]

73. Haralson County, Georgia, with a population just under 21,000 people[13], has lost almost 70 people to opioid overdoses since 1999.[14]

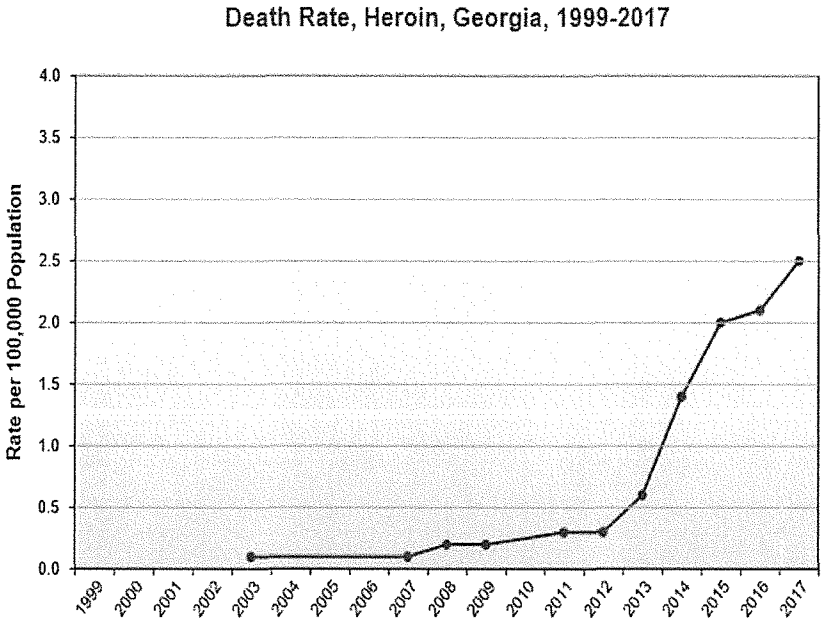


74. Emergency medical services administered the potentially life-saving opioid overdose reversal drug naloxone nearly 10,000 times in 2016 compared to a mere 4,500 in 2012.[15]

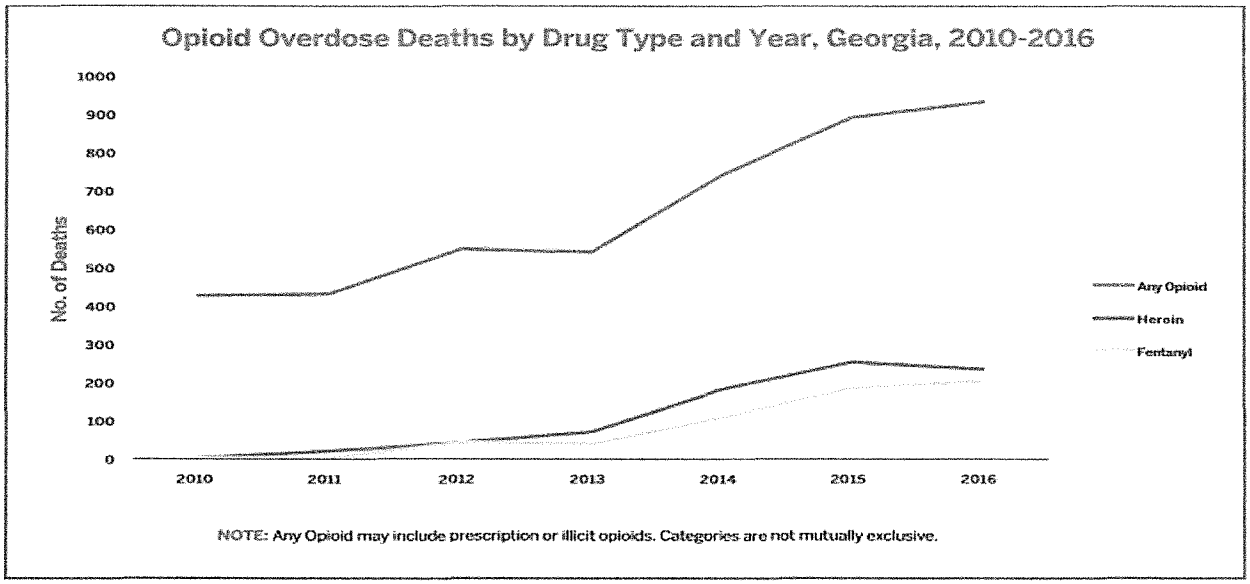
75. The health care costs alone associated with opioid misuse in Georgia were estimated at $447 million in 2007.[16] Given the explosion in opioid-related deaths, overdoses, and hospitalizations, the costs are now far greater than the 2007 estimate.

[12] https://www2.census.gov/library/publications/decennial/2010/cph-2/cph-2-12.pdf.
[13] *Id.*
[14] https://oasis.state.ga.us/trendingtool/index.html?redirectto=MortalityDrugOverdoses.
[15] Georgia Department of Audits and Accounts Performance Audit Division, Performance Audit Report No.17-11 (November 2017).

76. Heroin overdose deaths have skyrocketed too, as those addicted to prescription opioids often switch to a cheaper alternative to meet their addiction demands. Consequently, the heroin and fentanyl death rates correspond with the increase in opioid-related deaths.

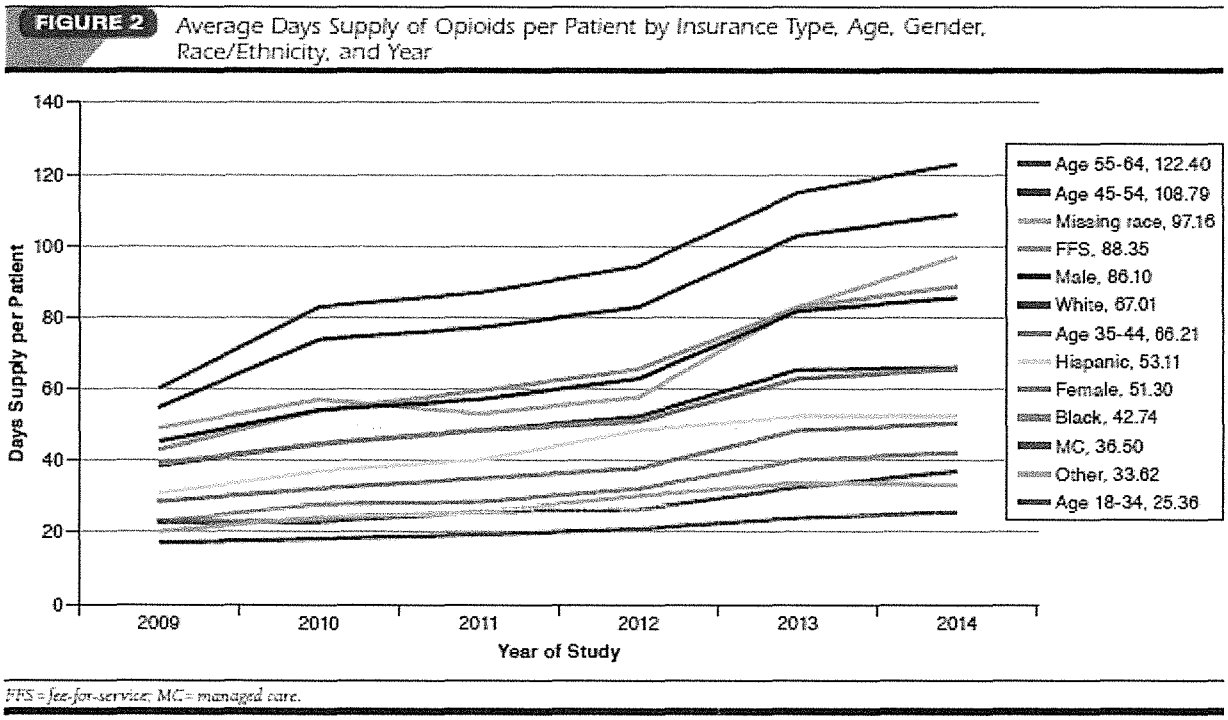


MEASURE	1999	2000	2001	2002	2003	2004	2005	2006	2007	2008	2009	2010	2011	2012	2013	2014	2015	2016	2017	1999-2017 TOTAL
Death Rate	*	*	*	*	0.1	*	*	*	0.1	0.2	0.2	*	0.3	0.3	0.6	1.4	2.0	2.1	2.5	0.6



[16] http://www.senate.ga.gov/sro/Documents/StudyCommRpts/OpioidsAppendix.pdf.

77. The death, addiction, and increased cost associated with prescription opioids is a direct consequence of Georgia's opioid prescription rate increase over the same time period. By 2013, Georgia's average prescription rate for opioids (90.7 per 100 persons) was well over the national average (79.3).[17] In 2016, there were 0.778 opioid prescriptions per person in Georgia, according to the CDC. Some counties in Georgia had well over 1 prescription per person, including Bacon County (1.57), Catoosa (1.16), Coffee (1.73), and Decatur (1.22).[18] According to Georgia Medicaid, the average days' supply of opioids has increased for all age groups from 2009 to 2014:



[17] CDC, *U.S. State Prescribing Rates, 2016,* https://www.cdc.gov/drugoverdose/maps/rxstate2016.html.
[18] CDC, *U.S. County Prescribing Rates, Opioids, 2016,* https://www.cdc.gov/drugoverdose/maps/rxcounty2016.html.

78. Not surprisingly, an estimated 180,000 Georgians have an opioid use disorder, which is more than the population of Macon, the fourth largest city in Georgia.[19] Sadly, 86.7% of those with a drug dependence or abuse go untreated.[20]

79. The State has incurred substantial, increasing costs to combat this opioid epidemic. Because the opioid epidemic has so deeply and negatively impacted Georgia, the State will continue to incur substantial costs in both combatting and responding to the crisis for years to come.

II. GEORGIA IS PART OF A NATIONAL CRISIS

80. The heartache felt in Georgia is part of a larger, national opioid crisis. In 2016, the President of the United States declared that an opioid and heroin epidemic existed within the country.[21] Annual opioid prescriptions now roughly equal the number of adults living in the United States.[22]

81. The opioid crisis is America's deadliest overdose crisis ever. Today, opioids are responsible for the majority of drug overdoses,[23] which have quadrupled nationally since 1999.[24] In just 2016, CDC data confirms at least 42,249 people died from opioid overdoses, which accounted for the majority (66.4%) of all drug overdose deaths in that year (63,632). From 1999

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[19] Georgia Department of Audits and Accounts Performance Audit Division, *Performance Audit Report No.17-11* (November 2017); Annual Estimates of the Resident Population for Incorporated Places of 50,000 or More, Ranked by July 1, 2017 Population: April 1, 2010 to July 1, 2017, https://factfinder.census.gov/faces/tableservices/jsf/pages/productview.xhtml?src=bkmk.

[20] https://www.aap.org/en-us/advocacy-and-policy/federal-advocacy/Documents/Opioid-StateFactsheets/opioid_fs_georgia.pdf.

[21] *See* Proclamation No. 9499, 81 Fed. Reg. 65, 173 (Sept. 16, 2016) (proclaiming "Prescription Opioid and Heroin Epidemic Awareness Week").

[22] *See* Robert M. Califf *et al.*, *A Proactive Response to Prescription Opioid Abuse*, 374 N. Eng. J. Med. 1480 (2016).

[23] *Id.*

[24] Drug Overdose Death Data, Ctrs. For Disease Control & Prevention, https://www.cdc.gov/drugoverdose/data/statedeaths.html. Drug deaths take a long time to certify, so this is the most recent available data. https://www.cdc.gov/nchs/data/vsrr/report001.pdf.

to 2016, more than 200,000 people have died in the United States from prescription opioid overdoses, and by 2016, people were dying at a rate five (5) times greater than in 1999.[25]

82. Moreover, this crisis has caused a significant spike in street drug use. In a November 2016 report, the DEA declared opioid prescription drugs, heroin, and fentanyl as the most significant drug-related threats to the United States.[26] Heroin overdoses have climbed sharply during the opioid epidemic, more than tripling over a four-year period according to the CDC. This increase has been shown to be closely tied to opioid pain reliever misuse and dependence. People who are addicted to prescription opioid painkillers are forty (40) times more likely to become addicted to heroin.[27] Heroin is pharmacologically similar to prescription opioids, and most current heroin users report prior non-medical use of prescription opioids before they initiated heroin use. In fact, non-medical use of prescription opioids has been identified to be one of, if not the, strongest serious risk factor for heroin use.[28]

83. The CDC estimates that approximately three out of four new heroin addicts in the United States started by abusing prescription opioids.[29]

84. Additionally, the youngest members of society have been affected by the opioid crisis. According to the CDC, 87 children died of opioid intoxication in 2015, an increase from just 16 in 1999. Toddlers and young children are increasingly being found unconscious or dead after consuming an adult's drugs, and there has been a surge of opioid-dependent newborns.

85. Opioids also pose a grave risk to veterans. They are twice as likely to die of an opioid overdose than the general population.[30]

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[25] https://www.cdc.gov/drugoverdose/data/prescribing.html.
[26] Rudd et al., *Increases in Drug and Opioid-Involved Overdose Deaths—United States, 2010-2015*, 65 Morbidity & Mortality Wkly. Rep. 1445, 1450 (2016).
[27] *See* CDC, U.S. Dep't of Health and Human Servs., *Today's Heroin Epidemic*, https://www.cdc.gov/vitalsigns/heroin/index.html (last updated July 7, 2015).
[28] *See* Wilson M. Compton, *Relationship Between Nonmedical Prescription-Opioid Use and Heroin*, 374 N. Eng. J. Med. 154 (2016).
[29] Heroin Overdose Data, CDC, https://www.cdc.gov/drugoverdose/data/heroin.html.

86. Overall, the National Institute on Drug Abuse identifies misuse and addiction to opioids as a "serious national crisis that affects public health as well as social and economic welfare."[31] The economic burden of prescription opioid use alone is $78.5 billion a year, including the costs of healthcare, lost productivity, addiction treatment, and criminal justice expenditures.[32] Since 2001, some estimates have suggested that the opioid crisis has cost the United States more than a trillion dollars, and may exceed over $500 billion over the next three years.[33]

III. THE HISTORY OF OPIOIDS AND ADDICTION

87. Opioids are highly addictive synthetic drugs derived from opium and are otherwise chemically similar to opium alkaloids. Due to concerns about their addictive properties, opioids have been regulated at the federal level as controlled substances by the DEA since 1970. The labels for scheduled opioids carry black box warnings of potential addiction and "[s]erious, life-threatening, or fatal respiratory depression" as a result of an excessive dose. The CDC has declared that "[o]pioid pain medication use presents serious risks, including overdose and opioid use disorder" (a diagnostic term for addiction).[34]

88. Opioids generally have been categorized as Schedule II or Schedule III drugs. Schedule II drugs have a high potential for abuse, have a currently accepted medical use, and may lead to severe psychological or physical dependence. 21 U.S.C. § 812. Schedule II drugs

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[30] Wilkie, Robert, Secretary for Veterans Affairs, *Fighting Pain and Addiction for Veterans*, https://www.whitehouse.gov/articles/fighting-pain-addiction-veterans/ (last checked, December 17, 2018).
[31] https://www.drugabuse.gov/drugs-abuse/opioids/opioid-overdose-crisis.
[32] *Id.* (citing at note 2 Florence CS, Zhou C, Luo F, Xu L, *The Economic Burden of Prescription Opioid Overdose, Abuse, and Dependence in the United States*, 2013, *MED CARE* 2016; 54(10):901-906,doi:10.1097/MLR.0000000000000625).
[33] https://www.npr.org/sections/health-shots/2018/02/13/585199746/cost-of-u-s-opioid-epidemic-since-2001-is-1-trillion-and-climbing.
[34] Deborah Dowell *et al.*, *CDC Guideline for Prescribing Opioids for Chronic Pain — United States, 2016*, 65 Morbidity and Mortality Weekly Report 1 (March 18, 2016), https://www.cdc.gov/mmwr/volumes/65/rr/rr6501e1.htm.

may not be dispensed without an original and/or faxed copy of a manually signed prescription (which may not be refilled) from a doctor and filled by a pharmacist who both must be licensed by their state and registered with the DEA. 21 U.S.C. § 829.

89. Opioids provide effective treatment for short-term post-surgical and trauma-related pain, and for palliative end-of-life care. They are approved by the FDA for use in the management of moderate to severe pain where use of an opioid analgesic is appropriate for more than a few days. Manufacturer Defendants, however, have manufactured, promoted, and marketed opioids for the management of chronic pain by misleading consumers and medical providers through misrepresentations or omissions regarding the appropriate uses, risks, and safety of long-term opioid therapy.

90. Contrary to Manufacturer Defendants' representations, evidence shows that opioid drugs are not effective to treat chronic pain and may worsen a patient's health. One study found that opioids as a class do not demonstrate improvement in functional outcomes over other non-addicting treatments. Most notably, it stated: "[O]ther analgesics were significantly more effective than were opioids."[35]

91. In 2013, in response to a petition to restrict the labels of extended-release opioid products, the FDA noted the "grave risks of opioids, the most well-known of which include addiction, overdose, and even death."[36] The FDA further warned that "[e]ven proper use of opioids under medical supervision can result in life-threatening respiratory depression, coma,

[35] Andrea D. Furlan, *Opioids for chronic noncancer pain: a meta-analysis of effectiveness and side effects*, 174 (11) Can. Med. Ass'n J. 1589-1594 (2006), https://www.ncbi.nlm.nih.gov/pmc/articles/PMC1459894/. This same study revealed that efficacy studies do not typically include data on opioid addiction. In many cases, patients who may be more prone to addiction are pre-screened out of the study pool. This does not reflect how doctors actually prescribe the drugs, because even patients who have past or active substance use disorders tend to receive higher doses of opioids.

[36] Letter from Janet Woodcock, M.D., Dir., Ctr. For Drug Evaluation and Research, U.S. Food and Drug Admin., U.S. Dep't of Health and Human Servs., to Andrew Kolodny, M.D., President, Physicians for Responsible Opioid Prescribing (Sept. 10, 2013), https://www.regulations.gov/contentStreamer?documentId=FDA-2012-P-0818-0793&attachmentNumber=1&contentType=pdf.

and death." The FDA required that, going forward, makers of extended-release opioid formulations clearly communicate these risks in their labels. Thus, the FDA confirmed what had previously been accepted practice in the treatment of pain – that the adverse outcomes from opioid use include "addiction, unintentional overdose, and death" and that long-acting or extended release opioids "should be used ***only when alternative treatments are inadequate***."[37]

92. Notably, in reaching its conclusion, the FDA did not rely on new or otherwise previously unavailable scientific studies regarding the properties or effects of opioids.

93. The risks of opioid use disorder and overdose risk are present even when opioids are taken as prescribed.[38] Studies have shown that between 20% and 40% of long-term users of opioids experience problems with opioid use disorders. One study has shown that the duration of opioid therapy is a strong risk factor for opioid use disorder, even more important than daily dose – which itself is a strong predictor of continued opioid use.

94. Moreover, this crisis has caused a significant spike in street drug use. In a November 2016 report, the DEA declared opioid prescription drugs, heroin, and fentanyl as the most significant drug-related threats to the United States.[39]

95. Opioids are extremely addictive. Studies have found diagnosed addiction[40] rates among opioid users in primary care settings as high as 26%.[41] Additionally, among opioid users who received four prescriptions in a year, 41.3% meet diagnostic criteria for a lifetime opioid-

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[37] *Id.* (Emphasis added).
[38] Letter from Janet Woodcock, M.D., Dir., Ctr. for Drug Eval. & Res., to Andrew Kolodny, M.D., Pres. Physicians for Responsible Opioid Prescribing, Re Docket No. FDA-2012-P-0818 (Sept. 10, 2013).
[39] Rudd et al., *Increases in Drug and Opioid-Involved Overdose Deaths—United States, 2010-2015*, 65 Morbidity & Mortality Wkly. Rep. 1445, 1450 (2016).
[40] Addiction is a spectrum of substance use disorders that range from misuse and abuse of drugs to addiction. *Diagnostic and Statistical Manual of Mental Disorders* (5th ed. 2013) ("DSM-V"). Throughout this Complaint, "addiction" refers to the entire range of substance abuse disorders. Individuals suffer negative consequences wherever they fall on the substance use disorder continuum.
[41] Deborah Dowell *et al.*, *CDC Guideline for Prescribing Opioids for Chronic Pain — United States, 2016*, 65 Morbidity and Mortality Weekly Report 1 (March 18, 2016), https://www.cdc.gov/mmwr/volumes/65/rr/rr6501e1.htm.

abuse disorder.[42]

96. Once a patient begins opioid treatment, it is extraordinarily difficult to stop. A 2017 CDC study determined that the probability of long-term use escalates most sharply after five days and surges again when one month of opioids are prescribed.[43] A patient initially prescribed one month of opioids has a 29.9% chance of still using at one year.[44] In one study, almost 60% of patients who used opioids for 90 days were still using them five years later.[45] When under the continuous influence of opioids over a period of time, patients grow tolerant to their analgesic effects. As tolerance increases, a patient requires progressively higher doses to obtain the same levels of pain reduction he or she has become accustomed to – up to and including dosage amounts that are considered by many physicians to be "frighteningly high."[46] And at higher doses, the effects of withdrawal are more substantial, leaving a patient at a much higher risk of addiction.

97. Tolerance to the respiratory depressive effects of opioids develops at a slower rate than tolerance to opioids' analgesic effects. Accordingly, the practice of continuously escalating dosages to match pain tolerance can, in fact, lead to overdose even where opioids are taken as recommended.[47] Patients receiving high doses of opioids as part of long-term opioid therapy are

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[42] Joseph A. Boscarino, Stuart N. Hoffman & John J. Han, *Opioid-Use Disorder Among Patients on Long-Term Opioid Therapy: Impact of Final DSM-5 Diagnostic Criteria on Prevalence and Correlates*, 6 Substance Abuse and Rehabilitation 83 (2015); *see also* Joseph A. Boscarino et al., *Prevalence of Prescription Opioid-Use Disorder Among Chronic Pain Patients: Comparison of the DSM-5 vs. DSM-4 Diagnostic Criteria*, 30 Journal of Addictive Diseases 185 (2011) (showing a 34.9% lifetime opioid use disorder).

[43] Anuj Shah, Corey J. Hayes & Bradley C. Martin, *Characteristics of Initial Prescription Episodes and Likelihood of Long-Term Opioid Use – United States, 2006-2015*, 66 Morbidity and Mortality Weekly Report 265–269 (2017).

[44] *Id.*

[45] Bradley C. Martin et al., *Long-Term Chronic Opioid Therapy Discontinuation Rates from the TROUP Study*, 26 J. Gen. Internal. Med. 1450 (2011).

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

[47] *See* Thomas R. Frieden and Debra Houry, *Reducing the Risks of Relief—The CDC Opioid-Prescribing Guideline*, 372 New Eng. J. Med 1501, 1503 (2016).

three to nine times more likely to suffer overdose from opioid-related causes than those on low doses.

98. One in every 550 patients on opioid treatment will die within, on average, 2.6 years after their first opioid prescription. That number increases to 1 in 32 for patients receiving 200 morphine-milligram-equivalent per day ("MME/day").

99. In short, there are no safe opioid doses, but the higher the dose and the longer the treatment, the more likely a patient will suffer serious health consequences.

100. While the risks and adverse effects of dependence, tolerance, and addiction are disclosed in the labels for Manufacturer Defendants' opioids, they are not disclosed and/or are minimized in Manufacturer Defendants' marketing.

IV. MANUFACTURER DEFENDANTS' FALSE, DECEPTIVE, AND UNFAIR MARKETING OF OPIOIDS.

101. The opioid epidemic did not happen by accident.

102. Before the 1990s, generally accepted standards of medical practice dictated that opioids should only be used short-term for acute pain, pain relating to recovery from surgery, or for cancer or palliative (end-of-life) care. Due to the lack of evidence that opioids improved patients' ability to overcome pain and function, coupled with evidence of greater pain complaints as patients developed tolerance to opioids over time and the serious risk of addiction and other side effects, the use of opioids for chronic pain was discouraged or prohibited. As a result, doctors generally did not prescribe opioids for chronic pain.

103. In an effort to reverse this common medical understanding, each Manufacturer Defendant conducted, and continues to conduct, a marketing scheme designed to mislead doctors and patients about the safety and efficacy of opioids for the treatment of chronic pain. The result of this scheme has been the use of opioids by a far broader group of patients who are more likely

to become addicted and suffer other adverse effects from the long-term use of opioids. Each Manufacturer Defendant spent, and continues to spend, millions of dollars on promotional activities and materials that falsely deny or trivialize the risks of opioids while overstating the benefits of using them for chronic pain.

104. Contrary to the language on their drugs' labels, Manufacturer Defendants have made false and misleading claims regarding the risks of using their drugs that: (1) downplayed the serious risk of addiction; (2) created and promoted the concept of "pseudoaddiction"; (3) exaggerated the effectiveness of screening tools and management techniques to prevent or mitigate addiction; (4) claimed that opioid dependence and withdrawal are easily managed; (5) denied the risks of higher opioid dosages; (6) asserted that other methods of pain relief pose greater risks than opioids; (7) claimed that extended release opioids provided effective pain relief for 12 hours; and/or (8) exaggerated the effectiveness of "abuse-deterrent" opioid formulations to prevent abuse and addiction. Manufacturer Defendants have also falsely touted the benefits of long-term opioid use, including the supposed ability of opioids to improve function and quality of life, even though there was no scientifically reliable evidence to support Manufacturer Defendants' claims.

105. Manufacturer Defendants disseminated these common messages directly, through their sales representatives and in speaker groups led by physicians Manufacturer Defendants recruited for the physicians' support of Manufacturer Defendants' marketing messages, and through unbranded marketing and industry-funded front groups. Through these efforts, Manufacturer Defendants sought to reverse the popular and medical understanding of opioids and their risks.

106. Manufacturer Defendants' efforts have been wildly successful. In an open letter to the nation's physicians in August 2016, the then-U.S. Surgeon General expressly connected this "urgent health crisis" to "heavy marketing of opioids to doctors . . . [m]any of [whom] were even taught – incorrectly – that opioids are not addictive when prescribed for legitimate pain."[48]

107. Manufacturer Defendants intentionally continued their conduct, as alleged herein, with knowledge that such conduct was creating a crisis and causing the harms and damages alleged herein.

A. Each Manufacturer Defendant Used Multiple Avenues to Disseminate Their False and Deceptive Statements about Opioids.

108. Manufacturer Defendants employed the same marketing plans and strategies and deployed the same message in Georgia as they did nationwide. They spread their false and deceptive statements throughout the State, both by marketing their branded opioids directly to doctors and patients and through seemingly unbiased and independent third parties that they controlled.

109. Manufacturer Defendants' direct marketing of opioids proceeded on numerous tracks. First, each Manufacturer Defendant conducted advertising campaigns touting the purported benefits of their branded drugs, including through advertising in medical journals. Upon information and belief, Manufacturer Defendants spent more than $14 million on medical journal advertising of opioids in 2011, nearly triple what they spent in 2001. Many of these branded ads deceptively portrayed the benefits of opioids for chronic pain.

110. Second, each Manufacturer Defendant promoted the use of opioids for chronic pain through detailers – sales representatives who visited individual doctors and medical staff in their offices – and small-group speaker programs. Each Manufacturer Defendant devoted

[48] Letter from Vivek H. Murthy, U.S. Surgeon General (Aug.2016)); *see* also, https://catalyst.nejm.org/ending-opioid-epidemic-call-action/.

massive resources to direct sales contacts with doctors. Upon information and belief, in 2014 alone, Manufacturer Defendants spent more than $133 million[49] on detailing branded opioids to doctors, more than twice what they spent on detailing in 2000. Sales representatives visited hundreds of thousands of doctors and disseminated Manufacturer Defendants' misleading marketing messages. In accordance with common industry practice, Manufacturer Defendants purchase and closely analyze prescription sales data from IMS Health Holdings, Inc. (now IQVIA), a healthcare data collection, management, and analytics corporation. This data allows them to precisely track the rates of initial and renewal prescribing by individual doctors, which allows them to target and tailor their appeals. Sales representatives visited hundreds of thousands of doctors and disseminated the misinformation and materials described above.

111. Third, Manufacturer Defendants marketed their opioids using unbranded advertising, paid speakers and key opinion leaders ("KOLs"), and industry-funded organizations posing as neutral and credible professional societies and patient advocacy groups (referred to hereinafter as "Front Groups"). By funding, directing, reviewing, editing, and distributing this unbranded advertising, Manufacturer Defendants controlled the deceptive messages disseminated by these third parties and acted in concert with them to promote opioids falsely and misleadingly for the treatment of chronic pain through scientific publications, treatment guidelines, Continuing Medical Education ("CME") programs, and medical conferences and seminars.

Key Opinion Leaders

112. Two of the most prominent KOLs were Dr. Russell Portenoy and Dr. Lynn Webster. Dr. Portenoy, former Chairman of the Department of Pain Medicine and Palliative Care

[49] The amount includes $108 million spent by Purdue, $13 million by Teva, $10 million by Endo, and $2 million by Allergan.

at Beth Israel Medical Center in New York, received research support, consulting fees, and honoraria from Cephalon/Teva, Endo, and Purdue (among others), and was a paid consultant to Cephalon/Teva and Purdue. Dr. Portenoy was instrumental in opening the door for the regular use of opioids to treat chronic pain. He served on the American Pain Society ("APS")/American Academy of Pain Medicine ("AAPM") Guidelines Committees, which endorsed the use of opioids to treat chronic pain, first in 1996 and again in 2009. He was also a member of the board of the American Pain Foundation ("APF"), which issued education guides for patients, reporters, and policy makers that touted the benefits of opioids for chronic pain and trivialized their risks, particularly the risk of addiction.

113. Dr. Portenoy later admitted that he "gave innumerable lectures in the late 1980s and '90s about addiction that weren't true." These lectures falsely claimed that fewer than 1% of patients would become addicted to opioids. According to Dr. Portenoy, because the primary goal was to "destigmatize" opioids, he and other doctors promoting them overstated their benefits and glossed over their risks. Dr. Portenoy also conceded that "[d]ata about the effectiveness of opioids does not exist."[50] Dr. Portenoy candidly stated: "Did I teach about pain management, specifically about opioid therapy, in a way that reflects misinformation? Well, ... I guess I did."[51]

114. Dr. Lynn Webster was the co-founder and Chief Medical Director of Lifetree Clinical Research, a pain clinic in Salt Lake City, Utah. Dr. Webster was President of the AAPM in 2013. He is a Senior Editor of Pain Medicine, which published Endo special advertising supplements touting Opana ER. Dr. Webster was the author of numerous CMEs sponsored by

[50] Thomas Catan & Evan Perez, *A Pain-Drug Champion Has Second Thoughts*, Wall St. J., Dec. 17, 2012, https://www.wsj.com/articles/SB10001424127887324478304578173342657044604.
[51] *Id.*

Cephalon/Teva, Endo, and Purdue. At the same time. Dr. Webster was receiving significant funding from Manufacturer Defendants (including nearly $2 million from Cephalon/Teva).

115. Dr. Webster created and promoted the Opioid Risk Tool, a five question, one-minute screening tool relying on patient self-reports that purportedly allows doctors to manage the risk that their patients will become addicted to or abuse opioids. The claimed ability to pre-sort patients likely to become addicted is an important tool in giving doctors confidence to prescribe opioids long-term, and for this reason, references to screening tools appear in various industry-supported guidelines. Versions of Dr. Webster's Opioid Risk Tool appear on, or are linked to, websites run by Endo and Purdue.

116. Dr. Webster also was a leading proponent of the concept of "pseudoaddiction," the notion that addictive behaviors should be seen not as warnings, but as indications of undertreated pain. As he and co-author Beth Dove wrote in their 2007 book *Avoiding Opioid Abuse While Managing Pain* - a book that is still available online - when faced with signs of aberrant behavior, increasing the dose "in most cases ... should be the clinician's first response."[52] Upon information and belief, Endo distributed this book to doctors. Years later, Dr. Webster reversed himself, acknowledging that "[pseudoaddiction] obviously became too much of an excuse to give patients more medication."[53]

Front Groups

117. Manufacturer Defendants also entered into arrangements with seemingly unbiased and independent patient and professional organizations to misleadingly promote opioids for the treatment of chronic pain. Under the direction and control of Manufacturer Defendants, these

[52] Lynn Webster & Beth Dove, *Avoiding Opioid Abuse While Managing Pain* (2007).
[53] John Fauber, *Painkiller Boom Fueled by Networking*, Milwaukee Wisc. J. Sentinel, Feb. 18, 2012, http://archive.jsonline.com/watchdog/watchdogreports/painkiller-boom-fueled-by-networking-dp3p2rn-139609053.html/.

Front Groups generated treatment guidelines, unbranded materials, and programs that touted the benefits of and minimized the risk associated with chronic opioid therapy. The Front Groups also assisted Manufacturer Defendants by responding to negative articles, by advocating against regulatory changes that would limit opioid prescribing in accordance with the scientific evidence, and by conducting outreach to vulnerable patient populations targeted by Manufacturer Defendants.

118. These Front Groups depended on Manufacturer Defendants for funding and, in some cases, for survival. Manufacturer Defendants exercised control over programs and materials created by these groups by collaborating on, editing, and approving their content. Manufacturer Defendants also funded their dissemination. In doing so, Manufacturer Defendants made sure that the Front Groups would generate only the messages that Manufacturer Defendants wanted to distribute. Despite this, the Front Groups held themselves out as independent entities serving the needs of their members – whether patients suffering from pain or doctors treating those patients.

119. Several of the most prominent of Manufacturer Defendants' Front Groups were the APF, APS, American Geriatrics Society ("AGS"), the Federation of State Medical Boards ("FSMB"), American Chronic Pain Association ("ACPA"), the Center for Practical Bioethics ("CPB"), the U.S. Pain Foundation ("USPF") and Pain & Policy Studies Group ("PPSG").[54]

120. The most well-known of these was the APF, which, upon information and belief, received more than $10 million in funding from opioid manufacturers from 2007 until it closed in May 2012. APF issued education guides for patients, reporters, and policy makers that touted

[54] *See generally, e.g.*, Letter from Sen. Ron Wyden, U.S. Senate Comm. On Fin., to Sec. Thomas E. Price, U.S. Dep't of Health and Human Servs., (May 5, 2015), https://www.finance.senate.gov/imo/media/doc/050817%20corrected%20Senator%20Wyden%20to%20Secretary%20Price%20re%20FDA%20Opioid%20Prescriber%20Working%20Group%20(5%20May%202017).pdf.

the benefits of opioids for chronic pain and trivialized their risks, particularly the risk of addiction. APF also launched a campaign to promote opioids for returning veterans, which has contributed to high rates of addiction and other adverse outcomes, including death, among returning soldiers. APF also engaged in a significant multimedia campaign, through radio, television and the internet, to educate patients about their "right" to pain treatment, namely opioids. All of APF's programs and materials were available nationally and were intended to reach citizens of the state.

121. The U.S. Senate Finance Committee began looking into APF in May 2012 to determine the links, financial and otherwise, between the organization and the manufacturers of opioid painkillers. The investigation caused considerable damage to APF's credibility as an objective and neutral third party, and Manufacturer Defendants stopped funding it. Within days of being targeted by the Senate investigation, APF's board voted to dissolve the organization "due to irreparable economic circumstances." APF "cease[d] to exist, effective immediately."[55]

122. Another Front Group for Manufacturer Defendants was the AAPM. With the assistance, prompting, involvement, and funding of Manufacturer Defendants, the AAPM issued purported treatment guidelines and sponsored and hosted medical education programs essential to Manufacturer Defendants' deceptive marketing of chronic opioid therapy.

123. The AAPM and the APS issued a joint guideline in 2009 ("AAPM/APS Guidelines") which recommended the use of opioids to treat chronic pain while overstating the benefits and downplaying the risks.[56] Doctors, especially the general practitioners and family

[55] Charles Ornstein & Tracy Weber, *Senate Panel Investigates Drug Companies' Ties to Pain Groups*, Wash. Post, May 8, 2012, https://www.washingtonpost.com/national/health-science/senate-panel-investigates-drug-companies-ties-to-pain-groups/2012/05/08/gIQA2X4qBU_story.html?utm_term=.70927b42a0aa.

[56] Roger Chou *et al.*, *Clinical Guidelines for the Use of Chronic Opioid Therapy in Chronic Non-Cancer Pain*, 10 J. Pain 113 (2009).

doctors targeted by Manufacturer Defendants, rely upon these treatment guidelines. Treatment guidelines not only directly inform doctors' prescribing practices but are cited throughout the scientific literature and referenced by third-party payors in determining whether they should cover treatments for specific indications. Pharmaceutical sales representatives employed by Endo, Allergan, and Purdue discussed the AAPM/APS Guidelines with doctors during individual sales visits.

124. Manufacturer Defendants worked together, through these Front Groups, to spread their deceptive messages about the risks and benefits of long-term opioid therapy.

B. Manufacturer Defendants' Marketing Scheme Misrepresented the Risks and Benefits of Opioids.

i. Manufacturer Defendants embarked upon a campaign of false, deceptive, and unfair representations grossly understating and misstating the dangerous addiction risks of the opioid drugs.

125. To convince physicians and patients that opioids are safe, Manufacturer Defendants deceptively trivialized and failed to disclose the risks of long-term opioid use, particularly the risk of addiction, through a series of misrepresentations that have been conclusively debunked by the FDA and CDC. These misrepresentations, often aimed at general practitioners and family doctors who lack the time and expertise to closely manage higher-risk patients on opioids, achieved their intended effect. Manufacturer Defendants' misrepresentations made these doctors feel more comfortable prescribing opioids to their patients and patients more comfortable starting opioid therapy for chronic pain. The misrepresentations, described below, reinforced each other and created the dangerously misleading impression that: (1) starting patients on opioids was low risk because most patients would not become addicted and because those at greatest risk for addiction could be identified and managed; (2) patients who displayed signs of addiction probably were not addicted and, in any event, could easily be weaned from the

drugs; (3) the use of higher opioid doses, which many patients need to sustain pain relief as they develop tolerance to the drugs, do not pose special risks; (4) opioid dependence can be easily overcome via tapering or other methods; and (5) the use of abuse-deterrent opioids lowers the risk of addiction and overdose. Manufacturer Defendants have not only failed to correct these misrepresentations, they continue to make them today.

126. The first category of false, deceptive, and unfair claims utilized by Manufacturer Defendants to convince doctors that opioids were safe for the long term treatment of pain is that the risk of addiction was low. However these claims are contrary to the longstanding scientific evidence. The CDC explained in its opioid-prescription guideline (the "2016 CDC Guideline") that there is "[e]xtensive evidence" of the "possible harms of opioids (including opioid use disorder [an alternative term for opioid addiction], [and] overdose . . .)."[57] The 2016 CDC Guideline states that "[o]pioid pain medication use presents serious risks, including overdose and opioid use disorder" and that "continuing opioid therapy for 3 months substantially increases risk for opioid use disorder."[58]

127. The FDA further exposed the falsity of Manufacturer Defendants' claims about the low risk of addiction when it announced changes to the labels for extended-release and long-acting ("ER/LA") opioids in 2013 and for immediate release ("IR") opioids in 2016. In its announcements, the FDA found that "most opioid drugs have 'high potential for abuse'" and that opioids "are associated with a substantial risk of misuse, abuse, NOWS [neonatal opioid withdrawal syndrome], addiction, overdose, and death." According to the FDA, because of the "known serious risks" associated with long-term opioid use, including "risks of addiction, abuse, and misuse, even at recommended doses, and because of the greater risks of overdose and

[57] Deborah Dowell *et al.*, *CDC Guideline for Prescribing Opioids for Chronic Pain—United States, 2016*, Morbidity & Mortality Wkly. Rep., Mar. 18, 2016, at 15.
[58] *Id.* at 2, 25.

death," opioids should be used only "in patients for whom alternative treatment options" like non-opioid drugs have proved inadequate.[59]

128. In addition to mischaracterizing the highly addictive nature of the drugs they were pushing, Manufacturer Defendants also fostered a fundamental misunderstanding of the signs of addiction. Specifically, Manufacturer Defendants misrepresented, to doctors and patients, that warning signs and/or symptoms of addiction were, instead, signs of undertreated pain and instructed doctors to increase the opioid prescription dose for patients who were already in danger. Dr. David Haddox, who would become a vice president at Purdue, termed this supposed phenomenon as "pseudoaddiction."

129. The CDC rejected the validity of pseudoaddiction, as it was a reason to push more opioid drugs onto already addicted patients.

130. A third category of false, deceptive, and unfair representations made by Manufacturer Defendants was that addiction risk screening tools, patient contracts, urine drug screens, and similar strategies allow doctors to reliably identify and safely prescribe opioids to patients predisposed to addiction.

131. The 2016 CDC Guideline confirms the lack of support for these claims. In its guideline, the CDC explains that there are no studies assessing the effectiveness of risk mitigation strategies "for improving outcomes related to overdose, addiction, abuse or misuse."[60]

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[59] Letter from Janet Woodcock, M.D., Dir., Ctr. For Drug Evaluation and Research, U.S. Food and Drug Admin., U.S. Dep't of Health and Human Servs., to Andrew Kolodny, M.D., President, Physicians for Responsible Opioid Prescribing (Sept. 10, 2013), https://www.regulations.gov/contentStreamer?documentId=FDA-2012-P-0818-0793&attachmentNumber=1&contentType=pdf.; Letter from Janet Woodcock, M.D., Dir., Ctr. For Drug Evaluation and Research, U.S. Food and Drug Admin., U.S. Dep't of Health and Human Servs., to Peter R. Mathers & Jennifer A. Davidson, Kleinfeld, Kaplan and Becker, LLP (Mar. 22, 2016), https://www.regulations.gov/contentStreamer?documentId=FDA-2014-P-0205-0006&attachmentNumber=1&contentType=pdf.

[60] Deborah Dowell et al., *CDC Guideline for Prescribing Opioids for Chronic Pain*—United States, 2016, Morbidity & Mortality Wkly. Rep., Mar. 18, 2016, at 15, https://www.cdc.gov/mmwr/volumes/65/rr/rr6501e1.htm.

132. A fourth category of deceptive messaging regarding dangerous opioids is Manufacturer Defendants' misrepresentations that opioid dependence could be easily eliminated. Manufacturer Defendants falsely claimed that opioid dependence can easily be addressed by tapering and that opioid withdrawal is not a problem, but they failed to disclose the increased difficulty of stopping opioids after long-term use.

133. In truth, the 2016 CDC Guideline explains that the symptoms of opioid withdrawal include abdominal pain, vomiting, diarrhea, sweating, tremor, tachycardia, drug cravings, anxiety, insomnia, spontaneous abortion, and premature labor in pregnant women.[61]

134. A fifth category of false, deceptive, and unfair statements made by Manufacturer Defendants to sell more of their drugs is that opioid dosages could be increased indefinitely without added risk. The ability to escalate dosages was critical to Manufacturer Defendants' efforts to market opioids for long-term use to treat chronic pain because, absent this misrepresentation, doctors would have abandoned treatment when patients built up tolerance and lower dosages did not provide pain relief.

135. Once again, the 2016 CDC Guideline reveals that Manufacturer Defendants' representations were lacking in scientific evidence. The 2016 CDC Guideline clarifies that the "[b]enefits of high-dose opioids for chronic pain are not established" while the "risks for serious harms related to opioid therapy increase at higher opioid dosage."[62] More specifically, the CDC explains that "there is now an established body of scientific evidence showing that overdose risk is increased at higher opioid dosages."[63] The CDC also states that there is an increased risk "for opioid use disorder, respiratory depression, and death at higher dosages."[64] That is why the CDC

[61] *Id.* at 26.
[62] 2016 CDC Guideline, *supra* note 57, at 22–23.
[63] *Id.* at 23–24.
[64] *Id.* at 21.

advises doctors to "avoid increasing dosage" to above 90 morphine milligram equivalents per day.[65] Additionally, a CDC clinical evidence review found that higher opioid dosages were associated with increased risks of motor vehicle injury, opioid use disorder, and overdoses, and that the increased risk rises in a dose-dependent manner. Another study found that higher daily doses and possible opioid misuse were also strong predictors of continued use, and associated with increased risk of overdoses, fractures, dependence, and death.

136. Manufacturer Defendants made misleading claims about the ability of their so-called abuse-deterrent opioid formulations to deter abuse. For example, Endo's advertisements for the 2012 reformulation of Opana ER claimed that it was designed to be crush resistant, in a way that suggested it was more difficult to abuse. This claim was false. The FDA warned in a 2013 letter that Opana ER Extended-Release Tablets' "extended-release features can be compromised, causing the medication to 'dose dump,' when subject to . . . forms of manipulation such as cutting, grinding, or chewing, followed by swallowing."[66] Endo's own studies, which it failed to disclose, showed that Opana ER could still be ground and chewed. In June 2017, the FDA requested that Opana ER be removed from the market.

i. Manufacturer Defendants embarked upon a campaign of false, deceptive, and unfair representations grossly overstating the benefits of the opioid drugs.

137. To convince doctors and patients that opioids should be used to treat chronic pain, Manufacturer Defendants also had to persuade them that there were significant benefits to long-term opioid therapy. Manufacturer Defendants falsely and misleadingly touted the benefits of

[65] *Id.* at 16.

[66] Letter from Janet Woodcock, M.D., Dir., Ctr. For Drug Evaluation and Research, U.S. Food and Drug Admin., U.S. Dep't of Health and Human Servs., to Robert Barto, Vice President, Reg. Affairs, Endo Pharm. Inc. (May 10,2013), at 5.

long-term opioid use and falsely and misleadingly suggested that scientific evidence supported these benefits.

138. But as the CDC Guideline makes clear, "[n]o evidence shows a long-term benefit of opioids in pain and function versus no opioids for chronic pain with outcomes examined at least 1 year later (with most placebo-controlled randomized trials ≤ 6 weeks in duration)" and that other treatments were more or equally beneficial and less harmful than long-term opioid use.[67]

139. In 2010, the FDA warned Allergan, in response to its advertising of Kadian, that "we are not aware of substantial evidence or substantial clinical experience demonstrating that the magnitude of the effect of the drug [Kadian] has in alleviating pain, taken together with any drug-related side effects patients may experience . . . results in any overall positive impact on a patient's work, physical and mental functioning, daily activities, or enjoyment of life."[68] And in 2008, upon information and belief, the FDA sent a warning letter to an opioid manufacturer, making it clear "that [the claim that] patients who are treated with the drug experience an improvement in their overall function, social function, and ability to perform daily activities . . . has not been demonstrated by substantial evidence or substantial clinical experience."

140. Manufacturer Defendants also falsely and misleadingly emphasized or exaggerated the risks of competing medications like nonsteroidal anti-inflammatory drugs ("NSAIDs"), so that doctors and patients would look to opioids first for the treatment of chronic pain. Once again, these misrepresentations by Manufacturer Defendants contravene pronouncements by and guidance from the FDA and CDC based on the scientific evidence.

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[67] *Id.* at 15.

[68] Letter from Thomas Abrams, Dir., Div. of Drug Mktg., Advert., & Commc'ns, U.S. Food & Drug Admin., to Doug Boothe, CEO, Actavis Elizabeth LLC (Feb. 18, 2010), https://www.fdanews.com/ext/resources/files/archives/a/ActavisElizabethLLC.pdf

Indeed, the FDA changed the labels for ER/LA opioids in 2013 and IR opioids in 2016 to state that opioids should only be used as a last resort "in patients for which alternative treatment options" like non-opioid drugs "are inadequate." And the 2016 CDC Guideline states that NSAIDs, not opioids, should be the first-line treatment for chronic pain, particularly arthritis and lower back pain.[69]

141. Purdue and the APF misleadingly promoted OxyContin as being unique among opioids in providing 12 continuous hours of pain relief with one dose. In fact, OxyContin does not last for 12 hours – a fact that Purdue has known at all times relevant to this action. Upon information and belief, Purdue's own research shows that OxyContin wears off in under six hours in one quarter of patients and in under 10 hours in more than half.

142. Cephalon/Teva deceptively marketed and continues to market its opioids Actiq and Fentora for chronic pain even though the FDA has expressly limited their use to the treatment of cancer pain in opioid tolerant individuals. Both Actiq and Fentora are extremely powerful fentanyl-based IR opioids. Neither is approved for or has been shown to be safe or effective for chronic pain. Indeed, the FDA expressly prohibited Cephalon/Teva from marketing Actiq for anything but cancer pain and refused to approve Fentora for the treatment of chronic pain because of the potential harm, including the high risk of "serious and life-threatening adverse events" and abuse – which are greatest in non-cancer patients.

[69] 2016 CDC Guideline, *supra* note 57, at 12.

ii. Each Manufacturer Defendant Made Materially Deceptive Statements and Concealed Material Facts in the Promotion of Their Opioid Products.

Purdue

143. Purdue made and/or disseminated deceptive statements and concealed material facts in marketing prescription opioids through multiple avenues, including but not limited to the following:

- Creating, sponsoring, and assisting in the distribution of patient education materials distributed to consumers that contained deceptive statements;
- Creating and disseminating advertisements that contained deceptive statements concerning the ability of opioids to improve function long-term and concerning the evidence supporting the efficacy of opioids long-term for the treatment of chronic non-cancer pain;
- Disseminating misleading statements concealing the true risk of addiction and promoting the deceptive concept of pseudoaddiction through Purdue's own unbranded publications and on internet sites Purdue operated that were marketed to and accessible by consumers;
- Distributing brochures to doctors, patients, and law enforcement officials that included deceptive statements concerning the indicators of possible opioid abuse;
- Sponsoring, directly distributing, and assisting in the distribution of publications that promoted the deceptive concept of pseudoaddiction, even for high-risk patients;
- Endorsing, directly distributing, and assisting in the distribution of publications that presented an unbalanced treatment of the long-term and dose-dependent risks of opioids versus NSAIDs;
- Providing significant financial support to pro-opioid KOL doctors who made deceptive statements concerning the use of opioids to treat chronic non-cancer pain;
- Providing needed financial support to pro-opioid pain organizations that made deceptive statements, including in patient education materials, concerning the use of opioids to treat chronic non-cancer pain;

- Assisting in the distribution of guidelines that contained deceptive statements concerning the use of opioids to treat chronic non-cancer pain and misrepresented the risks of opioid addiction;

- Endorsing and assisting in the distribution of CMEs containing deceptive statements concerning the use of opioids to treat chronic non-cancer pain;

- Developing and disseminating scientific studies that misleadingly concluded opioids are safe and effective for the long-term treatment of chronic non-cancer pain and that opioids improve quality of life, while concealing contrary data;

- Assisting in the dissemination of literature written by pro-opioid KOLs that contained deceptive statements concerning the use of opioids to treat chronic non-cancer pain;

- Creating, endorsing, and supporting the distribution of patient and prescriber education materials that misrepresented the data regarding the safety and efficacy of opioids for the long-term treatment of chronic non-cancer pain, including known rates of abuse and addiction and the lack of validation for long-term efficacy;

- Targeting veterans by sponsoring and disseminating patient education marketing materials that contained deceptive statements concerning the use of opioids to treat chronic non-cancer pain;

- Targeting the elderly by assisting in the distribution of guidelines that contained deceptive statements concerning the use of opioids to treat chronic non-cancer pain and misrepresented the risks of opioid addiction in this population;

- Exclusively disseminating misleading statements in education materials to hospital doctors and staff while purportedly educating them on new pain standards;

- Making deceptive statements concerning the use of opioids to treat chronic non-cancer pain to prescribers through in-person detailing; and

- Withholding from law enforcement the names of prescribers Purdue believed to be facilitating the diversion of its opioids, while simultaneously marketing opioids to these doctors by disseminating patient and prescriber education materials and advertisements and CMEs they knew would reach these same prescribers.

144. Illustrative examples of Purdue's false, deceptive and/or unfair claims include the following:

- Purdue published a pamphlet in 2011 entitled Providing Relief, Preventing Abuse, which, upon information and belief, described pseudoaddiction as a concept that "emerged in the literature" to describe the inaccurate interpretation of [drug-seeking behaviors] in patients who have pain that has not been effectively treated."

- Upon information and belief, Purdue ran a series of ads, called "pain vignettes," for OxyContin in 2012 in medical journals. These ads featured chronic pain patients and recommended OxyContin for each. One ad described a "54-year-old writer with osteoarthritis of the hands" and implied that OxyContin would help the writer work more effectively.

- Upon information and belief, Purdue's "In the Face of Pain" website promoted the notion that if a patient's doctor does not prescribe what, in the patient's view, is a sufficient dosage of opioids, he or she should find another doctor who will.

- Purdue presented a 2015 paper at the College on the Problems of Drug Dependence challenging the correlation between opioid dosage and overdose.[70]

- Upon information and belief, Purdue sponsored a CME program titled "Path of the Patient, Managing Chronic Pain in Younger Adults at Risk for Abuse." In a role play, a chronic pain patient with a history of drug abuse tells his doctor that he is taking twice as many hydrocodone pills as directed. The narrator notes that because of pseudoaddiction, the doctor should not assume the patient is addicted even if he persistently asks for a specific drug, seems desperate, hoards medicine, or "overindulges in unapproved escalating doses." The doctor treats this patient by prescribing a high-dose, long-acting opioid.

- Upon information and belief, Purdue sponsored a 2011 webinar, "Managing Patient's Opioid Use: Balancing the Need and Risk," which claimed that screening tools, urine tests, and patient agreements prevent "overuse of prescriptions" and "overdose deaths."

- As recently as 2015, upon information and belief, Purdue has represented in scientific conferences that "bad apple" patients – and not opioids – are the source of the addiction crisis and that once those "bad apples" are identified, doctors can safely prescribe opioids without causing addiction.

[70] The College on Problems of Drug Dependence, *About the College*, http://cpdd.org (last visited Dec. 27, 2017).

- In 2007, Purdue sponsored a CME entitled "Overview of Management Options" that was available for CME credit and available until at least 2012. The CME was edited by a KOL and taught that NSAIDs and other drugs, but not opioids, are unsafe at high dosages.

- Purdue sponsored APF's A Policymaker's Guide to Understanding Pain & Its Management, which claims that less than 1% of children prescribed opioids will become addicted and that pain is undertreated due to "[m]isconceptions about opioid addiction."[71] The guide further taught that dosage escalations are "sometimes necessary," and that "the need for higher doses of medication is not necessarily indicative of addiction," but inaccurately downplayed the risks from high opioid dosages.[72]

- Purdue (along with Cephalon/Teva) sponsored APF's "Treatment Options: A Guide for People Living with Pain (2007)," which suggested that addiction is rare and limited to extreme cases of unauthorized dose escalations, obtaining duplicative opioid prescriptions from multiple sources, or theft. The guide further claims that some patients "need" a larger dose of an opioid, regardless of the dose currently prescribed. The guide stated that opioids have "no ceiling dose" and insinuated that they are therefore the most appropriate treatment for severe pain.[73] The guide also counseled patients that opioids "give [pain patients] a quality of life we deserve."[74] This publication is still available online.[75]

- Purdue (along with Endo and Cephalon/Teva) sponsored and/or distributed "Responsible Opioid Prescribing" (2007), which taught that behaviors such as "requesting drugs by name," "demanding or manipulative behavior," seeing more than one doctor to obtain opioids, and hoarding are all signs of pseudoaddiction, rather than true addiction.[76] It also taught that relief of pain by opioids, by itself, improved patients' function.[77] The 2012 edition, which remains available for sale online, continues to teach that pseudoaddiction is real.[78]

- Seeking to overturn the criminal conviction of a doctor for illegally prescribing opioids, APF and NFP, Front Groups for Manufacturer Defendants, including Purdue, argued in an *amicus* brief to the United

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[71] Am. Pain Found., *A Policymaker's Guide to Understanding Pain and Its Management* 6 (2011) [hereinafter APF, *Policymaker's Guide*], http://assets.documentcloud.org/documents/277603/apf-policymakers-guide.pdf.
[72] *Id.* at 32.
[73] Am. Pain Found., *Treatment Options: A Guide for People Living in Pain* (2007) [hereinafter APF, *Treatment Options*], https://assets.documentcloud.org/documents/277605/apf-treatmentoptions.pdf.
[74] *Id.*
[75] *Id.*
[76] Scott M. Fishman, M.D., *Responsible Opioid Prescribing: A Physician's Guide* (2007) at 62.
[77] *Id.*
[78] *See* Scott M. Fishman, M.D., *Responsible Opioid Prescribing: A Physician's Guide* (2d ed. 2012).

States Fourth Circuit Court of Appeals that "patients rarely become addicted to prescribed opioids," citing research by their KOL, Dr. Portenoy.[79] The *amicus* brief also argued that "there is no 'ceiling dose'" for opioids.[80]

Endo

145. Endo made and/or disseminated deceptive statements and concealed material facts in marketing prescription opioids through multiple avenues, including but not limited to the following:

- Creating, sponsoring, and assisting in the distribution of patient education materials that contained deceptive statements;
- Creating and disseminating advertisements that contained deceptive statements concerning the ability of opioids to improve function long-term and concerning the evidence supporting the efficacy of opioids long-term for the treatment of chronic non-cancer pain;
- Creating and disseminating paid advertisement supplements in academic journals promoting chronic opioid therapy as safe and effective for long term use for high risk patients;
- Creating and disseminating advertisements that falsely and inaccurately conveyed the impression that Endo's opioids would provide a reduction in oral, intranasal, or intravenous abuse;
- Disseminating misleading statements concealing the true risk of addiction and promoting the misleading concept of pseudoaddiction through Endo's own unbranded publications and on internet sites Endo sponsored or operated;
- Endorsing, directly distributing, and assisting in the distribution of publications that presented an unbalanced treatment of the long-term and dose-dependent risks of opioids versus NSAIDs;
- Providing significant financial support to pro-opioid KOLs, who made deceptive statements concerning the use of opioids to treat chronic non-cancer pain;

[79] Brief of the American Pain Foundation, the National Pain Foundation, and the National Foundation for the Treatment of Pain in Support of Appellant and Reversal of the Conviction, *United States v. Hurowitz*, No.05-4474 (4th Cir. Sept. 8, 2005) [hereinafter Brief of APF] at 9.
[80] *Id.*

- Providing needed financial support to pro-opioid pain organizations – including over $5 million to the organization responsible for many of the most egregious misrepresentations – that made deceptive statements, including in patient education materials, concerning the use of opioids to treat chronic non-cancer pain;

- Targeting the elderly by assisting in the distribution of guidelines that contained deceptive statements concerning the use of opioids to treat chronic non-cancer pain and misrepresented the risks of opioid addiction in this population;

- Endorsing and assisting in the distribution of CMEs containing deceptive statements concerning the use of opioids to treat chronic non-cancer pain;

- Developing and disseminating scientific studies that deceptively concluded opioids are safe and effective for the long-term treatment of chronic non-cancer pain and that opioids improve quality of life, while concealing contrary data;

- Directly distributing and assisting in the dissemination of literature written by pro-opioid KOLs that contained deceptive statements concerning the use of opioids to treat chronic non-cancer pain, including the concept of pseudoaddiction;

- Creating, endorsing, and supporting the distribution of patient and prescriber education materials that misrepresented the data regarding the safety and efficacy of opioids for the long-term treatment of chronic non-cancer pain, including known rates of abuse and addiction and the lack of validation for long-term efficacy; and

- Making deceptive statements concerning the use of opioids to treat chronic non- cancer pain to prescribers through in-person detailing.

146. Illustrative examples of Endo's false, deceptive, and/or unfair claims include the following:

- Endo sponsored a website, "Pain Knowledge," which, upon information and belief, claimed in 2009 that "[p]eople who take opioids as prescribed usually do not become addicted" and that opioid dosages may be increased until "you are on the right dose of medication for your pain." Additionally, upon information and belief, the website claimed 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." Elsewhere, the website touted improved quality of life (as well as "improved function") as

benefits of opioid therapy. The grant request that Endo approved for this project specifically indicated National Initiative on Pain Control's ("NIPC") intent to make misleading claims about function.

- Upon information and belief, another Endo website, PainAction.com, stated "Did you know? Most chronic pain patients do not become addicted to the opioid medications that are prescribed for them." Endo also distributed an "Informed Consent" document on PainAction.com that misleadingly suggested that only people who "have problems with substance abuse and addiction" are likely to become addicted to opioid medications.

- Upon information and belief, Endo distributed a pamphlet with the Endo logo entitled "Living with Someone with Chronic Pain," which stated that: "Most health care providers who treat people with pain agree that most people do not develop an addiction problem."

- Endo paid for a 2007 supplement in the Journal of Family entitled "Pain Management Dilemmas in Primary Care: Use of Opioids," which emphasized the effectiveness of screening tools, claiming that patients at high risk of addiction could safely receive chronic opioid therapy using a "maximally structured approach" involving toxicology screens and pill counts.

- Endo distributed and made available on its website (opana.com) a pamphlet promoting Opana ER with photographs depicting patients with physically demanding jobs, such as construction workers, chefs, and teachers, implying that the drug would provide long-term pain-relief and functional improvement.

- Endo distributed a pamphlet edited by a KOL entitled "Understanding Your Pain: Taking Oral Opioid Analgesics" (2004 Endo Pharmaceuticals PM-0120). In Q & A form at, it asked "If I take the opioid now, will it work later when I really need it?" The response is, "The dose can be increased. . . You won't 'run out' of pain relief."[81]

- Endo distributed "Responsible Opioid Prescribing" (2007), which taught that behaviors such as "requesting drugs by name," "demanding or manipulative behavior," seeing more than one doctor to obtain opioids, and hoarding are all signs of pseudoaddiction, rather than true addiction.[82] It also taught that relief of pain by opioids, by itself, improved patients'

[81] Margo McCaffery & Chris Pasero, Endo Pharm., *Understanding Your Pain: Taking Oral Opioid Analgesics.* (Russell K Portenoy, M.D., ed.,2004).
[82] Scott M. Fishman, M.D., *Responsible Opioid Prescribing: A Physician's Guide* (2007) at 62.

function.[83] The 2012 edition, which remains available for sale online, continues to teach that pseudoaddiction is real.[84]

- Endo sponsored a National Initiative on Pain Control ("NIPC") CME program in 2009 entitled "Chronic Opioid Therapy: Understanding Risk While Maximizing Analgesia," which, upon information and belief, promoted pseudoaddiction by teaching that a patient's aberrant behavior was the result of untreated pain. Endo appears to have substantially controlled NIPC by funding NIPC projects; developing, specifying, and reviewing content; and distributing NIPC materials.

- Endo was the sole sponsor, through NIPC, of a series of CMEs entitled "Persistent Pain in the Older Patient."[85] Upon information and belief, a CME disseminated via webcast claimed that chronic opioid therapy has been "shown to reduce pain and improve depressive symptoms and cognitive functioning."

- Seeking to overturn the criminal conviction of a doctor for illegally prescribing opioids, APF and NFP, Front Groups for Manufacturer Defendants (including Endo), argued in an *amicus* brief to the United States Fourth Circuit Court of Appeals that "patients rarely become addicted to prescribed opioids," citing research by their KOL, Dr. Portenoy.[86] The *amicus* brief also argued that "there is no 'ceiling dose'" for opioids.[87]

Mallinckrodt

147. Mallinckrodt made and/or disseminated deceptive statements and concealed facts in marketing prescription opioids through multiple avenues, including but not limited to the following:

- Creating, sponsoring, and assisting in the distribution of patient education materials that contained deceptive statements;

- Directly disseminating deceptive statements through internet sites over which Mallinckrodt exercised final editorial control and approval stating

[83] *Id.*
[84] *See* Scott M. Fishman, M.D., *Responsible Opioid Prescribing: A Physician's Guide* (2d ed. 2012).
[85] *E.g.*, NIPC, *Persistent Pain and the Older Patient* (2007), https://www.painedu.org/Downloads/NIPC/Activities/B173_Providence_RI_%20Invite.pdf
[86] Brief of the American Pain Foundation, the National Pain Foundation, and the National Foundation for the Treatment of Pain in Support of Appellant and Reversal of the Conviction, *United States v. Hurowitz*, No.05-4474 (4th Cir. Sept. 8, 2005) [hereinafter Brief of APF] at 9.
[87] *Id.*

that opioids are safe and effective for the long-term treatment of chronic non-cancer pain and that opioids improve quality of life while concealing contrary data;

- Disseminating deceptive statements concealing the true risk of addiction and promoting the deceptive concept of pseudoaddiction through internet sites over which Mallinckrodt exercised final editorial control and approval;

- Promoting opioids for the treatment of conditions for which Mallinckrodt knew, due to the scientific studies it conducted, that opioids were not efficacious and concealing this information;

- Sponsoring, directly distributing, and assisting in the dissemination of patient education publications over which Mallinckrodt exercised final editorial control and approval, which presented an unbalanced treatment of the long-term and dose dependent risks of opioids versus NSAIDs;

- Providing significant financial support to pro-opioid KOLs, who made deceptive statements concerning the use of opioids to treat chronic non-cancer pain;

- Providing necessary financial support to pro-opioid pain organizations that made deceptive statements, including in patient education materials, concerning the use of opioids to treat chronic non-cancer pain;

- Targeting the elderly by assisting in the distribution of guidelines that contained deceptive statements concerning the use of opioids to treat chronic non-cancer pain and misrepresented the risks of opioid addiction in this population;

- Targeting the elderly by sponsoring, directly distributing, and assisting in the dissemination of patient education publications targeting this population that contained deceptive statements about the risks of addiction and the adverse effects of opioids, and made false statements that opioids are safe and effective for the long-term treatment of chronic non-cancer pain and improve quality of life, while concealing contrary data;

- Endorsing and assisting in the distribution of CMEs containing deceptive statements concerning the use of opioids to treat chronic non-cancer pain;

- Directly distributing and assisting in the dissemination of literature written by pro-opioid KOLs that contained deceptive statements concerning the use of opioids to treat chronic non-cancer pain, including the concept of pseudoaddiction;

- Creating, endorsing, and supporting the distribution of patient and prescriber education materials that misrepresented the data regarding the safety and efficacy of opioids for the long-term treatment of chronic non-cancer pain, including known rates of abuse and addiction and the lack of validation for long-term efficacy;

- Targeting veterans by sponsoring and disseminating patient education marketing materials that contained deceptive statements concerning the use of opioids to treat chronic non-cancer pain; and

- Making deceptive statements concerning the use of opioids to treat chronic non- cancer pain to prescribers through in-person detailing.

148. Illustrative examples of Mallinckrodt's false, deceptive, and/or unfair claims include the following:

- Mallinckrodt, through an organization it controls called the C.A.R.E.S. (Collaborating and Acting Responsibly to Ensure Safety) Alliance, which ostensibly is devoted to responsible prescribing and reducing opioid pain medication abuse, published a book titled *Defeat Chronic Pain Now!* that made the following misrepresentations:

    1. "Only rarely does opioid medication cause a true addiction; It is currently recommended that every chronic pain patient suffering from moderate to severe pain be viewed as a potential candidate for opioid therapy."

    2. "When chronic pain patients take opioids to treat their pain, they rarely develop a true addiction and drug craving."

    3. "Only a minority of chronic pain patients who are taking long-term opioids develop tolerance."

    4. "The bottom line: Only 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."

    5. "Here are the facts. It 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."

    6. "Studies have shown that many chronic pain patients can experience significant pain relief with tolerable side effects from opioid narcotic medication when taken daily and no addiction.

When prescribed appropriately to a chronic pain patient who does not have a prior history of addiction."

- Mallinckrodt's website, in a section on responsible use of opioids, claims that "[t]he effective pain management offered by our medicines helps enable patients to stay in the workplace, enjoy interactions with family and friends, and remain an active member of society."[88]

- Seeking to overturn the criminal conviction of a doctor for illegally prescribing opioids, APF and NFP, Front Groups for Manufacturer Defendants (including Mallinckrodt), argued in an *amicus* brief to the United States Fourth Circuit Court of Appeals that "patients rarely become addicted to prescribed opioids," citing research by their KOL, Dr. Portenoy.[89] The *amicus* brief also argued that "there is no 'ceiling dose'" for opioids.[90]

Cephalon/Teva

149. Cephalon/Teva made and/or disseminated deceptive statements and concealed material facts in marketing prescription opioids through multiple avenues, including but not limited to the following:

- Creating, sponsoring, and assisting in the distribution of patient education materials that contained deceptive statements;

- Sponsoring and assisting in the distribution of publications that promoted the deceptive concept of pseudoaddiction, even for high-risk patients;

- Providing significant financial support to pro-opioid KOL doctors who made deceptive statements concerning the use of opioids to treat chronic non-cancer pain and break through chronic non-cancer pain;

- Developing and disseminating scientific studies that deceptively concluded opioids are safe and effective for the long-term treatment of chronic non-cancer pain in conjunction with Cephalon/Teva's potent rapid-onset opioids;

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[88] http://www.mallinckrodt.com/corporate-responsibility/responsible-use (Last Accessed October 25, 2018)

[89] Brief of the American Pain Foundation, the National Pain Foundation, and the National Foundation for the Treatment of Pain in Support of Appellant and Reversal of the Conviction, *United States v. Hurowitz*, No.05-4474 (4th Cir. Sept. 8, 2005) [hereinafter Brief of APF] at 9.

[90] Id.

- Providing needed financial support to pro-opioid pain organizations that made deceptive statements, including in patient education materials, concerning the use of opioids to treat chronic non-cancer pain;

- Endorsing and assisting in the distribution of CMEs containing deceptive statements concerning the use of opioids to treat chronic non-cancer pain;

- Endorsing and assisting in the distribution of CMEs containing deceptive statements concerning the use of Cephalon/Teva's rapid-onset opioids;

- Directing its marketing of Cephalon/Teva's rapid-onset opioids to a wide range of doctors, including general practitioners, neurologists, sports medicine specialists, and workers' compensation programs, serving chronic pain patients;

- Making deceptive statements concerning the use of Cephalon/Teva's opioids to treat chronic non-cancer pain to prescribers through in-person detailing and speakers' bureau events, when such uses are unapproved and unsafe; and

- Making deceptive statements concerning the use of opioids to treat chronic non-cancer pain to prescribers through in-person detailing and speakers' bureau events.

150. Illustrative examples of Cephalon/Teva's false, deceptive and/or unfair claims include the following:

- Cephalon/Teva (along with Purdue) sponsored APF's "Treatment Options: A Guide for People Living with Pain" (2007), which suggested that addiction is rare and limited to extreme cases of unauthorized dose escalations, obtaining duplicative opioid prescriptions from multiple sources, or theft. The guide further claims that some patients "need" a larger dose of an opioid, regardless of the dose currently prescribed. The guide stated that opioids have "no ceiling dose" and insinuated that they are therefore the most appropriate treatment for severe pain.[91] The guide also counseled patients that opioids "give [pain patients] a quality of life we deserve."[92] This publication is still available online.[93]

- Cephalon/Teva (along with Endo and Purdue) sponsored and/or distributed "Responsible Opioid Prescribing" (2007), which taught that behaviors such as "requesting drugs by name," "demanding or

[91] APF, *Treatment Options*, *supra* note 73, at 12.
[92] APF, *Treatment Options*, *supra* note 73.
[93] APF, *Treatment Options, supra* note 73.

manipulative behavior," seeing more than one doctor to obtain opioids, and hoarding are all signs of pseudoaddiction, rather than true addiction.[94] It also taught that relief of pain by opioids, by itself, improved patients' function.[95] The 2012 edition, which remains available for sale online, continues to teach that pseudoaddiction is real.[96]

- Seeking to overturn the criminal conviction of a doctor for illegally prescribing opioids, APF and NFP, Front Groups for Manufacturer Defendants (including Cephalon/Teva), argued in an *amicus* brief to the United States Fourth Circuit Court of Appeals that "patients rarely become addicted to prescribed opioids," citing research by their KOL, Dr. Portenoy.[97] The *amicus* brief also argued that "there is no 'ceiling dose'" for opioids.[98]

Allergan

151. Allergan made and/or disseminated deceptive statements and concealed materials facts in marketing prescription opioids through multiple avenues, including but not limited to the following:

- Making deceptive statements concerning the use of opioids to treat chronic non-cancer pain to prescribers through in-person detailing;
- Creating and disseminating advertisements that contained deceptive statements that opioids are safe and effective for the long-term treatment of chronic non-cancer pain and that opioids improve quality of life;
- Creating and disseminating advertisements that concealed the risk of addiction in the long-term treatment of chronic, non-cancer pain; and
- Developing and disseminating scientific studies that deceptively concluded opioids are safe and effective for the long-term treatment of chronic non-cancer pain and that opioids improve quality of life while concealing contrary data.

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[94] Scott M. Fishman, M.D., *Responsible Opioid Prescribing: A Physician's Guide* (2007) at 62.
[95] *Id.*
[96] The College on Problems of Drug Dependence, *About the College*, http://cpdd.org (last visited Dec. 27, 2017). *See* Scott M. Fishman, M.D., *Responsible Opioid Prescribing: A Physician's Guide* (2d ed. 2012).
[97] Brief of the American Pain Foundation, the National Pain Foundation, and the National Foundation for the Treatment of Pain in Support of Appellant and Reversal of the Conviction, *United States v. Hurowitz*, No.05-4474 (4th Cir. Sept. 8, 2005) [hereinafter Brief of APF] at 9.
[98] *Id.*

152. Illustrative examples of Allergan's false, deceptive and/or unfair claims include the following:

- Allergan's predecessor caused a patient education brochure, "Managing Chronic Back Pain," to be distributed beginning in 2003 that admitted that opioid addiction is possible, but misleadingly claimed that it is "less likely if you have never had an addiction problem." Based on Allergan's acquisition of its predecessor's marketing materials along with the rights to Kadian, it appears that Allergan continued to use this brochure in 2009 and beyond.
- Upon information and belief, Allergan distributed an advertisement claiming that the use of Kadian to treat chronic pain would allow patients to return to work, relieve "stress on your body and your mental health," and help patients enjoy their lives.

- Seeking to overturn the criminal conviction of a doctor for illegally prescribing opioids, APF and NFP, Front Groups for Manufacturer Defendants (including Allergan), argued in an *amicus* brief to the United States Fourth Circuit Court of Appeals that "patients rarely become addicted to prescribed opioids," citing research by their KOL, Dr. Portenoy.[99] The *amicus* brief also argued that "there is no 'ceiling dose'" for opioids.[100]

iii. Manufacturer Defendants Have a History of Criminal and Civil Charges for their Unlawful Conduct.

153. In 2007, Purdue settled criminal and civil charges concerning its misbranding of OxyContin and entered into a corporate integrity agreement with the Office of Inspector General of the U.S. Department of Health and Human Services. While the State of Georgia's damages related to the epidemic were unknown and were not correlated with Defendants' conduct at the time, Purdue was forced to admit it illegally marketed and promoted OxyContin by claiming it was less addictive and less subject to abuse than other pain medications. Purdue agreed to pay nearly $635 million in fines, and three of its executives pled guilty to federal criminal charges for misleading regulators, doctors, and patients about OxyContin's risk of addiction and its potential

[99] Brief of the American Pain Foundation, the National Pain Foundation, and the National Foundation for the Treatment of Pain in Support of Appellant and Reversal of the Conviction, *United States v. Hurowitz*, No.05-4474 (4th Cir. Sept. 8, 2005) [hereinafter Brief of APF] at 9.
[100] *Id.*

to be abused. At the time, this was one of the largest settlements with a drug company for marketing misconduct.[101]

154. While the State of Georgia's damages related to the epidemic were unknown and were not correlated with Defendants' conduct at the time, in 2008, Cephalon/Teva pled guilty to a criminal violation of the Federal Food, Drug and Cosmetic Act for its misleading promotion of Actiq and two other drugs and agreed to pay $425 million.[102]

155. In 2015, the Indiana Department of Public Health determined that an HIV outbreak in southeastern Indiana was linked to injection of the prescription painkiller Opana,[103] the first documented HIV outbreak in the United States associated with injection of a prescription painkiller. After the outbreak, the FDA required "that Endo Pharmaceuticals remove [Opana ER] from the market." The agency sought removal "based on its concern that the benefits of the drug may no longer outweigh its risks."[104]

156. In 2017, the Department of Justice fined Mallinckrodt $35 million for failure to report suspicious orders of controlled substances, including opioids, and for violating recordkeeping requirements.[105] Mallinckrodt was aware that it was fulfilling suspicious orders through chargeback data it collected to provide rebates or other discounts to the distributor or other third parties. Manufacturers of pharmaceuticals offer discounts, known as "chargebacks,"

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[101] Barry Meier, *In Guilty Plea, OxyContin Maker to Pay $600 Million*, N.Y. Times (May 10, 2007), http://www.nytimes.com/2007/05/10/business/11drug-web.html.

[102] Press Release, U.S. Dep't of Justice, Biopharmaceutical Company, Cephalon/Teva, to Pay $425 Million & Enter Plea to Resolve Allegations of Off-Label Marketing (Sept. 29, 2008), https://www.justice.gov/archive/opa/pr/2008/September/08-civ-860.html.

[103] Press Release, State of Indiana Health Department, *available at* http://www.in.gov/activecalendar/EventList.aspx?view=EventDetails&eventidn=210259&information_id=211489&type=&syndicate=syndicate.

[104] CNN Wire, *FDA wants Opioid at Center of Scott County HIV Outbreak Pulled off Market,* Fox59.com (June 9, 2017 7:45 A.M.) http://fox59.com/2017/06/09/fda-wants-opioid-at-centerof-scott-county-hiv-outbreak-pulled-off-market/; Press Release, FDA Requests Removal of Opana ER for Risks Related to Abuse, *available at* https://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm562401.htm.

[105] Press Release, *Mallinckrodt Agrees to Pay Record $35 Million Settlement for Failure to Report Suspicious Orders of Pharmaceutical Drugs and for Recordkeeping Violations, available at* https://www.affna.org/733572-2/.

based on sales to certain downstream customers. Distributors provide information on the downstream customer purchases to obtain the discount. The settlement requires a manufacturer to utilize chargeback and similar data to monitor and report to the DEA suspicious sales of its oxycodone at the next level in the supply chain, typically sales from distributors to independent and small chain pharmacy and pain clinic customers.

V. DISTRIBUTOR DEFENDANTS' UNLAWFUL DISTRIBUTION OF OPIOIDS

157. While Manufacturer Defendants created the demand for opioids, Distributor Defendants accelerated the opioid crisis which is arguably the worst drug crisis in Georgia and American history. Distributor Defendants serve as the critical choke point. They are obligated in Georgia, as well as to all states they do business in, to monitor, detect, report, investigate, or otherwise prevent the fulfillment of suspicious orders of prescription opioids destined for dispensing physicians and pharmacies in Georgia. If they fail in their duty, the foreseeable harm to the State of Georgia is the diversion of prescription opioids for illegitimate purposes.

158. Faced with this critically important duty, Distributor Defendants ignored it, and over time, flooded the market with opioid prescription drugs. These actions led to the widespread diversion of opioids for illegitimate purposes, which foreseeably devastated communities throughout the State of Georgia.

159. Distributor Defendants' unlawful conduct was actively concealed from the government authorities for years. Indeed, the State did not learn, and still does not know the full extent, of Distributor Defendants' unlawful conduct in Georgia until after the United States District Court overseeing the Multi-District Litigation in Cleveland ordered the full release of ARCOS data, which tracks and details each and every shipment of controlled substances throughout the country, including into the State of Georgia. This data, when viewed in its total

form, illustrates Distributor Defendants' indifference to their obligations. Additional discovery will reveal the full extent of Distributor Defendants' conduct.

A. Wholesale Drug Distributors are Obligated under State Law to Monitor, Detect, Report, Investigate, or Otherwise Prevent the Fulfillment of Suspicious Orders.

160. Opioids are a controlled substance and are categorized as having a "high potential for abuse" under Georgia law. *See* O.C.G.A. § 16-13-24; *see also* 21 U.S.C.A. §§ 812(b), 812(2)(A)-(C).

161. Distributor Defendants have numerous obligations under Georgia law related to the distribution of controlled substances. These obligations include the requirement that they operate in compliance with applicable Federal, State and local laws and regulations, including, among other things, the Georgia Controlled Substances Act, O.C.G.A. § 16-13-1, *et seq.* ("GCSA"), and the federal Controlled Substances Act[106]. These obligations are legal duties owed to the State of Georgia.

162. Each Defendant is required, pursuant to the GCSA, to register with the Georgia State Board of Pharmacy. Registration as a distributor in Georgia is contingent upon Distributor Defendants' maintenance of effective controls against diversion of controlled substances into other than legitimate medical, scientific, or industrial channels. *See, e.g.,* O.C.G.A. § 16-13-36. The State of Georgia relies on each Distributor Defendant's representation that it meets its duties.

163. Each Distributor Defendant was further required to register with the DEA, pursuant to the federal Controlled Substances Act. *See* GA. COMP. R. & REGS. 480-7-.03(10); 21

[106] *See* GA. COMP. R. & REGS. 480-7-.03(10) ("Wholesale drug distributors shall operate in compliance with applicable Federal, State, and local laws and regulations" and "[w]holesale drug distributors that deal in controlled substances shall register with the appropriate State controlled substance authority and with the Drug Enforcement Administration (DEA), and shall comply with all applicable State, Local, and DEA regulations").

U.S.C. § 823(b), (e); and 28 C.F.R. § 0.100. Each Distributor Defendant is a "registrant" as a wholesale distributor in the chain of distribution of Schedule II controlled substances with a duty to comply with all security requirements imposed under that statutory scheme.

164. Manufacturers and wholesale distributors have a duty to maintain adequate records of transactions involving a controlled substance. O.C.G.A. § 16-13-39.

165. Distributor Defendants are further obligated to "design and operate a system to disclose to the registrant [distributor] suspicious orders of controlled substances." *See* 21 C.F.R. § 1307.74(b); *see also* GA. COMP. R. & REGS. 480-7-.03(10).[107] Once discovered, Distributor Defendants have a duty to maintain records of suspicious orders of controlled substances received (GA. COMP. R. & REGS. 480-20-.02) and automatically submit reports of any suspicious orders of controlled substances to the Georgia Drugs and Narcotics Agency (O.C.G.A. § 26-4-115).

166. Suspicious orders include, but are not limited to, orders of unusual size, orders deviating substantially from a normal pattern, and orders of unusual frequency. O.C.G.A. § 26-4-115; 21 C.F.R. § 1301.74(b).

167. The suspicious order criteria are disjunctive and are not all inclusive.[108] For example, if an order deviates substantially from a normal pattern, the size of the order does not matter and the order should be reported as suspicious. Likewise, a wholesale distributor need not wait for a normal pattern to develop over time before determining whether an order is suspicious. The size of an order alone, regardless of whether it deviates from a normal pattern, is enough to

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[107] *See also* HDMA and the National Association of Chain Drug Stores ("NACDS"), 2016 WL 1321983, at *4 ("[R]egulations...in place for more than 40 years require distributors to report suspicious orders of controlled substances to DEA based on information readily available to them (e.g., a pharmacy's placement of unusually frequent or large orders).").

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

trigger the wholesale distributor's responsibility to report the order as suspicious. The determination of whether an order is suspicious depends not only on the ordering patterns of the customer but also on the patterns of the entirety of the wholesale distributor's customer base and the patterns throughout the relevant segment of the wholesale distributor industry. Distributor Defendants know all of this information the course and scope of their operations.[109]

168. In addition to reporting all suspicious orders, distributors know they must also stop shipment on any order flagged as suspicious, and only ship orders which were flagged as potentially suspicious if, after conducting due diligence, the ***distributor*** can determine that the order is not likely to be diverted into illegal channels. *See Southwood Pharm., Inc.*, 72 Fed. Reg. 36487-01, 36501 (Drug Enf't Admin. July 3, 2007); *Masters Pharmaceutical, Inc. v. DEA*, 861 F.3d 206 (D.C. Cir. 2017).

169. Fulfilling these obligations plays a critical role in protecting against the diversion of controlled substances. As the DEA advised all registrants, including each Defendant, in a letter dated September 27, 2006, wholesale distributors are "one of the key components of the distribution chain. If the closed system is to function properly … distributors must be vigilant in deciding whether a prospective customer can be trusted to deliver controlled substances only for lawful purposes." [110] According to the DEA, "***[t]his responsibility is critical***, as … the illegal distribution of controlled substances has a substantial and detrimental effect on the health and general welfare of the American people" and "just one distributor that uses its DEA registration

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[109] *Id.*

[110] *See* Letter from Joseph T. Rannazzisi, Deputy Assistant Adm'r, Office of Diversion Control, Drug. Enf't Admin., U.S. Dep't of Justice, to Cardinal Health (Sept. 27, 2006) [hereinafter Rannazzisi Letter] ("This letter is being sent to every commercial entity in the United States registered with the Drug Enforcement Agency (DEA) to distribute controlled substances. The purpose of this letter is to reiterate the responsibilities of controlled substance distributors in view of the prescription drug abuse problem our nation currently faces."), *filed in Cardinal Health, Inc. v. Holder*, No. 1:12-cv-00185-RBW (D.D.C. Feb. 10, 2012), ECF No. 14-51.

to facilitate diversion ***can cause enormous harm***." [111] Thus, all Defendants knew how critical their responsibility was to society, including to the State of Georgia.

170. In a second letter to all DEA registrants on December 27, 2007, the DEA again reminded Defendants of their statutory and regulatory duties to "maintain effective controls against diversion" and to "design and operate a system to disclose to the registrant suspicious orders of controlled substances."[112] The letter further explained:

- "Filing a monthly report of completed transactions (e.g., "excessive purchase report" or "high unity purchases") does not meet the regulatory requirement to report suspicious orders." Their responsibility "does not end merely with the filing of a suspicious order report ... [they] must conduct an independent analysis of suspicious orders prior to completing a sale to determine whether the controlled substances are likely to be diverted from legitimate channels. Reporting an order as suspicious will not absolve the registrant of responsibility if the registrant knew, or should have known, that the controlled substances were being diverted."

- Suspicious orders include "orders of unusual size, orders deviating substantially from a normal pattern, and orders of an unusual frequency. These criteria are disjunctive and are not inclusive. For example, if an order deviates substantially from a normal pattern, the size of the order does not matter and the order should be reported as suspicious."

- "Registrants that rely on rigid formulas to define whether an order is suspicious may be failing to detect suspicious orders. For example, a system that identifies orders as suspicious only if the total amount of a controlled substance ordered during one month exceeds the amount ordered the previous month by a certain percentage or more is insufficient. This system fails to identify orders placed by a pharmacy if the pharmacy placed unusually large orders from the beginning of its relationship with the distributor. Also, this system would not identify orders as suspicious if the order were solely for one highly abused controlled substance if the orders never grew substantially. Nevertheless, ordering one highly abused controlled substance and little or nothing else deviates from the normal pattern of what pharmacies generally order."

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[111] *Id.* at 2. (emphasis added).

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

- A drug distributor must, when reporting a suspicious order, "be clear in their communication with DEA that the registrant is actually characterizing an order as suspicious. Daily, weekly, or monthly reports submitted by registrant indicating 'excessive purchases' do not comply with the requirement to report suspicious orders, even if the registrant calls such reports 'suspicious order reports.'"

- Critically, drug distributors that "routinely report suspicious orders, yet fill these orders without first determining that order is not being diverted into other than legitimate medical, scientific, and industrial channels, may be failing to maintain effective controls against diversion. Failure to maintain effective controls against diversion is inconsistent with the public interest as that term is used in 21 U.S.C. 823 and 824, and may result in the revocation of the registrant's DEA Certificate of Registration." [113]

171. Distributor Defendants knew they were required to monitor, detect, investigate, report, and halt suspicious orders. Industry compliance guidelines established by the Healthcare Distribution Management Association ("HDMA"), the trade association of pharmaceutical distributors, explain that distributors are "[a]t the center of a sophisticated supply chain" and therefore "are uniquely situated to perform due diligence to help support the security of the controlled substances they deliver to their customers." The guidelines set forth recommended steps in the "due diligence" process, and note in particular: if an order meets or exceeds a distributor's threshold, as defined in the distributor's monitoring system, or is otherwise characterized by the distributor as an order of interest, the distributor should not ship to the customer, in fulfillment of that order, any units of the specific drug code product as to which the order met or exceeded a threshold or as to which the order was otherwise characterized as an order of interest.[114]

172. Distributor Defendants acknowledge that they "have not only statutory and regulatory responsibilities to detect and prevent diversion of controlled prescription drugs but

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[113] *Id.*

[114] Healthcare Distribution Management Association (HDMA) *Industry Compliance Guidelines: Reporting Suspicious Orders and Preventing Diversion of Controlled Substances, filed in Cardinal Health, Inc. v. Holder*, No. 12-5061 (D.C. Cir. Mar.7, 2012), Doc. No. 1362415 (App'x B).

undertake such efforts as responsible members of society."[115] Each Distributor Defendant owes a duty to satisfy its obligations under state and federal law to prevent the diversion into illicit markets in the state.

B. Distributor Defendants Breached their Duties.

173. Distributor Defendants breached their duty to monitor, detect, investigate, refuse, and report suspicious orders of prescription opioids originating from pharmacies and dispensers in Georgia, and/or in areas from which Distributor Defendants knew opioids were likely to be diverted to Georgia residents.

174. Each Distributor Defendant sold prescription opioids, including hydrocodone and/or oxycodone, to retailers in the State and/or to retailers from which Defendants knew prescription opioids were likely to be diverted to residents of the state.

175. The sheer volume of prescription opioids distributed to pharmacies in the State of Georgia, and/or to pharmacies and dispensing physicians from which Distributor Defendants knew the opioids were likely to be diverted into the state, is and was excessive for the medical need of the community and facially suspicious. Some red flags are so obvious that no legitimate distributor of controlled substances can reasonably claim ignorance of them.[116]

176. Distributor Defendants breached their duty to "design and operate a system to disclose to the registrant suspicious orders of controlled substances."[117]

177. Distributor Defendants failed to meet their reporting obligations related to suspicious orders originating from the state, and/or which Distributor Defendants knew were

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[115] *See* Brief of Healthcare Distribution Management Association as *Amicus Curiae* for Cardinal Health, 2012 WL 1637016, at *2, filed in *Cardinal Health, Inc. v Department of Justice*, No.12-5061 (D.C. Cir. 2012). (emphasis added).

[116] *Masters Pharmaceuticals, Inc.*, 80 Fed. Reg. 55418-01, 55482 (Sept. 15, 2015) (citing *Holiday CVS, L.L.C., d/b/a CVS/Pharmacy Nos. 219 and 5195*, 77 Fed. Reg. 62316-01, 62322 (2012)).

[117] *See supra,* paragraph 165.

likely to be diverted to the state, to state and federal authorities, including the Georgia Drugs and Narcotics Agency ("GDNA") and the DEA.

178. Not only did they fail to report, but Distributor Defendants unlawfully filled suspicious orders in the State of Georgia and/or in areas from which Distributor Defendants knew opioids were likely to be diverted to Georgia.

179. The foreseeable harm resulting from Distributor Defendants breach of these duties was the diversion of prescription opioids for illegitimate purposes, harm to the public interest, and the resulting crisis plaguing Georgia today.

180. Because of Distributor Defendants' refusal to abide by their legal obligations, the DEA has repeatedly taken administrative action to attempt to force compliance. These actions include the following:

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

- On November 28, 2007, the DEA issued an Order to Show Cause and Immediate Suspension Order against the Cardinal Health Auburn, Washington Distribution Center ("Auburn Facility") for failure to maintain effective controls against diversion of hydrocodone;

- On December 5, 2007, the DEA issued an Order to Show Cause and Immediate Suspension Order against the Cardinal Health Lakeland, Florida Distribution Center ("Lakeland Facility") for failure to maintain effective controls against diversion of hydrocodone;

- On December 7, 2007, the DEA issued an Order to Show Cause and Immediate Suspension Order against the Cardinal Health Swedesboro, New Jersey Distribution Center ("Swedesboro Facility") for failure to maintain effective controls against diversion of hydrocodone;

- On January 30, 2008, the DEA issued an Order to Show Cause and Immediate Suspension Order against the Cardinal Health Stafford, Texas Distribution Center

("Stafford Facility") for failure to maintain effective controls against diversion of hydrocodone;

- On May 2, 2008, McKesson Corporation entered into an Administrative Memorandum of Agreement ("2008 MOA") with the DEA which provided that McKesson would pay a $13.25 million civil fine and "maintain a compliance program designed to detect and prevent the diversion of controlled substances, inform DEA of suspicious orders required by 21 C.F.R. § 1301.74(b), and follow the procedures established by its Controlled Substance Monitoring Program;"

- On September 30, 2008, Cardinal Health entered into a Settlement and Release Agreement and Administrative Memorandum of Agreement with the DEA related to its Auburn Facility, Lakeland Facility, Swedesboro Facility, and Stafford Facility. The document also referenced allegations by the DEA that Cardinal Health failed to maintain effective controls against the diversion of controlled substances at its distribution facilities located in McDonough, GA, Valencia, CA and Denver, CO;

- On February 2, 2012, the DEA issued an Order to Show Cause and Immediate Suspension Order against the Cardinal Health Lakeland Facility for failure to maintain effective controls against diversion of oxycodone. Violations included exponentially increasing shipments of Oxycodone to several known pill mills in Florida subsequent to the MOA agreed upon to resolve the prior ISO in 2008 at the Lakeland Facility (shipments of Schedule II opioids to these 4 pharmacies increased 803% from 2008 to 2009, and 162% from 2009 to 2010);

- On December 23, 2016, Cardinal Health agreed to pay a $44 million fine to the DEA to resolve the civil penalty portion of the administrative action taken against the Lakeland Facility, for failing to report suspicious orders of controlled substances; and

- On January 5, 2017, McKesson Corporation entered into an Administrative Memorandum Agreement with the DEA wherein it agreed to pay a $150 million civil penalty for violation of the 2008 MOA as well as failure to identify and report suspicious orders at its facilities in Aurora, CO, Aurora, IL, Delran, NJ, LaCrosse, WI, Lakeland, FL, Landover, MD, La Vista, NE, Livonia, MI, Methuen, MA, Sante Fe Springs, CA, Washington Courthouse, OH and West Sacramento, CA.

181. The unlawful conduct by Distributor Defendants is purposeful and intentional and Distributor Defendants acted with actual malice in breaching their duties. Distributor Defendants refused, and continue to refuse, to abide by the duties imposed by state and federal law which are required to legally acquire and maintain a license to distribute prescription opiates. These

repeated failures over an extended period demonstrate wanton, willful, or reckless conduct or criminal indifference to civil obligations affecting the rights of others.

C. Distributor Defendants Used the Courts and the Legislative Process in an Effort to Exculpate their Wrongs and Misrepresented their Compliance with their Legal Duties.

182. Distributor Defendants have used the courts and the legislative process in an effort to exculpate their wrongful conduct, and to further avoid their obligations to report and halt fulfillment of suspicious orders. Additionally, Distributor Defendants have repeatedly misrepresented their compliance with their legal duties and have wrongfully and repeatedly disavowed those duties to mislead regulators and the public regarding Distributor Defendants' compliance with their obligations.

183. In *Masters Pharmaceuticals*, the HDMA (a trade association controlled by Distributor Defendants), and the National Association for Chain Drug Stores ("NACDS") submitted *amicus* briefs stating that the legal duty of wholesale distributors was limited to reporting suspicious orders.[118] The Court of Appeals for the District of Columbia recently issued its opinion affirming that a wholesale drug distributor does, in fact, have duties beyond reporting. *See Masters Pharm., Inc. v. DEA*, 861 F.3d 206 (D.C. Cir. 2017). The D.C. Circuit Court upheld the revocation of Master Pharmaceutical's license and determined that DEA regulations require that in addition to reporting suspicious orders, distributors must "decline to ship the order, or conduct some 'due diligence' and— if they are able to determine that the order is not likely to be diverted into illegal channels— ship the order." *Id.* at 212. A distributor's investigation must dispel all the red flags giving rise to the suspicious circumstance prior to shipping a suspicious order. *Id.* at 226. The Circuit Court also rejected the argument made by HDMA and NACDS (quoted above), that, allegedly, the DEA had created or imposed new duties. *Id.* at 220.

[118] Brief for HDMA and NACDS, *supra* note 107, 2016 WL 1321983, at *4–5.

184. Additionally, Distributor Defendants, individually and collectively through trade groups in the industry, pressured the U.S. Department of Justice to "halt" prosecutions and lobbied Congress to strip the DEA of its ability to immediately suspend distributor registrations. The result was a "sharp drop in enforcement actions" and the passage of the "Ensuring Patient Access and Effective Drug Enforcement Act" which raised the burden for the DEA to revoke a distributor's license from "imminent harm" to "immediate harm" and provided the industry the right to "cure" any violations of law before a suspension order can be issued.[119]

185. In addition to taking actions to limit regulatory prosecutions and suspensions, Distributor Defendants undertook to fraudulently convince government regulators in states like Georgia, as well as the public, that they were complying with their legal obligations, including those imposed by licensing regulations. Through such statements, Distributor Defendants attempted to assure the public that they were working to curb the opioid epidemic when they were not.

186. For example, a Cardinal Health executive claimed that Cardinal Health uses "advanced analytics" to monitor its supply chain and represented that it was being "as effective and efficient as possible in constantly monitoring, identifying, and eliminating any outside criminal activity."[120]

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[119] *See* Lenny Bernstein & Scott Higham, *Investigation: The DEA Slowed Enforcement While the Opioid Epidemic Grew Out of Control*, Wash. Post, Oct. 22, 2016, https://www.washingtonpost.com/investigations/the-dea-slowed-enforcement-while-the-opioid-epidemic-grew-out-of-control/2016/10/22/aea2bf8e-7f71-11e6-8d13-d7c704ef9fd9_story.html?utm_term=.e2d89d4ccd07; Lenny Bernstein & Scott Higham, *Investigation: U.S. Senator Calls for Investigation of DEA Enforcement Slowdown Amid Opioid Crisis*, Wash. Post, Mar. 6, 2017, https://www.washingtonpost.com/investigations/us-senator-calls-for-investigation-of-dea-enforcement-slowdown/2017/03/06/5846ee60-028b-11e7-b1e9-a05d3c21f7cf_story.html?utm_term=.bf8b934d4329; Eric Eyre, *DEA Agent: "We Had No Leadership" in WV Amid Flood of Pain Pills*, Charleston Gazette-Mail, Feb. 18, 2017,https://www.wvgazettemail.com/news/health/dea-agent-we-had-no-leadership-in-wv-amid-flood/article_928e9bcd-e28e-58b1-8e3f-f08288f539fd.html.

[120] Lenny Bernstein *et al.*, *How Drugs Intended for Patients Ended Up in the Hands of Illegal Users: "No One Was Doing Their Job,"* Wash. Post, Oct.22, 2016, https://www.washingtonpost.com/investigations/how-drugs-intended-for-patients-ended-up-in-the-hands-of-illegal-users-no-one-was-doing-their-job/2016/10/22/10e79396-30a7-11e6-8ff7-7b6c1998b7a0_story.html?utm_term=.77ea62345bdc.

187. Similarly, McKesson publicly stated that it has a "best-in-class controlled substance monitoring program to help identify suspicious orders," and claimed it is "deeply passionate about curbing the opioid epidemic in our country."[121]

188. Given Cardinal Health's and McKesson's historical conduct, either these statements are false or misleading, or these companies ignored their monitoring programs.

189. By misleading government regulators and the public about the effectiveness of their controlled substance monitoring programs, Distributor Defendants successfully concealed facts which would have aroused suspicion of the claims that the State now asserts while at the same time allowing these Defendants to make billions in profits from this scheme at the expense of the State of Georgia. The State did not know of the existence or scope of Distributor Defendants' industry-wide fraud and could not have acquired such knowledge earlier through the exercise of reasonable diligence. Distributor Defendants, however, knew that government regulators and the public would rely on their statements.

190. The wrongful actions and omissions of Distributor Defendants which have caused the diversion of opioids and which have been a substantial contributing factor to and/or proximate cause of the opioid crisis are alleged in greater detail in the State's racketeering allegations below.

191. Distributor Defendants have resisted, defied, and breached their duties under state and federal law, taken advantage of their superior knowledge and position over government entities, and abused the privilege of distributing controlled substances in the State of Georgia, causing enormous harm to the State of Georgia.

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[121] Scott Higham *et al.*, *Drug Industry Hired Dozens of Officials from the DEA as the Agency Tried to Curb Opioid Abuse*, Wash. Post, Dec. 22, 2016, https://www.washingtonpost.com/investigations/key-officials-switch-sides-from-dea-to-pharmaceutical-industry/2016/12/22/55d2e938-c07b-11e6-b527-949c5893595e_story.html?utm_term=.fd9df7d2e66a.

VI. MANUFACTURER DEFENDANTS' UNLAWFUL FAILURE TO PREVENT DIVERSION AND MONITOR, REPORT, AND PREVENT SUSPICIOUS ORDERS

192. Manufacturer Defendants had the same obligations to prevent diversion related to the fulfillment of suspicious prescription opioid orders as Distributor Defendants.

193. Under Georgia and federal law, Manufacturer Defendants are required to comply with substantially the same licensing and permitting requirements as Distributor Defendants and the same rules regarding prevention of diversion and reporting suspicious orders, as set out above.

194. Manufacturer Defendants had access to and possession of the information necessary to meet their legal obligations to prevent diversion of prescription opioids. For example, Manufacturer Defendants engaged in the practice of paying "chargebacks' to opioid distributors and built receipt of this information into the payment structure for opioids. Thus, Manufacturer Defendants knew – just as Distributor Defendants knew – the volume, frequency, and pattern of opioid orders being placed and filled.

195. The Department of Justice has recently confirmed these legal obligations to prevent diversion apply to Manufacturer Defendants, fining Mallinckrodt $35 million for failing to report suspicious orders of controlled substances, including opioids, and for violating recordkeeping requirements.[122] Mallinckrodt agreed that its "system to monitor and detect suspicious orders did not meet the standards outlined in letters from the DEA Deputy Administrator, Office of Diversion Control, to registrants dated September 27, 2006 and December 27, 2007."

[122] *See* Press Release, U.S. Dep't of Justice, Mallinckrodt Agrees to Pay Record $35 Million Settlement for Failure to Report Suspicious Orders of Pharmaceutical Drugs and for Record keeping Violations (July 11, 2017), https://www.justice.gov/opa/pr/mallinckrodt-agrees-pay-record-35-million-settlement-failure-report-suspicious-orders.

196. The same duties imposed by federal law on Mallinckrodt were imposed upon all Manufacturer Defendants. Indeed, the Report and Recommendation issued by the federal court overseeing the opioid Multi-District Litigation determined that Manufacturer Defendants, not just distributors, owed a duty to report, investigate, and halt suspicious orders.[123]

197. The same business practices utilized by Mallinckrodt regarding "charge backs" and receipt and review of data from opioid distributors regarding orders of opioids were utilized industry-wide among opioid manufacturers and distributors, including, upon information and belief, the other Manufacturer Defendants.

198. Through, *inter alia*, the charge-back data, Manufacturer Defendants could monitor, detect, investigate, report, or otherwise prevent the fulfilment of suspicious orders of opioids yet intentionally and unlawfully failed to do so as required by Georgia and federal law.

199. Manufacturer Defendants have also misrepresented their compliance with Georgia and federal law.

200. Manufacturer Defendants enabled the illegal diversion of opioids, aided criminal activity, and disseminated massive quantities of prescription opioids into the black market.

201. The wrongful actions and omissions of Manufacturer Defendants which have caused the diversion of opioids and which have been a substantial contributing factor to and/or proximate cause of the opioid crisis are alleged in greater detail in the State's racketeering allegations below.

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[123] *In Re: National Prescription Opiate Litigation*, No. 1:18-op-45090, 2018 WL 4895856, (N.D. Ohio Oct 5, 2018) (Report and Recommendation of Magistrate Judge on Defendants' Motion to Dismiss); adopted by the District Court, *In Re: National Prescription Opiate Litigation*, No. 1:18-op-45090, ECF No. 1203, (N.D. Ohio Dec. 19, 2018) (Opinion and Order adopting in part and rejecting in part Magistrate Judge's Report and Recommendation)

VII. ALL DEFENDANTS ACTED IN CONCERT TO ILLEGALLY MARKET AND DISTRIBUTE OPIOIDS IN VIOLATION OF GEORGIA'S RICO STATUTE.

202. The goal of Manufacturer and Distributor Defendants was the same: to create a large and excessive market for opioids, to bolster their revenue, to increase their profits, and to grow their share of the prescription painkiller market by unlawfully and surreptitiously increasing the volume of opioids they sold. Defendants utilized their superior knowledge and posture to accomplish this goal, taking advantage of limited governmental resources to mislead and manipulate regulators in furtherance of their illegal scheme. Manufacturer Defendants unlawfully marketed their opioids to overturn years of medical concerns regarding the safety and efficacy of opioids for the treatment of chronic pain. And then all Defendants refused to comply with their obligations (and further concealed this refusal) to prevent the diversion of controlled substances so as to continuously expand the quantity of opioids they could manufacture and distribute. As discussed more fully below, Defendants acted in concert through a pattern of racketeering activity to achieve these unlawful goals in violation of Georgia's RICO statute, O.C.G.A. § 16-14-4.

A. The Enterprises

203. Defendants engaged in a pattern of racketeering activity through the following relevant enterprises in violation of Georgia's RICO statute and, as explained more fully below, in aid of the "Opioid Enterprise":

Opioid Promotion Enterprise

204. The Opioid Promotion Enterprise is an association-in-fact within the meaning of O.C.G.A. § 16-14-3(3), consisting of Manufacturer Defendants, including their employees and agents; Front Groups, including their employees and agents; KOLs; and other as yet unknown marketing firms, distribution agents or monitoring entities employed by Defendants in

furtherance of the Opioid Promotion Enterprise. All entities acted to enable Defendants to fraudulently market and promote opioids as scientifically safe and effective.

205. The Opioid Promotion Enterprise acted to conceal the true risks and dangers of opioids from the medical community and the public, including Georgia, and made misleading statements and misrepresentations about opioids that downplayed the risk of addiction and exaggerated the benefits of opioid use, as described in this Complaint.

206. The Opioid Promotion Enterprise acted together through common schemes and courses of conduct with the purpose of increasing sales and profits through disseminated misrepresentations about the addictive nature and risks and benefits of opioids.

Opioid Diversion Enterprise

207. The Opioid Diversion Enterprise is an association-in-fact enterprise between Manufacturer Defendants and Distributor Defendants. Each Defendant was associated with, and conducted or participated in, the affairs of the Opioid Diversion Enterprise, the purpose of which was to engage in the unlawful sale of opioids, to permit the distribution and fulfillment of suspicious orders of prescription opioids, and to deceive state regulators into believing that Defendants were faithfully fulfilling their legal obligations. The Opioid Diversion Enterprise was designed to, and did, increase Defendants' profits by masking an excessive supply of opioids directed at the State of Georgia, including through unlawful manipulation of government officials.

The Opioid Enterprise

208. Each Defendant was a member of an association-in-fact enterprise within the meaning of O.C.G.A. § 16-14-3(3), hereinafter referred to as the "Opioid Enterprise," through

which Defendants conducted their pattern of racketeering activity in this jurisdiction and throughout the United States.

209. The association-in-fact enterprises (Opioid Promotion Enterprise and Opioid Diversion Enterprise) and the Healthcare Distribution Alliance ("HDA"), a legal enterprise, were each used by Defendants to conduct the Opioid Enterprise by engaging in a pattern of racketeering activity.

210. To coordinate their pattern of racketeering activity in furtherance of their similar intents and designs, Defendants used the 0HDA, a distinct legal entity that satisfies the definition of a Georgia RICO enterprise.

211. The HDA is a nonprofit corporation formed under the laws of the District of Columbia and doing business in Virginia. As a nonprofit corporation, the HDA qualifies as an "enterprise" within the definition set out in O.C.G.A. § 16-14-3(3) because it is a corporation and a legal entity.

212. All Defendants were members, participants, and/or sponsors of the HDA and utilized the HDA to conduct their pattern of racketeering activity in this jurisdiction.

213. Each Defendant is a legal entity separate and distinct from the HDA. The HDA serves the interests of distributors and manufacturers beyond Defendants. The HDA exists separately from the Opioid Enterprise, and each Defendant exists separately from the HDA.

214. At all relevant times, the Opioid Enterprise: (a) had an existence separate and distinct from each Defendant; (b) was separate and distinct from the pattern of racketeering in which Defendants engaged; (c) was an ongoing and continuing organization consisting of legal entities, including each Defendant; (d) characterized by interpersonal relationships among the Defendants; (e) had sufficient longevity for the enterprise to pursue its purpose; and (f)

functioned as a continuing unit. Each member of the Opioid Enterprise participated in the conduct of the enterprise, including patterns of racketeering activity, and shared in the astounding growth of profits supplied by fraudulently inflating opioid sales generated as a result of the Opioid Enterprise members' disregard for their duty to prevent diversion of their drugs into the illicit market and then manipulating an increase in production quotas, all so Defendants would have a larger pool of prescription opioids from which to profit.

215. As explained above, the Opioid Enterprise also engaged in efforts to lobby against enforcement officials' authority to hold Defendants responsible for disregarding their duty to prevent diversion. They further attempted to use the courts and the legal legislative process to exculpate their wrongful conduct.

216. The Opioid Enterprise functioned by selling, supplying, and distributing prescription opioids. While there are some legitimate uses and/or needs for prescription opioids, Defendants, through their illegal enterprise, engaged in a pattern of racketeering activity that involves a fraudulent and unlawful scheme to increase revenue by disregarding and violating their obligations under Georgia law regarding the maintenance of effective controls against diversion of prescription opioids and the identification, investigation, and reporting of suspicious orders of prescription opioids. The goal of Defendants' scheme targeted the State of Georgia and was designed to increase profits from opioid sales at the direct expense of the State of Georgia. But Defendants' profits were limited by the above-referenced laws and the production quotas set by applicable law and regulatory and enforcement officials, so Defendants refused to meet their obligations, which were designed to prevent the diversion of their prescription opioids into the illicit drug market. The end result of this strategy was to create an artificially high baseline of prescription opioids, thereby artificially increasing Defendants' production quotas (and the

baseline for reporting suspicious orders) for prescription opioids. Although built on a continuous trend of suspicious orders, this baseline falsely justified a far larger pool of opioids for Defendants to manufacture and distribute in Georgia.

217. The HDA led to the formation of interpersonal relationships and an organization between the Defendants. Although the entire HDA membership directory is private, the HDA website confirms that each of Distributor Defendants and Manufacturer Defendants are members. And the HDA and each Distributor Defendant sought the active membership and participation of Manufacturer Defendants by advocating that one of the benefits of membership was the ability to develop direct relationships between manufacturers and distributors at high executive levels.

218. The HDA's councils, committees, task forces, and working groups provided Manufacturer and Distributor Defendants with the opportunity to work closely together in shaping their common goals and forming the enterprise's organization.

219. Defendants maintained their interpersonal relationships by working together, exchanging information, and driving the unlawful sales of their opioids through their contractual relationships, including through chargeback data. Manufacturer Defendants engaged in an industry-wide practice of paying rebates and chargebacks to Distributor Defendants for sales of prescription opioids. As reported in the Washington Post, identified by Senator McCaskill, and acknowledged by the HDA, there is an industry-wide practice whereby Manufacturer Defendants paid Distributor Defendants rebates and/or chargebacks on their prescription opioid sales.

220. These contracts were negotiated at the highest levels, demonstrating ongoing relationships between Manufacturer and Distributor Defendants. In return for the rebates and chargebacks, Distributor Defendants provided Manufacturer Defendants with highly detailed

information regarding their prescription opioid sales, including purchase orders, ship notices, acknowledgements, and invoices. Manufacturer Defendants used this information to gather high-level data regarding overall distribution and to direct Distributor Defendants on how to most effectively sell the prescription opioids.

221. Taken together, the interaction, breadth and depth of relationships between and among Manufacturer and Distributor Defendants reflects an extraordinary level of interaction and coordination between two groups in a tightly knit industry. Manufacturer and Distributor Defendants were not two separate groups operating in isolation or two groups forced to work together in a closed system. Defendants operated together as a group, working together on multiple fronts, to engage in the unlawful sale and distribution of prescription opioids.

B. Defendants' Conduct in Aid of the Opioid Enterprise

222. During the time period alleged in this Complaint, Defendants participated in the Opioid Enterprise by fraudulently marketing and selling opioids as scientifically safe and effective, and, in the process, convincing state regulators and the public that opioids could be sold and used to treat chronic pain without fear of addiction or diversion. At the same time, Defendants acted to conceal the true risks and dangers of opioid use from Georgia, the medical community and the public, and made misleading statements and misrepresentations about opioids that downplayed the rick of addiction and exaggerated the benefits of opioid use as described in detail in this Complaint.

223. Defendants used numerous forms of direct marketing, front groups, paid speakers, unbranded promotion, and other methods as identified in this Complaint to ensure that the Opioid Enterprise was successful in its efforts.

224. All of Defendants' efforts constituted a common course of conduct designed to ensure that the Opioid Enterprise unlawfully increased sales and profits through concealment and misrepresentations about the addictive nature and effective use of Defendants' drugs.

225. Moreover, Defendants exerted control over, conducted, and/or participated in the Opioid Enterprise by fraudulently failing to comply with their obligations to Georgia to monitor, detect, report, investigate, or otherwise prevent the fulfillment of suspicious orders of prescription opioids. These obligations existed specifically to prevent fulfillment of suspicious orders of opioids, thereby saving the State of Georgia substantial cost and expense that foreseeably would result in the event significant diversion of highly addictive controlled substances occurred.

226. Defendants disseminated false and misleading statements to the State of Georgia and other regulatory entities that Defendants were complying with their obligations to maintain effective controls against diversion of prescription opioids and that they were further adhering to their obligations to monitor, detect, report, investigate, or otherwise prevent the fulfillment of suspicious orders. Defendants refused to meet these obligations even when they had actual knowledge of drug diversion activity.

227. Defendants engaged in an industry-wide practice of paying rebates and chargebacks to incentivize unlawful opioid prescription sales. Manufacturer Defendants used the chargeback program to acquire detailed, high-level data regarding sales of the opioids they manufactured. And Manufacturer Defendants used this high-level information to target Distributor Defendants' sales efforts to regions where prescription opioids were selling in larger volumes.

228. Manufacturer Defendants lobbied government entities to increase Aggregate Production Quotas, year after year, by submitting net disposal information that Manufacturer Defendants knew included sales that were suspicious and involved the diversion of opioids that had not been properly investigated or reported by Defendants.

229. Distributor Defendants developed "know your customer" questionnaires and files. This information, compiled pursuant to comments from the DEA in 2006 and 2007, was intended to help Defendants identify suspicious orders or customers who were likely to divert prescription opioids. The "know your customer" questionnaires informed Defendants of the number of pills that the pharmacies sold, how many non-controlled substances are sold compared to controlled substances, whether the pharmacy buys from other distributors, and the types of medical providers in the area, including pain clinics, general practitioners, hospice facilities, and cancer treatment facilities. These questionnaires put the recipients on notice of suspicious orders under Georgia law. Despite this detailed knowledge of their customers, Defendants continued to fail to report suspicious orders.

230. Defendants also worked together to ensure that the Aggregate Production Quotas, Individual Quotas, and Procurement Quotas allowed by the DEA stayed high and ensured that suspicious orders were not reported to government entities – particularly the State of Georgia. By not meeting their obligations to prevent the diversion of prescription opioids, Defendants ensured that government regulators had no basis for decreasing or refusing to increase the production quotas for prescription opioids due to diversion of suspicious orders. Defendants influenced production quotas in the following ways:

- Distributor Defendants assisted the Opioid Enterprise and Manufacturer Defendants in their lobbying efforts through Pain Care Forum, a Front Group of Defendants;

- Distributor Defendants invited the participation, oversight and control of Manufacturer Defendants by including them in the HDA, including on the councils, committees, task forces, and working groups;

- Distributor Defendants provided sales information to Manufacturer Defendants regarding their prescription opioids, including reports of all opioids prescriptions filled by Distributor Defendants;

- Manufacturer Defendants used a chargeback program(s) to ensure delivery of Distributor Defendants' sales information;

- Manufacturer Defendants obtained sales information from QuintilesIMS (formerly IMS Health) that gave them a "stream of data showing how individual doctors across the nation were prescribing [opioids]";

- Distributor Defendants accepted rebates and chargebacks for orders of prescription opioids;

- Manufacturer Defendants used Distributor Defendants' sales information and the data from QuintilesIMS to instruct Distributor Defendants to focus their distribution efforts to specific areas where the purchase of prescription opioids was most frequent;

- Defendants identified suspicious orders of prescription opioids and then continued filling those unlawful orders without reporting them, knowing that they were suspicious and/or being diverted into the illicit drug market;

- Defendants refused to report suspicious orders of prescription opioids despite repeated investigation and punishment of Distributor Defendants by government entities for failure to report suspicious orders;

- Defendants withheld information regarding suspicious orders and illicit diversion from the DEA and the State of Georgia because it would have revealed that the "medical need" for and the net disposal of their drugs did not justify the production quotas set by the DEA; and

- The scheme devised and implemented by Defendants amounted to a common course of conduct characterized by a refusal to maintain effective controls against diversion, and all designed and operated to ensure the continued unlawful sale of controlled substances in direct violation of Georgia law.

231. In furtherance of their scheme, the Opioid Enterprise (including each Defendant) directly targeted the State of Georgia by: (1) failing to monitor, detect, report, investigate or

otherwise prevent the fulfillment of suspicious orders of prescription opioids within or affecting the State of Georgia; (2) representing to the State that Defendants had appropriate controls to monitor, detect, report, investigate or otherwise prevent the fulfillment of suspicious orders of prescription opioids within or affecting the State of Georgia when they in fact did not; and/or (3) representing to the State of Georgia that Defendants were in fact monitoring, detecting, reporting, or otherwise preventing the fulfillment of suspicious orders of prescription opioids within or affecting the State of Georgia when they in fact were not. In the process, Defendants falsely justified and supported the manufacture, sale and distribution of substantial quantities of prescription opioids within and affecting the State of Georgia, at its direct expense.

VIII. DEFENDANTS' UNLAWFUL CONDUCT AND BREACHES OF LEGAL DUTIES CAUSED THE HARM ALLEGED HEREIN AND SUBSTANTIAL DAMAGES.

232. As Manufacturer Defendants' efforts to expand the market for opioids increased, so have the rates of prescription and sale of their products. Distributor Defendants' continued indifference to their legal duties led to the unlawful shipment of massive quantities of opioids into the state, fueling the epidemic to levels never seen before. Consequently, the rates of opioid-related substance abuse, hospitalization, death, costs to the State of Georgia, and billions in profits to Defendants all track the rates of prescription, sale, and distribution of opioid products – all fostered by Defendants' efforts.

233. There is a "parallel relationship between the availability of prescription opioid analgesics through legitimate pharmacy channels and the diversion and abuse of these drugs and associated adverse outcomes."[124]

[124] Dart RC, Severtson SG, Bucher-Bartelson B. *Trends in opioid analgesic abuse and mortality in the United States*, N Engl J Med. 2015;372(16):1573–1574.

234. Opioid analgesics are widely diverted and improperly used, and the widespread use of the drugs has resulted in a national epidemic of opioid overdose deaths and addictions.[125]

235. The epidemic is "directly related to the increasingly widespread misuse of powerful opioid pain medications."[126]

236. The increased abuse of prescription painkillers along with growing sales have contributed to many overdoses and deaths.[127]

237. As shown above, the opioid epidemic has escalated in the state with devastating effects. Substantial opiate-related substance abuse, hospitalization, and death correlates directly with Defendants' increased distribution of opiates.

238. Because of the well-established relationship between the use of prescription opiates and the use of non-prescription opioids – like heroin and illicit (i.e., illegally manufactured) fentanyl – the massive distribution of opioids caused the opioid epidemic to become an opioid, heroin, and fentanyl crisis.

239. Defendants repeatedly and purposefully breached their duties under state and federal law, and such breaches are direct and proximate causes of, and/or substantial factors leading to, the widespread diversion of prescription opioids for illegitimate purposes into the state.

240. The unlawful diversion of prescription opioids is a direct and proximate cause of, and/or substantial factor leading to, the opioid epidemic, prescription opioid abuse, addiction, morbidity, and mortality in the state. This diversion and the epidemic are direct causes of foreseeable harms incurred by the State.

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[125] Elspeth Shipton et al., *Deaths from Opioid Overdosing: Implications of Coroners' Inquest Reports 2008–2012 and Annual Rise in Opioid Prescription Rates: A Population-Based Cohort Study*, Pain & Therapy (2012).
[126] *Id.*
[127] https://www.cdc.gov/drugoverdose/data/prescribing.html.

241. Defendants' intentional and/or unlawful conduct resulted in direct and foreseeable past, present, and future economic damages for which the State seeks relief, as alleged herein. The State also seeks the means to abate the epidemic created by Defendants' wrongful and/or unlawful conduct.

242. The State seeks economic damages from Defendants as reimbursement for the costs associated with past, present, and future efforts to permanently eliminate the hazards to public health and safety and abate this crisis.

IX. STATUTES OF LIMITATIONS ARE TOLLED, AND DEFENDANTS ARE ESTOPPED FROM ASSERTING STATUTES OF LIMITATIONS AS DEFENSES.

A. Continuing Conduct

243. The State contends that it continues to suffer harm from Defendants' unlawful actions.

244. The continued tortious and unlawful conduct by Defendants causes a repeated or continuous injury. The damages have not occurred all at once, but have continued to occur and have increased as time progresses. The tort is not completed nor have all the damages been incurred until the wrongdoing ceases. The wrongdoing and unlawful activity by Defendants have not ceased. The public nuisance remains unabated.

B. Equitable Estoppel

245. Defendants are equitably estopped from relying upon a statute of limitations defense because they undertook efforts to purposefully conceal their unlawful conduct and fraudulently assure the public, including the State and its citizens, that they were undertaking efforts to comply with their obligations under the state and federal controlled substances laws, all with the goal of protecting their registered manufacturer or distributor status in the State and to

continue generating profits. Defendants affirmatively assured the public, including the State and its citizens, that they were working to curb the opioid epidemic.

246. As explained above, Defendants misrepresented the effectiveness of their internal protocol and procedures to prevent diversion as well as their compliance with applicable state and federal laws governing the prevention of diversion.

247. Moreover, in furtherance of their effort to affirmatively conceal their conduct and avoid detection, Distributor Defendants, through their trade associations HDMA and NACDS, filed an *amicus* brief in the *Masters Pharmaceuticals* case, which made the following statements:[128]

- "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."
- "DEA regulations that have been in place for more than 40 years require distributors to report suspicious orders of controlled substances to DEA based on information readily available to them (e.g., a pharmacy's placement of unusually frequent or large orders)."
- "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."
- "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."
- "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."

248. Through the above statements made on their behalf by their trade associations, and other similar statements assuring their continued compliance with their legal obligations,

[128] Brief for HDMA and NACDS, 2016 WL 1321983, *supra* note 107, at *3-4, *25.

Distributor Defendants not only acknowledged that they understood their obligations under the law, but they further affirmed that their conduct complied with those obligations.

249. Distributor Defendants have also concealed and prevented discovery of critical information necessary to uncovering their wrongful conduct, including data from the ARCOS database, that would have confirmed their identities and the extent of their wrongful and illegal activities within the state. Moreover, Defendants used their superior knowledge and position, as well as their ability to operate in darkness, to conceal material facts and to manipulate state entities and officials so they could continue their conduct unabated.

250. Manufacturer Defendants distorted the meaning or import of studies they cited and offered them as evidence for propositions that the studies did not support. Manufacturer Defendants promoted the concept of "pseudoaddiction" to an unsuspecting medical community. Manufacturer Defendants provided the medical community with false and misleading information about ineffectual strategies to avoid or control opioid addiction. Manufacturer Defendants recommended to the medical community that dosages be increased, without disclosing the risks. Manufacturer Defendants spent millions of dollars over a period of years on a misinformation campaign aimed at highlighting opioids' alleged benefits, disguising the risks, and promoting sales. The medical community, consumers, and the State were duped by Manufacturer Defendants' campaign to misrepresent and conceal the truth about the opioid drugs that they were aggressively pushing in the state.

251. Defendants intended that their actions and omissions would be relied upon, including by the State and consumers in the state. Due to Defendants' actions and omissions, the State, and consumers in the state, did not know, and did not have the means to know, the truth.

252. The State, and consumers in the state, reasonably relied on Defendants' affirmative statements regarding compliance with their legal obligations and consent orders.

C. Fraudulent Concealment

253. The State's claims are further subject to equitable tolling, stemming from Defendants' knowing and fraudulent concealment of the facts alleged herein. As alleged herein, Defendants knew of the wrongful acts set forth above, and had material information pertinent to their discovery, and concealed them from the State and its citizens. Because of Defendants' conduct, the State did not know, or could not have known through the exercise of reasonable diligence, of its causes of action.

254. Defendants' fraudulent misrepresentations, suppressions, and concealments of material facts also constitute a fraudulent concealment from the State of Georgia of the existence of causes of action by which the State could have sought recovery from Defendants for its injuries suffered because of Defendants' wrongful conduct.

255. As a proximate result of Defendants' fraudulent misrepresentations, suppressions, and concealments, the State of Georgia has been, and continues to be, injured and has incurred damages as stated herein.

256. As such, to the extent one would even apply, the limitations period has been tolled, and the State of Georgia has brought this action upon discovering the existence of the facts underlying the causes of action alleged herein, within the limitations period. O.C.G.A. § 9-3-96.

257. The purposes of the statutes of limitations period are satisfied because Defendants cannot claim prejudice due to a late filing where the State of Georgia filed suit promptly upon

discovering the facts essential to its claims, described herein, which Defendants knowingly concealed.

258. The continued tortious and unlawful conduct by Defendants causes a repeated or continuous injury. The damages have not occurred all at once but have continued to occur and have increased as time progresses. The harm is not completed nor have all the damages been incurred until the wrongdoing ceases. The wrongdoing and unlawful activity by Defendants have not ceased because the public nuisance remains unabated.

259. The medical community, consumers, and the State of Georgia were duped by Defendants' campaign to misrepresent and conceal the truth about the opioid drugs that they were aggressively pushing in the state.

260. The State reasonably relied on Defendants' affirmative statements regarding their purported compliance with their obligations under the law and consent orders.

261. The State's claims are equitably tolled because Defendants knowingly and fraudulently concealed the facts and their wrongful acts, and the material information pertinent to their discovery, which Defendants concealed from the State. The State did not know, or could not have known through the exercise of reasonable diligence, of its claims, as a result of Defendants' conduct.

CLAIMS FOR RELIEF

COUNT I

GEORGIA RACKETEER INFLUENCED AND CORRUPT ORGANIZATIONS (O.C.G.A. § 16-14-4)

(All Defendants)

262. Plaintiff, the State of Georgia, incorporates and re-alleges each of the paragraphs

above as though fully set forth herein.

263. The State, by and through its Attorney General, is authorized to institute this civil action. *See* O.C.G.A. § 16-14-6(b).

264. The Georgia RICO Act states that "[i]t shall be unlawful for any person, through a pattern of racketeering activity or proceeds derived therefrom, to acquire or maintain, directly or indirectly, any interest in or control of any enterprise, real property, or personal property of any nature, including money." O.C.G.A. § 16-14-4.

265. Defendants have engaged in "racketeering activity" as defined by Section 16-14-3(4)-(5) to wit:

- "commit[ing], [or] attempting to commit, or to solicit, coerce, or intimidate another person to commit any crime which is chargeable by indictment under the laws of [Georgia] involving" ... violations of "Article 2 of Chapter 13 ["The 'Georgia Controlled Substances Act.'"] O.C.G.A. § 16-14-3(5)(A)(xxxiv).

- committing "any act . . . involving . . . dealing in narcotic or dangerous drugs, ..." O.C.G.A. § 16-14-3(5)(B).

- engaging in "any conduct defined as 'racketeering activity' under 18 U.S.C. § 1961 (1), ..." O.C.G.A. § 16-14-3(5)(C).[129]

266. Defendants violated the Georgia RICO Act by each of the following:

- acquiring or maintaining an interest or control of an enterprise, including personal property and money, through a pattern of racketeering activity as defined by the Georgia RICO Act. O.C.G.A. § 16-14-4(a).

[129] The State cites federal statutes and federal regulations in its Complaint to define the contours of the duty owed by Defendants under Georgia law, not to allege an independent federal cause of action or to create a substantial federal question. Citations to federal question subject matter jurisdiction pursuant to 28 U.S.C. § 1331 is not invoked by the State or its Complaint, as it sets forth herein exclusively viable state law claims against Defendants. Nowhere herein does the State plead, expressly or implicitly, any cause of action or request any remedy that arises under federal law. The issues presented in the allegations of this Complaint do not implicate any substantial federal issues and do not turn on the necessary interpretation of federal law. Specifically, the causes of action asserted, and the remedies sought herein, are founded upon the statutory, common, and decisional laws of the State of Georgia. Further, the assertion of federal jurisdiction over the claims made herein would improperly disturb the congressionally approved balance of federal and state responsibilities. Even where a federal regulation informs some part of the case, that does not convert any state legal cause of action into any federal question, substantial or otherwise, because it is Georgia law, and not any federal authority, that supports the existence of the duties owed.

- conducting or participating in the affairs of the Opioid Enterprise through a pattern of racketeering activity. O.C.G.A. § 16-14-4(b).

- conspiring or endeavoring to violate the above subsections (a) and/or (b) of O.C.G.A. § 16-14-4. O.C.G.A. § 16-14-4(c).

267. Defendants' Opioid Promotion Enterprise existed as an "enterprise" as defined in the Georgia RICO Act. O.C.G.A. § 16-14-3(3).

268. Defendants' Opioid Diversion Enterprise existed as an "enterprise" as defined in the Georgia RICO Act. O.C.G.A. § 16-14-3(3).

269. The Opioid Enterprise existed as an "enterprise" as defined in the Georgia RICO Act. O.C.G.A. § 16-14-3(3).

270. Defendants have engaged in "racketeering activity," within the relevant time period, by "committing at least two such acts of racketeering activity in furtherance of one or more ... schemes, or transactions that have the same or similar intents, results, ... victims, or methods of commission or otherwise are interrelated by distinguishing characteristics and [which] are not isolated incidents."

A. Relevant Enterprises

271. As stated in Section VII of the Complaint, Manufacturer Defendants formed the Opioid Promotion Enterprise to enable Defendants to fraudulently market and sell opioids as scientifically safe and effective and to change the prescribing habits of doctors.

272. As stated in Section VII of the Complaint, Manufacturer and Distributor Defendants formed the Opioid Diversion Enterprise to increase profits generated by the sale of opioids. The Opioid Diversion Enterprise aimed to increase the quotas set by the DEA, increase the number of opioids prescribed, and ignore the statutorily imposed obligation to prevent the illicit diversion of their opioids throughout the United States and Georgia in particular. Indeed, to increase their profits, their goal was to mislead and manipulate regulators so that they could sell

opioids in the State of Georgia and other states and to further take advantage of their superior knowledge and posture, as well as the State of Georgia's (and other government entities') limited resources, to ultimately create a large and continuously excessive, market for opioids.

273. As stated in Section VII of the Complaint, each Defendant and the HDA were members of an association-in-fact enterprise, the "Opioid Enterprise," through which Defendants conducted their pattern of racketeering activity in this jurisdiction and throughout the United States.

274. Consequently, Defendants targeted the State of Georgia and other states to violate laws specifically created to prevent the epidemic we now face, thereby causing direct, substantial, and foreseeable cost to the State of Georgia.

B. Pattern of Racketeering Activity

275. Defendants, through the Opioid Enterprise, engaged in a pattern of racketeering activity as defined in O.C.G.A. § 16-14-3(4) by, within the relevant time period, "engaging in at least two such acts of racketeering activity in furtherance of one or more ... schemes, or transactions that have the same or similar intents, results, ... victims, or methods of commission or otherwise are interrelated by distinguishing characteristics and [which] are not isolated incidents."

276. Defendants conducted and participated in violations of the Georgia Controlled Substances Act, Article 2 of Chapter 13 of Title 16 of the Georgia Code, and "racketeering activity" within the meaning of 18 U.S.C. § 1961, including mail fraud (18 U.S.C. § 1341) and wire fraud (18 U.S.C. § 1343); and 18 U.S.C. § 1961(D) by the felonious manufacture, importation, receiving, concealment, buying, selling, or otherwise dealing in a controlled substance or listed chemical (as defined in section 102 of the Controlled Substances Act),

punishable under any law of the United States. *See* O.C.G.A. § 16-14-3(5)(A)(xxxiv); *see also* O.C.G.A. § 16-13-42(a).

C. The Predicate Acts: Violations of the Georgia Controlled Substances Act; Mail and Wire Fraud

277. Defendants carried out, or attempted to carry out, a scheme to defraud federal and state regulators, including the State and its agencies, and the American public by knowingly conducting or participating in the conduct of the Opioid Enterprise through a pattern of racketeering activity within the meaning of 18 U.S.C. § 1961(1)(A),(B),(C), and (D) that employed the use of mail and wire facilities, in violation of 18 U.S.C. §§ 1341 (mail fraud) and 1343 (wire fraud).

278. Defendants committed, conspired to commit, and aided and abetted in the commission of at least two predicate acts of racketeering activity within the past four years. Defendants' multiple acts of racketeering activity were related to each other, posed a threat of continued racketeering activity, and therefore constitute a "pattern of racketeering activity." The racketeering activity was made possible by Defendants' regular use of the facilities, services, distribution channels, and employees of the Opioid Enterprise. Defendants participated in the scheme to defraud by using mail, telephone, and the internet to transmit mailings and wires in interstate or foreign commerce.

279. Defendants used, directed the use of, and caused to be used thousands of interstate mail and wire communications in service of their scheme through virtually uniform misrepresentations, concealments, and material omissions regarding their compliance with their mandatory reporting requirements and the actions necessary to carry out their unlawful goal of selling prescription opioids as scientifically safe and effective, without reporting suspicious orders or the diversion of opioids into the illicit market.

280. Defendants devised and knowingly carried out a material scheme and artifice to defraud by means of materially false or fraudulent pretenses, representations, promises, or omissions of material facts. For the purpose of executing the illegal scheme, Defendants committed these racketeering acts, which number in the thousands, intentionally and knowingly with the specific intent to advance the illegal scheme.

281. Defendants' predicate acts of racketeering activity (O.C.G.A. § 16-14-3(5)) include, but are not limited to:

- Violation of the Georgia Controlled Substances Act: Defendants violated Article 2 of Chapter 13 of Title 16, specifically O.C.G.A. § 16-13-42, by failing to make, keep, or furnish . . . records, notifications, . . . or information required" by that Act, using "communications facilities" in "committing or in causing or facilitating the commission of any act or acts constituting a felony" under the Act, and "attempting or conspiring to commit offenses defined in" the Act.

- False Statements to Government Officials: Defendants violated O.C.G.A. § 16-10-20 by knowingly and willfully falsifying, concealing, or covering up material facts by any trick, scheme, or device; making false, fictitious, or fraudulent statements or representations; and making or using false writings or documents, with knowledge that the same contains false, fictitious, or fraudulent statements or entries, in any matter within the jurisdiction of any department or agency of state government or of the government, in particular, by making such statements, or concealing material facts in communications to the Georgia Pharmacy Board and Georgia Drugs and Narcotics Agency, in particular, in reports required by Article 6, Chapter 4 of Title 26 related to regulation of manufacturers, distributors, and pharmacies.

- Mail Fraud: Defendants violated 18 U.S.C. § 1341 by sending or receiving, or by causing to be sent and received, materials via U.S. mail or commercial interstate carriers for the purpose of executing the unlawful scheme to design, manufacture, market, and sell the prescription opioids by means of false pretenses, misrepresentations, promises, and omissions.

- Wire Fraud: Defendants violated 18 U.S.C. § 1343 by transmitting and/or receiving, or by causing to be transmitted and/or received, materials by wire for the purpose of executing the unlawful scheme to design, manufacture, market, and sell the prescription opioids by means of false pretenses, misrepresentations, promises, and omissions.

282. Defendants' actions in furtherance of this pattern of racketeering include, but are not limited to, the transmission, delivery, or shipment of the following by Manufacturer Defendants, Distributor Defendants, or third parties that were foreseeably caused to be sent as a result of Defendants' illegal scheme, including but not limited to:

- The prescription opioids themselves;
- Documents and communications that facilitated the manufacture, purchase and unlawful sale of prescription opioids;
- Defendants' DEA registrations;
- Documents and communications that supported and facilitated Defendants' DEA registrations;
- Documents and communications that supported and facilitated Defendants' requests for higher aggregate production quotas, individual production quotas, and procurement quotas;
- Defendants' records and reports that were required to be submitted to the DEA pursuant to 21 U.S.C. § 827;
- Documents and communications related to Defendants' mandatory DEA reports pursuant to 21 U.S.C. § 823 and 21 C.F.R. §1301.74;
- Documents and communications related to Defendants' mandatory reports pursuant to O.C.G.A. § 16-13-39;
- Documents and communications submitted pursuant to O.C.G.A. § 16-13-36 and GA. COMP. R. & REGS. 480-20-.02;
- Documents and communications related to Defendants' mandatory reports pursuant to O.C.G.A. § 26-4-115 and the regulations promulgated thereunder;
- Documents and communications related to Defendants' mandatory reports pursuant to O.C.G.A. § 26-4-115.1 and the regulations promulgated thereunder;

- Documents and communications related to Defendants' approval, licensing and confirmation process to distribute and sell opioids within the State of Georgia;

- Documents intended to facilitate the manufacture and distribution of Defendants' prescription opioids, including bills of lading, invoices, shipping records, reports, and correspondence;

- Documents for processing and receiving payment for prescription opioids;

- Payments from Distributor Defendants to Manufacturer Defendants;

- Rebates and chargebacks from Manufacturer Defendants to Distributor Defendants;

- Payments to Defendants' lobbyists through the Pain Care Forum;

- Payments to Defendants' trade organizations, like the HDA, for memberships and/or sponsorships;

- Deposits of proceeds from Defendants' manufacture and distribution of prescription opioids; and

- Other documents and things, including electronic communications.

283. Several Defendants also entered into corporate integrity agreements with various entities, including the Office of Inspector General and the United States Department of Health and Human Services, which required those Defendants annually to certify in writing that they had implemented effective compliance programs and were otherwise in compliance with laws and regulations regarding, among other things, the manufacture and distribution of opioids. Defendants submitted through the mail and wires certifications that were false and misleading, in furtherance of the Opioid Enterprise's operation and goals, including false and misleading certifications required annually under the following:

- Section V of the Deferred Prosecution Agreement entered in *United States of America v. Endo Pharmaceuticals, Inc.*, No. 1:14-CR-00066-MAD, ECF No. 2 (N.D.N.Y. Feb. 21, 2014);

- Section III of the Corporate Integrity Agreement Between the Office of Inspector General of the Department of Health and Human Services and Endo Pharmaceuticals, Inc. (fully executed on Feb. 21, 2014);

- Section III of the Corporate Integrity Agreement between the Office of Inspector General of the Department of Health and Human Services and Purdue Pharma, L.P. (fully executed on May 8, 2007).

284. The mail and wire transmissions described herein were made in furtherance of Defendants' scheme and common course of conduct to deceive regulators and the public that Defendants were complying with their state and federal obligations to identify and report suspicious orders of prescription opioids all while Defendants were knowingly allowing millions of doses of prescription opioids to divert into the illicit drug market. Defendants' scheme and common course of conduct was intended to increase or maintain high production quotas for their prescription opioids from which they could profit.

285. Defendants committed crimes that are chargeable by indictment under the laws of Georgia and punishable as felonies under the laws of the United States. Specifically, O.C.G.A. § 16-13-42 makes it a felony to distribute or dispense a controlled substance in violation of § 16-13-41 or to refuse or fail to make, keep, or furnish any record, notification, order form, statement, invoice, or information required under Article 2 of Chapter 13 of Title 16 of the Georgia code. Furthermore, 21 U.S.C. § 843(a)(4) makes it unlawful for any person to knowingly or intentionally furnish false or fraudulent information in, or to omit any material information from, any application, report, record, or other document required to be made, kept, or filed under that subchapter. A violation of § 843(a)(4) is punishable by up to four years in jail, making it a felony. 21 U.S.C. § 843(d)(1).

286. By intentionally misrepresenting, or by causing its agents to misrepresent, the safety and effectiveness of their prescription opioids, Defendants engaged in a fraudulent scheme and unlawful course of conduct constituting a pattern of racketeering activity.

287. By intentionally refusing to report and halt suspicious orders of their prescription opioids, Defendants engaged in a fraudulent scheme and unlawful course of conduct constituting a pattern of racketeering activity.

288. It was foreseeable to Defendants that refusing to report and halt suspicious orders would harm the State by allowing the flow of prescription opioids from appropriate medical channels into the illicit drug market.

289. The last racketeering incident occurred within five years of the commission of a prior incident of racketeering.

D. RICO Damages and Injunction

290. Defendants' violations of law and their pattern of racketeering activity directly and proximately caused the State's injuries because the State paid for costs associated with the opioid epidemic. These harms are ongoing and will continue into the foreseeable future.

291. The State's injuries were, and are being, proximately caused by Defendants' racketeering activities. But for Defendants' conduct, the State would not have paid the exorbitant costs and expenditures required as a result of the epidemic affecting Georgia and would not have suffered the harm it now suffers and will continue to suffer. Indeed, these damages are borne by Georgia.

292. The State seeks all legal relief as allowed by law, including actual damages, treble damages, equitable relief, costs to abate the crisis, forfeiture as deemed proper by the Court, attorney's fees and all costs and expenses of suit, and pre and post-judgment interest.

293. The State seeks equitable relief under Georgia RICO as allowed by law (O.C.G.A. § 16-14-6(a)(2)), including appropriate orders and judgments imposing reasonable restrictions upon the future activities of Defendants, including, but not limited to, prohibiting any Defendant from engaging in the same type of endeavor(s).

E. Certificate of Public Importance

294. Attached to this Complaint is a certificate of public importance pursuant to O.C.G.A. § 16-14-12.

COUNT II

RICO CONSPIRACY (O.C.G.A. § 16-14-4(c))

(All Defendants)

295. Plaintiff, the State of Georgia, incorporates and re-alleges each of the paragraphs above as though fully set forth herein.

296. The State brings this claim against all Defendants. At all relevant times, Defendants were associated with the Opioid Enterprise and agreed and conspired to violate O.C.G.A. §16-14-4(b). That is, they agreed to conduct and participate, directly and indirectly, in the conduct of the affairs of the Opioid Enterprise through a pattern of racketeering activity. Under O.C.G.A. § 16-14-4(c) it is unlawful for "any person to conspire to violate" § 16-14-4(b), among other provisions.

297. Defendants conspired to violate O.C.G.A. § 16-14-4(b), as alleged more fully in Count I, by conducting the affairs of the Opioid Enterprise through a pattern of racketeering activity.

COUNT III

PUBLIC NUISANCE
(O.C.G.A. § 41-1-1)

(All Defendants)

298. Plaintiff, the State of Georgia, incorporates and re-alleges each of the paragraphs above as though fully set forth herein.

299. A nuisance is "anything that causes hurt, inconvenience, or damage to another and the fact that the act done may otherwise be lawful shall not keep it from being a nuisance." O.C.G.A. § 41-1-1.

300. Under Georgia law, a "public nuisance" is defined as one "which damages all persons who come within the sphere of its operation, though it may vary in its effects on individuals." O.C.G.A. § 41-1-2

301. "Significant interference with 'the public health, the public safety, the public peace, the public comfort or the public convenience' may support a finding of public nuisance." *City of College Park v. 2600 Camp Creek, LLC*, 293 Ga. App. 207, 208 (2008). For example, the illegal dealing of drugs constitutes ample evidence of a public nuisance. *Moreland v. Cheney*, 267 Ga. 469 (1997).

302. The public nuisance caused by Defendants includes the over-saturation, unlawful availability, and abuse of opioids in the state for non-medical purposes, as well as the adverse social and environmental outcomes associated with widespread illegal opioid use. Manufacturer Defendants deceptively marketed their opioids to change the prescribing habits of doctors and increase their use for non-cancer chronic pain. Distributor Defendants knowingly, intentionally, recklessly, and/or negligently disseminated massive quantities of prescription opioids to suspect

physicians and pharmacies and into the black market, including so-called "pill mills" and other dealers.

303. Defendants knew or should have known that their promotion of opioid use and failure to prevent the diversion of opioids for illicit use would create a public nuisance. As a Schedule II controlled substance, prescription opioids are as addictive and dangerous as heroin and, not surprisingly, addiction to prescription opioids has caused an increase in the prevalence of heroin within the state.

304. Defendants' actions were a substantial factor in opioids becoming widely available and widely used. Without Defendants' actions, opioid use would not have become so widespread and the enormous public health hazard of opioid overuse, abuse, and addiction that now exists would have been averted.

305. The public nuisance created by Defendants has caused, and continues to cause, significant harm to, and the expenditure of taxpayer dollars by, the State, including, but not limited to:

i. The staggering rate of opioid use among adults in Georgia has led to unnecessary opioid abuse, addiction, injuries, overdose, and deaths. It has also resulted in increased crime and property damage in the state.

ii. Infants have been born addicted to opioids due to pre-natal exposure, causing severe withdrawal symptoms, lasting developmental impacts, and, in some instances, death.

iii. Defendants' success in extending the market for opioids to new patients and chronic conditions has also created an abundance of drugs available for illicit use and fueled a new wave of addiction, abuse, and injury. Defendants' scheme created a new secondary market for opioids – providing both the supply of narcotics to sell and the demand of addicts to buy them.

iv. The diversion of opioids into the secondary, illicit market and the increase in the number of individuals who abuse or are addicted to opioids has

placed unnecessary and excessive demands on the medical, public health, law enforcement, and financial resources of the State.

v. Adults and children in Georgia who have never taken opioids have also suffered the costs of Defendants' public nuisance. Many have endured both the emotional and financial costs of caring for loved ones addicted to or injured by opioids, and the loss of companionship, wages, or other support from family members who have used, abused, become addicted to, overdosed on, or been killed by opioids. All of these problems harm the State by diminishing its revenues and forcing it to make increased expenditures.

vi. The addictive nature of prescription opioids has also spawned a new crisis of heroin and fentanyl abuse and death. Use and overdoses from use of heroin and heroin contaminated with fentanyl have skyrocketed as users have switched from prescription opioids to illegal opioids.

306. The State's public resources are being unreasonably consumed in efforts to address the opioid epidemic, thereby eliminating available resources that could be used to benefit the public at large in Georgia.

307. At all relevant times, Defendants possessed the right, ability, knowledge, opportunity, and position to control the nuisance-causing outflow of prescription opioids to pharmacy locations and other points of sale in Georgia. Defendants had the power to shut off the supply of illicit opioids into the state, or to control their flow so that widespread diversion did not occur. Defendants could have stopped providing false information to the market about the dangers of opioids and the highly addictive nature of their opioid products. Had Defendants adhered to their duties, as discussed in detail in this Complaint, there would be no opioid crisis.

308. As a direct and proximate result of the public nuisance, the State of Georgia has sustained harm by spending a substantial amount of money trying to respond, assess, and solve the societal harms caused by Defendants' nuisance-causing activity, including, but not limited to: costs and economic impact associated with healthcare, addiction treatment, and hospital services; child and family services; education; elevated crime rates; judicial services; incarceration rates;

medical examinations; burials; tax collections; a diminished tax base; economic development; diminished property values; and law enforcement and responder costs. Moreover, Georgia finds itself in need of costly new infrastructure and programs necessary to mitigate the nuisance.

309. For all of these reasons, this public nuisance is extraordinary in its scope and severity. It is not the result of a discrete incident or emergency of the kind the State would reasonably expect to respond to but is instead an unprecedented epidemic unseen in Georgia's history. This nuisance is man-made, and a consequence of Defendants' premeditated plan to profit by targeting multiple victims, including the State of Georgia, over a prolonged period of time using misconduct, corruption and deceit.

310. The nuisance created by Defendants' conduct is abatable.

311. Defendants should be required to pay the expenses the State has incurred or will incur in the future to respond to this corporate-made crisis and further to fully abate the nuisance.

COUNT IV

NEGLIGENCE

(All Defendants)

312. Plaintiff, the State of Georgia, incorporates and re-alleges each of the paragraphs above as though fully set forth herein.

313. The elements of negligence under Georgia law are that a defendant has "a legal duty; breached that duty; a causal connection exists between the defendant's conduct and the plaintiff's injury; and the plaintiff suffered damages." *Seymour Elec. and Air Conditioning Service, Inc. v. Statom*, 309 Ga. App. 677 (2011).

314. Each Defendant had an obligation and duty to exercise reasonable care in the manufacturing, marketing, and distribution of highly dangerous opioid drugs in the state.

315. Each Defendant owed a duty to the State and its people, and to the public health and safety of the people of Georgia, because the injuries and harms to the State were foreseeable, and in fact were foreseen by each Defendant.

316. Defendants breached this duty by failing to take any action to prevent or reduce the improper and unlawful manufacture, marketing as well as distribution of the opioid drugs.

317. Reasonably prudent wholesale drug manufactures, marketers, and distributors would have anticipated the scourge of opioid addiction that would wreak havoc on communities, including the State of Georgia, when weighed against Defendants' conduct. Defendants were repeatedly warned by law enforcement. The escalating amounts of addictive drugs flowing through Defendants' businesses and the sheer volume of these prescription opioids further alerted Defendants that addiction was fueling the increased consumption and that legitimate medical purposes were not being served.

318. Defendants knew or should have known that opioids were unreasonably dangerous and were likely to cause addiction.

319. As a direct and proximate result of Defendants' negligence, the State has suffered and continues to suffer injury including, but not limited to, incurring excessive costs related to diagnosis, treatment, and cure of addiction to opioids, bearing the massive costs of these illnesses and conditions by having to provide necessary resources for care, treatment facilities, and law enforcement services for Georgia's residents, and using Georgia's resources in relation to opioid use and abuse. The crisis has also impacted the State of Georgia's economy, resulting in economic losses to the State.

320. Defendants were negligent in failing to monitor and guard against third-party misconduct and participated and enabled such misconduct.

321. Defendants were negligent in failing to disclose suspicious orders for opioids to the State pursuant to the requirements of Georgia law and the federal Controlled Substances Act.

322. Defendants' acts and omissions combined and concurred to impose an unreasonable risk of harm to others and combined and concurred with the negligent and/or criminal acts of third parties to impose an unreasonable risk of harm to others.

323. Defendants are in a class of a limited number of parties that can legally manufacture and distribute opioids which places them in a position of great trust by the State.

324. The trust placed in Defendants by the State through the license to manufacture and distribute opioids in Georgia creates a duty on behalf of Defendants to prevent diversion of the medications they supply.

325. Defendants breached their duty to exercise the degree of care, prudence, watchfulness, and vigilance commensurate to the dangers involved in the transaction of their businesses.

326. Defendants are in exclusive control of the management of the opioids they manufacture, market, and distribute in Georgia.

327. The State is without fault and the injuries to the State and its residents would not have occurred in the ordinary course of events had Defendants used due care commensurate to the dangers involved in the manufacture and distribution of opioids.

328. The State is entitled to recover damages caused by Defendants' negligence in an amount to be determined at trial.

COUNT V

UNJUST ENRICHMENT

(All Defendants)

329. Plaintiff, the State of Georgia, incorporates and re-alleges each of the paragraphs above as though fully set forth herein.

330. As an expected and intended result of their conscious wrongdoing as set forth in this Complaint, Defendants have profited and benefited from the opioid epidemic.

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

332. For years, the State has conferred a benefit on Defendants by allowing them to market, promote, and distribute opioids in Georgia and by attempting to address all aspects of the opioid epidemic, including, but not limited to: supplying emergency care and treatment to opioid users; education, counseling and therapy to opioid users; police protection and law enforcement as a result of opioid users; abatement of nuisances; increased costs to public institutions; and other efforts and remedial measures designed to address and curb the increasing epidemic, all of which conferred a benefit on Defendants, which continued to have more customers and a market in Georgia for profiteering.

333. The State has conferred a benefit upon Defendants by paying for Defendants' externalities: the cost of the harms caused by Defendants' improper marketing, promotion and distribution practices. Moreover, the State has incurred expenditures for special programs over and above the State's ordinary public services.

334. Defendants directly profited from the State's remedial expenditures. Without such expenditures, there would not have been a profitable market for these dangerous and addictive drugs. These expenditures have helped to sustain Defendants' businesses.

335. Defendants' misconduct alleged in this Complaint does not concern a discrete event or discrete emergency of the sort that the State would reasonably expect to occur, and is not part of the normal and expected costs of a state government's existence. The State alleges wrongful acts which are neither discrete nor of the sort a State can reasonably expect.

336. Defendants were, and are, aware of these obvious benefits, and their retention of these benefits is unjust. The misconduct alleged in this Complaint is ongoing and persistent.

337. Because of their conscious failure to exercise due diligence in preventing diversion, Defendants obtained enrichment that they would not otherwise have obtained. This enrichment was without justification.

338. Defendants have unjustly retained benefits to the detriment of the State, and Defendants' retention of such benefits violates the fundamental principles of justice, equity, and good conscience.

339. Defendants, through the wrongful conduct described above, have been unjustly enriched at the expense of the State.

340. In equity and good conscience, it would be unjust and inequitable to permit Defendants to enrich themselves at the expense of the State.

341. The State seeks an order compelling Defendants to disgorge all unjust enrichment to the State and awarding such other, further, and different relief as this Honorable Court may deem just.

COUNT VI

CIVIL CONSPIRACY

(All Defendants)

342. Plaintiff, the State of Georgia, incorporates and re-alleges each of the paragraphs above as though fully set forth herein.

343. Defendants engaged in (1) a common design between two or more persons, (2) to accomplish by concerted action an unlawful purpose, or a lawful purpose by unlawful means, (3) an overt act in furtherance of the conspiracy, and (4) resulting in injury to the State.

344. Defendants engaged in one or more unlawful tortious activities to further the conspiracy. The objects of the conspiracy were racketeering, nuisance, negligence, fraud, misrepresentation and other unlawful tortious conduct as described above in this Complaint. Defendants knew that these objects were unlawful and would be accomplished by unlawful means such as fraud, misrepresentations, and omissions.

345. Defendants had a meeting of the minds on the object of or course of action for this conspiracy. Defendants knew and agreed upon the unlawful object of or course of action for this conspiracy. Defendants also knew that their wrongful actions would inflict injury upon the targets of the conspiracy, including the State of Georgia and its residents.

346. As described above, Defendants committed multiple unlawful and overt acts to further the object of or course of action for this conspiracy as described above.

347. These unlawful acts proximately caused the damages suffered by the State. Accordingly, the State is entitled to recover its actual damages.

348. Defendants conspired to create a public nuisance and to commit tortious conduct and are therefore liable for the damages flowing from the conspiracy.

COUNT VII

FALSE ADVERTISING
(O.C.G.A. § 10-1-420, *et seq.*)

(All Defendants)

349. Plaintiff, the State of Georgia, incorporates and re-alleges each of the paragraphs above as though fully set forth herein.

350. Defendants, in marketing opioids, made numerous false statements about the nature of these drugs, including:

a. that they are safe;

b. that they are appropriate for the treatment of chronic, non-cancer pain;

c. that they can improve bodily and mental function long-term or otherwise improve quality of life;

d. that they are safe and effective for continued, long-term use;

e. that they are not addictive;

f. that pseudoaddiction is a legitimate medical concept;

g. that patients who seem addicted are merely "pseudoaddicted," and should be treated with more opioids;

h. that opioid addiction is the product of problem patients and doctors, not inherently of opioids; and

i. that opioid abuse and addiction manifest themselves through snorting and injecting the drugs, and not oral or topical administration.

351. These false statements were made in order to induce residents of Georgia to purchase Defendants' opioids.

352. These false statements were disseminated in public in the state through marketing brochures, websites, publications, advertising in periodicals, educational materials, speeches

sponsored by Defendants, misleading scientific studies, statements to medical professionals, and endorsement of statements by others.

353. Defendants knew or should have known these statements were false.

354. The State seeks injunctive relief to curtail Defendants' false advertising and marketing pursuant to O.C.G.A. § 10-1-423.

COUNT VIII

NEGLIGENCE PER SE

(All Defendants)

355. Plaintiff, the State of Georgia, incorporates by reference all other paragraphs of this Complaint as if fully set forth here, and further alleges as follows.

356. Georgia law provides that "[w]hen the law requires a person to perform an act for the benefit of another or to refrain from doing an act which may injure another, although no cause of action is given in express terms, the injured party may recover for the breach of such legal duty if he suffers damage thereby." O.C.G.A. § 51-1-6.

357. Defendants were under an obligation to implement a system to monitor, identify, investigate, and halt suspicious orders and to stop and report confirmed suspicious orders. Furthermore, Georgia law incorporates federal requirements set out under the Controlled Substances Act and related controlled substance laws and regulations.

358. Each Defendant has an affirmative duty under Georgia and federal law to act as a gatekeeper guarding against the diversion of the highly addictive, dangerous opioid drugs. Federal law requires that distributors of Schedule II drugs, including opioids, maintain "effective control against diversion of particular controlled substances into other than legitimate medical,

scientific, and industrial channels." 21 U.S.C. § 823(b)(1). Those requirements are adopted and incorporated into Georgia law, as set out above.

359. Defendants failed to implement an effective system for accomplishing this duty and continued to ship suspicious orders to pharmacies and other dispensers in Georgia, and they did not report such sales to the proper legal authorities of the State of Georgia.

360. As a result, opioid drugs have been diverted, illicitly used, and abused, resulting in thousands of overdoses, hospitalizations, and deaths. Thousands of Georgia residents are now struggling with addiction. Criminal enterprises are increasing the supply of heroin and fentanyl to exploit the market for opioid addiction.

361. The purpose of the disclosure requirement for suspicious orders of opioids is to alert governing agencies and officials of the potential for abuse and harm resulting from large quantities of opioids within a community.

362. The State falls within the class of persons that O.C.G.A. § 26-4-115 was intended to protect.

363. The expense incurred by the State in combating the opioid epidemic is the harm that the reporting requirements of O.C.G.A. § 26-4-115 and 21 U.S.C. § 823(b) were intended to prevent or mitigate.

364. The State seeks economic losses (direct, incidental, or consequential pecuniary losses) resulting from Defendants' tortious activity.

365. The State seeks all legal and equitable relief as allowed by law.

COUNT IX

BREACH OF STATUTORY DUTY
(O.C.G.A. § 51-1-6)

(All Defendants)

366. Plaintiff, the State of Georgia, incorporates by reference all other paragraphs of this Complaint as if fully set forth here, and further alleges as follows.

367. As explained in the facts section of this Complaint, Defendants' failure to monitor and report suspicious orders of opioids and shipment of suspicious orders resulted in injury to the State and its people.

368. The purpose of the disclosure requirement for suspicious orders of opioids is to alert governing agencies and officials of the potential for abuse and harm resulting from large quantities of opioids within a community, so drug diversion does not occur.

369. Failure to comply with the Georgia Controlled Substances Act constitutes negligence *per se*.

370. The expense incurred by the State in combating the opioid epidemic is the harm that the reporting requirements of O.C.G.A. § 26-4-115 were intended to prevent or mitigate.

371. The State seeks economic losses (direct, incidental, or consequential pecuniary losses) resulting from Defendants' tortious activity.

372. The State seeks all legal and equitable relief as allowed by law.

PUNITIVE DAMAGES

(All Defendants)

373. Plaintiff, the State of Georgia, re-alleges all paragraphs of this Complaint as if set forth fully herein.

374. By engaging in the above-described unfair and/or intentionally deceptive acts, Defendants acted with actual malice and with conscious disregard for the rights of others and/or in a reckless, wanton, willful, or gross manner.

375. Defendants' actions had a great probability of causing substantial harm.

376. When such harm materialized, Defendants acted with a prolonged indifference to the dire consequences of their wrongful conduct.

377. Defendants were selling dangerous drugs statutorily categorized as posing a high potential for abuse and severe dependence. Thus, Defendants knowingly traded in drugs that presented a high degree of danger if prescribed incorrectly or diverted to other than legitimate medical, scientific, or industrial channels.

378. Because of the severe level of danger posed by, and indeed visited upon the State and the State's citizenry and communities by, these dangerous drugs, Defendants owed a high duty of care to ensure that these drugs were only used for proper medical purposes.

379. Defendants not only failed to live up this duty, but actively sought to undermine it in order to increase the volume of drugs they could sell.

380. Defendants chose profit over the safety of the community, and an award of punitive damages is appropriate as punishment and a deterrent.

381. In light of Defendants' wrongful conduct, an award of punitive damages is necessary to deter future operations that harm the public.

382. By engaging in the above-described wrongful conduct, Defendants also engaged in willful misconduct and exhibited an entire want of care that gives rise to the presumption of a conscious indifference to consequences.

TRANSFER TO BUSINESS COURT REQUESTED

383. Plaintiff, the State of Georgia, re-alleges all paragraphs of this Complaint as if set forth fully herein.

384. The State of Georgia respectfully moves this Court to immediately transfer the above-styled case to the Business Case Division of Gwinnett County Superior Court.

385. The amount in controversy of this case exceeds, or is likely to exceed, $1 million.

386. This case involves complex issues of law with multiple parties, extensive documentary evidence, complex discovery issues, and claims involving complex business-related practices and transactions.

PRAYER FOR RELIEF

WHEREFORE, the State of Georgia prays for an Order that this Honorable Court:

A. Enter judgment against Defendants and in favor of the State of Georgia;

B. Award nominal, economic and/or consequential damages in an amount sufficient to fairly and completely compensate the State of Georgia for all compensable damages under Georgia law;

C. Award pre-judgment and post-judgment interest as provided by law, and award such interest at the highest legal rate;

D. Enter an order of abatement and permanent injunction against all Defendants prohibiting them from engaging in the unlawful conduct detailed herein, including over-promotion and over-supply of opioids in and around Georgia, the entry of any appropriate orders and judgments imposing reasonable restrictions upon the future activities of Defendants, including, but not limited to, prohibiting any Defendant from engaging in the same type of

endeavor(s) and, further, for injunctive relief to curtail Defendants' false advertising and marketing pursuant to O.C.G.A. § 10-1-423;

E. Enter an order requiring Defendants to fund an "abatement fund" for the purpose of abating the opioid nuisances, and further order Defendants to pay damages sufficient to fund an abatement plan;

F. Award the State the costs of suit, including reasonable attorneys' fees as provided by law;

G. Require Defendants to disgorge their unjustly acquired profits and other monetary benefits resulting from their unlawful conduct and provide restitution to the State of Georgia; and

H. Award such further and additional relief as the Court may deem just and proper under the circumstances.

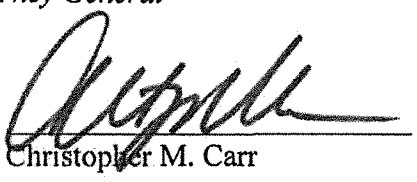
JURY DEMAND

The State of Georgia demands, and is entitled to, a trial by jury on all issues so triable.

Dated this 3rd day of January, 2019.

Respectfully submitted,

Christopher M. Carr
Attorney General

By: 
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