UNITED STATES DISTRICT COURT
FOR THE WESTERN DISTRICT OF KENTUCKY

WARREN COUNTY, *Plaintiff*, vs **TEVA PHARMACEUTICAL INDUSTRIES LTD.;** **TEVA PHARMACEUTICALS USA, INC.** **CEPHALON, INC.;** **JOHNSON & JOHNSON;** **JANSSEN PHARMACEUTICALS, INC.;** **ORTHO-MCNEIL-JANSSEN PHARMACEUTICALS, INC.** n/k/a JANSSEN PHARMACEUTICALS, INC.; **JANSSEN PHARMACEUTICA, INC.** n/k/a JANSSEN PHARMACEUTICALS, INC.; **ENDO HEALTH SOLUTIONS INC.;** **ENDO PHARMACEUTICALS, INC.;** **QUALITEST PHARMACEUTICAL INC.;** **ABBVIE INC.,** **KNOLL PHARMACEUTICAL COMPANY;** **ALLERGAN PLC** f/k/a ACTAVIS PLC.; **ALLERGAN FINANCE LLC** f/k/a ACTAVIS INC. f/k/a WATSON PHARMACEUTICALS, INC.; **WATSON LABORATORIES, INC**.; **ACTAVIS LLC**; **ACTAVIS PHARMA, INC.** f/k/a WATSON PHARMA, INC.; **MALLINCKRODT PLC;** **MALLINCKRODT, LLC;** **MALLINCKRODT BRAND PHARMACEUTICALS;** **COVIDIEN PLC;** **SPECGX LLC;** **CARDINAL HEALTH, INC.;** **MCKESSON CORPORATION;** **AMERISOURCEBERGEN CORPORATION;**	Civil Action No. _____ COMPLAINT AND JURY DEMAND

WALGREENS BOOT ALLIANCE, INC. d/b/a WALGREEN CO.**;**
WAL-MART STORES, INC.;
CVS HEALTH;
RITE AID CORPORATION;
THE KROGER COMPANY; AND
DOES 1 – 100, INCLUSIVE.

Defendants.

PLAINTIFF'S ORIGINAL COMPLAINT

I. PRELIMINARY STATEMENT

1. Opioid abuse and addiction are a national public health crisis. According to the Centers for Disease Control ("CDC"), over 70,000 Americans died of a drug overdose in 2017, of which 67.8% (47,600) involved opioids. The number of deaths in the United States (hereafter, "U.S.") and the prevalence of opioids were both worse in 2017 than a year prior.[1]

2. Unlike the crack cocaine and crystal methamphetamine epidemics that preceded it, this public health crisis was created by the corporate business plan of pharmaceutical manufacturers, including Teva Pharmaceuticals USA, Inc.; Teva Pharmaceutical Industries Ltd; Cephalon, Inc.; Johnson & Johnson; Janssen Pharmaceuticals, Inc.; Ortho-McNeil-Janssen Pharmaceuticals, Inc. n/k/a Janssen Pharmaceuticals, Inc.; Janssen Pharmaceutica, Inc. n/k/a Janssen Pharmaceuticals, Inc.; Endo Pharmaceuticals Inc.; Endo Health Solutions Inc.; Qualitest Pharmaceuticals Inc.; Abbvie Inc.; Knoll Pharmaceutical Company; Allergan PLC f/k/a Actavis PLC.; Allergan Finance LLC. f/k/a Actavis Inc. f/k/a Watson Pharmaceuticals, Inc.; Watson Laboratories Inc.; Actavis LLC.; Actavis Pharma, Inc. f/k/a Watson Pharma, Inc.; Mallinckrodt PLC; Mallinckrodt Brand Pharmaceutical, Inc.; Mallinckrodt LLC; Covidien PLC and SpecGx

1 Ctr. for Disease Control & Prevention, Drug Overdose Deaths, https://www.cdc.gov/drugoverdose/data/statedeaths.html. According to the CDC, over 63,000 Americans died of a drug overdose in 2016, of which 66.4 percent (42,249) involved opioids. (Ctr. for Disease Control & Prevention, Morbidity and Mortality Weekly Report, March 30, 2016, Overdose Deaths, 2015-2016, https://www.cdc.gov/mmwr/volumes/67/wr/mm6712a1.htm?s_cid=mm6712a1_w.)

LLC, who used misrepresentations regarding the risks and benefits of opioids to enable the widespread prescribing of opioids for common, chronic pain conditions like low back pain, arthritis, and headaches.[2]

3. In addition, these pharmaceutical manufacturers, along with McKesson Corporation, AmerisourceBergen Drug Corporation, Cardinal Health, Inc., Walgreens Boots Alliance d/b/a Walgreen Co., Wal-Mart Stores, Inc., CVS Health, Rite Aid Corporation, and the Kroger Company failed to maintain effective controls, and to investigate, report, and take steps to terminate suspicious orders (such as, orders of unusual size, orders deviating substantially from a normal pattern, and orders of unusual frequency).

4. Further, Walgreens Boots Alliance d/b/a Walgreen Co., Wal-Mart Stores, Inc., CVS Health, Rite Aid Corporation, and the Kroger Company held special obligations under the law as registered retail pharmacies. On thousands of occasions, these pharmacies ignored unresolvable red flags and filled prescriptions outside the usual course of practice and for other than a legitimate medical purpose, leading directly to the diversion of millions of pills of highly abused opioid controlled substances.

5. The County brings this action to redress Defendants' campaign of unfairly, deceptively, and fraudulently marketing, promoting and distributing opioids.

6. Pharmaceutical manufacturers, including Teva Pharmaceuticals USA, Inc.; Teva Pharmaceutical Industries Ltd; Cephalon, Inc.; Johnson & Johnson; Janssen Pharmaceuticals, Inc.; Ortho-McNeil-Janssen Pharmaceuticals, Inc. n/k/a Janssen Pharmaceuticals, Inc.; Janssen Pharmaceutica, Inc. n/k/a Janssen Pharmaceuticals, Inc.; Endo Pharmaceuticals Inc.; Endo Health Solutions Inc.; Qualitest Pharmaceuticals Inc.; Abbvie Inc.; Knoll Pharmaceutical Company;

[2] Consistent with the commonly accepted medical usage, the term "chronic pain" as used herein refers to non-cancer pain lasting three months or longer.

Allergan PLC f/k/a Actavis PLC.; Allergan Finance LLC. f/k/a Actavis Inc. f/k/a Watson Pharmaceuticals, Inc.; Watson Laboratories Inc.; Actavis LLC.; Actavis Pharma, Inc. f/k/a Watson Pharma, Inc.; Mallinckrodt PLC; Mallinckrodt Brand Pharmaceutical, Inc.; Mallinckrodt LLC; Covidien PLC.; and SpecGx LLC manufacture, market, and sell prescription opioid pain medications, including the brand-name drugs Actiq, Fentora, Opana/Opana ER, Percodan, Percocet, Zydone, Xartemis XR, Exalgo, Nucynta/Nucynta ER, and Duragesic, and generic drugs such as oxycodone.

7. Pharmaceutical distributors, McKesson Corporation, AmerisourceBergen Drug Corporation, Cardinal Health, Inc., Walgreens Boots Alliance d/b/a Walgreen Co., Wal-Mart Stores, Inc., CVS Health, Rite Aid Corporation, and the Kroger Company distribute opioid medications, including the medications listed above, to pharmacies, pain clinics and other dispensaries across the country and in and around the County.

8. Retail pharmacies, Walgreens Boots Alliance d/b/a Walgreen Co., Wal-Mart Stores, Inc., CVS Health, Rite Aid Corporation, and the Kroger Company are required to review prescriptions issued from licensed and DEA-registered practitioners, such as physicians, and ultimately choose whether or not to fill the issued prescription for the end-user customer. Retail Pharmacies are the final line of defense in preventing the diversion of opioid medications, such as those listed above, for improper use, abuse, or illicit sale, and have consistently failed to fulfill their obligation. While the Pharmacy Defendants have few brick-and-mortar locations within the State, prescriptions filled by these Pharmacy Defendants in other states frequently make their way into Kentucky through various licit and illicit means.

9. Prescription opioids are narcotics. They are derived from and possess properties similar to opium and heroin, and they are regulated as controlled substances. Opioids can create

an addictive, euphoric high. At higher doses, they can slow the user's breathing, causing potentially fatal respiratory depression. Most patients receiving more than a few weeks of opioid therapy will experience severe and often prolonged withdrawal symptoms. When using opioids continuously, patients grow tolerant to their analgesic effects (i.e. to relief of pain)—requiring progressively higher doses and increasing the risks of withdrawal, addiction, and overdose.

10. Because the medical community recognized these dangers, they originally used opioids cautiously and sparingly, typically only for short-term acute pain—where brief use limited the need for escalating doses and the risk of addiction—or for palliative (end-of-life) care. Consequently, the market for prescription opioids was sharply constrained.

11. The above-named pharmaceutical manufacturers began to promote opioids generally, and their own opioids in particular, as safe, effective, and appropriate for even long-term use for routine pain conditions.

12. As part of this strategy, these pharmaceutical manufacturers misrepresented the risk of addiction for pain patients as modest, manageable, and outweighed by the benefits of opioid use.

13. From the day they made the opioids, to the day the medicines were consumed in our communities, including in and around the County, the pharmaceutical manufacturers had control over the information that they chose to spread and emphasize as part of their massive marketing campaign. Consequently, by providing misleading information to doctors about addiction being rare and opioids being safe even in high doses, then pressuring doctors into prescribing more and more of their products by arguing, among other things, that they fail to meet the standard of care if their patients continue to complain of pain, the pharmaceutical

manufacturers created a population of addicted patients, including in the County, who sought opioids at never-before-seen rates.

14. On the supply side, the crisis was fueled and sustained by those involved in the supply chain of opioids, including manufacturers, distributors, pharmacies, and individuals (together, "Defendants"), who failed to maintain effective controls over the distribution of prescription opioids and against diversion, and who instead have actively sought to evade such controls and ignore red flags of potential diversion.

15. Defendants have contributed substantially to the opioid crisis by selling and distributing far greater quantities of prescription opioids than they know could be necessary for legitimate medical uses, while failing to report or take steps to halt suspicious orders when they were identified, thereby exacerbating the oversupply of such drugs and fueling an illegal secondary market.

16. As many as 1 in 4 patients who receive prescription opioids long-term for chronic pain in primary care settings struggles with addiction. In 2014, almost 2 million Americans were addicted to prescription opioids and another 600,000 to heroin. From 1999 to 2015, more than 183,000 people died in the U.S. from overdoses related to prescription opioids. Overdose deaths involving prescription opioids were five times higher in 2017 than in 1999.

17. As a direct and foreseeable result of Defendants' conduct, communities across the nation, including the County, are now swept up in what the CDC has called a "public health epidemic" and what the U.S. Surgeon General has deemed an "urgent health crisis."[3] The increased volume of opioid prescription correlates directly with skyrocketing addiction, overdose and death; black markets for diverted prescriptions opioids; and a concomitant rise in heroin and

[3] CDC, Examining the Growing Problems of Prescription Drug and Heroin Abuse (Apr. 29, 2014), available at http://www.cdc.give.washington/testimony/2014/t20140429.htm; Vivek H. Murthy, Letter from the Surgeon General, August 2016, available at http://turnthetiderx.org.

fentanyl abuse by individuals who can no longer legally acquire or simply cannot afford prescription opioids.

18. This explosion in opioid use and the concurrent explosion in Defendants' profits have come at the expense of patients and have caused ongoing harm and damages to the County. As the then CDC director concluded in 2016: "We know of no other medication routinely used for a nonfatal condition that kills patients so frequently."[4]

19. A substantial amount of the costs associated with opioid use and opioid abuse disorder is borne by government entities. The necessary and costly responses to the opioid crisis include the handling of emergency responses to overdoses, providing addiction treatment, handling opioid-related investigations, arrests, adjudications, and incarceration, treating opioid-addicted newborns in neonatal intensive care units, burying the dead, and placing thousands of children in foster care, among others.

20. Defendants have not changed their ways or corrected their past misconduct but instead are continuing to fuel the crisis. Within the next hour, 5 Americans will die from opioid overdoses; 2 babies will be born already addicted to opioids and begin to go through withdrawal; and drug manufacturers and distributors will earn millions from the sale of opioids.

21. Accordingly, the County brings this action to hold Defendants accountable for their conduct and to seek damages, abatement, and any other injunctive and equitable relief within this Court's powers to redress and halt Defendants' unfair, deceptive, and unlawful practices.

[4] Thomas R. Frieden and Debra Houry, New England Journal of Medicine, "Reducing the Risks of Relief—The CDC Opioid-Prescribing Guideline" at 1503 (Apr. 21, 2016).

22. The County brings this action to redress the campaign of unfairly, deceptively, and fraudulently marketing, promoting, and distributing opioids undertaken by these pharmaceutical manufacturers and pharmacies.

II. PARTIES

A. PLAINTIFF

23. Plaintiff, Warren County of Kentucky(hereafter, the "County"), by and through the undersigned attorneys, against Defendants Teva Pharmaceuticals USA, Inc., Teva Pharmaceutical Industries Ltd; Cephalon, Inc., Johnson & Johnson; Janssen Pharmaceuticals, Inc.; Ortho-McNeil-Janssen Pharmaceuticals, Inc. n/k/a Janssen Pharmaceuticals, Inc.; Janssen Pharmaceutica, Inc., n/k/a Janssen Pharmaceuticals Inc.; Endo Health Solutions Inc., Endo Pharmaceuticals, Inc., Qualitest Pharmaceuticals Inc., Abbvie Inc.; Knoll Pharmaceutical Company; Allergan PLC f/k/a Actavis PLC, Allergan Finance, LLC f/k/a Actavis, Inc. f/k/a Watson Pharmaceuticals, Inc., Watson Laboratories, Inc., Actavis LLC, Actavis Pharma, Inc. f/k/a Watson Pharma, Inc., Mallinckrodt, PLC, Mallinckrodt LLC, Mallinckrodt Brand Pharmaceuticals, Covidien PLC, SpecGx, LLC, McKesson Corporation, Cardinal Health, Inc., AmerisourceBergen Corporation, Walgreens Boot Alliance, Inc., Wal-Mart Stores, Inc., CVS Health, Rite Aid Corporation, the Kroger Company, and Does 1 – 100, alleges as follows:

24. The County, provides a wide range of services on behalf of its residents, including services for families and children, public health, public assistance, and law enforcement.

B. DEFENDANTS

a. Manufacturer Defendants

25. The following pharmaceutical manufacturers are hereafter collectively referred to as "Manufacturer Defendants": Teva Pharmaceuticals USA, Inc., Teva Pharmaceutical Industries Ltd; Cephalon, Inc., Endo Pharmaceuticals Inc.; Endo Health Solutions Inc.; Qualitest

Pharmaceuticals Inc.; Johnson & Johnson; Janssen Pharmaceuticals, Inc.; Ortho-McNeil-Janssen Pharmaceuticals, Inc. n/k/a Janssen Pharmaceuticals, Inc.; Janssen Pharmaceutica, Inc. n/k/a Janssen Pharmaceuticals, Inc.; Abbvie Inc.; Knoll Pharmaceutical Company; Allergan PLC f/k/a Actavis PLC, Allergan Finance, LLC f/k/a Actavis, Inc. f/k/a Watson Pharmaceuticals, Inc., Watson Laboratories, Inc., Actavis LLC, Actavis Pharma, Inc. f/k/a Watson Pharma, Inc.; Mallinckrodt PLC; Mallinckrodt Brand Pharmaceutical, Inc.; Mallinckrodt LLC; Covidien PLC and SpecGx LLC.

26. Teva Pharmaceuticals USA, Inc. (hereafter, "Teva USA") is a Delaware corporation with its principal place of business in North Wales, Pennsylvania.

27. Cephalon, Inc. (hereafter, "Cephalon") is a Delaware corporation with its principal place of business in Frazer, Pennsylvania and may be served through its registered agent for service of process, Corporate Creations Network Inc., 3411 Silverside Road Tatnall Building Ste 104, Wilmington, DE 19810.

28. In October 2011, Teva USA acquired Cephalon. Teva USA and Cephalon work together closely to market and sell Cephalon products in the U.S., including in and around the County. Teva USA also sells generic opioids throughout the U.S. and in and around County. In August 2016, Teva Pharmaceutical Industries Ltd., which is based in Israel and is Teva USA's parent company, acquired Allergan PLC, including the generic opioid business that Allergan had previously operated. These parties are collectively referred to herein as "Teva."

29. Teva manufactures, promotes, sells, and distributes opioids such as Actiq, a fentanyl lollipop, and Fentora, a dissolving pill, throughout the U.S. and in the County. Actiq and Fentora have been approved by the U.S. Food and Drug Administration ("FDA") only for the

"management of breakthrough cancer pain in patients 16 years of age and older, who are already receiving and are tolerant to opioid therapy for their underlying persistent cancer pain."[5]

30. Yet, between 2001 and 2006 Cephalon promoted Actiq for use by non-cancer patients for "migraines, sickle-cell pain crises, injuries, and in anticipation of changing wound dressings or radiation therapy. Cephalon also promoted Actiq for use with patients who were not opioid tolerant."[6] Consequently, in 2008, Cephalon pled guilty to a criminal violation of the Federal Food, Drug and Cosmetic Act for marketing Actiq and two other drugs for uses not approved by the Food and Drug Administration (FDA) and agreed to pay $425 million.[7]

31. Teva's opioid business impacts Plaintiff County.

32. Janssen Pharmaceuticals, Inc. is a Pennsylvania corporation with its principal place of business in Titusville, New Jersey. It may be served through its registered agent for service of process, CT Corporation System, 600 North 2nd St, Suite 401, Harrisburg, PA 17101. Janssen Pharmaceuticals, Inc. is a wholly owned subsidiary of Johnson & Johnson (hereafter known as "J&J"), a New Jersey corporation with its principal place of business in New Brunswick, New Jersey, and may be served through its registered agent for service of process, Attention: Legal Department, One Johnson & Johnson Plaza, New Brunswick, NJ 08933. Ortho-McNeil-Janssen Pharmaceuticals, Inc., now known as Janssen Pharmaceuticals, Inc., is a Pennsylvania corporation with its principal place of business in Titusville, New Jersey. Janssen Pharmaceutica, Inc., now known as Janssen Pharmaceuticals, Inc., is a Pennsylvania corporation with its principal place of business in Titusville, New Jersey.

[5] https://www.accessdata.fda.gov/drugsatfda_docs/label/2011/020747s033lbl.pdf
https://medlineplus.gov/druginfo/meds/a605043.html
[6] https://www.justice.gov/archive/opa/pr/2008/September/08-civ-860.html
[7] https://www.justice.gov/archive/opa/pr/2008/September/08-civ-860.html

33. J&J is the only company that owns more than 10% of Janssen Pharmaceuticals' stock and corresponds with the FDA regarding Janssen's products.

34. Upon information and belief, County alleges that J&J controls the sale and development of Janssen Pharmaceuticals' drugs and Janssen's profits inure to J&J's benefit. J&J also asserts control over Janssen through its management team. According to Janssen's website, the "leadership team that guides Janssen" contains several J&J executives.[8]

35. J&J imposes a code of conduct on Janssen as a pharmaceutical subsidiary of J&J. Documents posted on J&J's and Janssen's websites confirm J&J's control of the development and marketing of opioids by Janssen. One code of conduct on Janssen's website "Ethical Code for the Conduct of Research and Development," names only J&J and does not mention Janssen anywhere within the document. The "Ethical Code for the Conduct of Research and Development" posted on the Janssen website is J&J's company-wide Ethical Code, which it requires all of its subsidiaries to follow.

36. Similarly, the "Every Day Health Care Compliance Code of Conduct" posted on Janssen's website is a J&J company-wide document that describes Janssen as one of the "pharmaceutical Companies of Johnson and Johnson" and as one of the "Johnson & Johnson Pharmaceutical Affiliates". It governs how "[a]ll employees of Johnson & Johnson Pharmaceutical Affiliates," including those of Janssen, "market, sell, promote, research, develop, inform and advertise Johnson & Johnson Pharmaceutical Affiliates' products." All Janssen officers, directors, employees, and sales associates must certify that they have "read, understood and will abide by" the code. Thus, the code governs all forms of marketing at issue in this case.

[8] Members of Janssen's "leadership team" include Joaquin Duato, Vice Chairman of the Executive Committee, Johnson & Johnson; Paul Stoffels, M.D. Vice Chairman of the Executive Committee, Chief Scientific Officer, Johnson & Johnson; Jennifer Taubert, Executive Vice President, Worldwide Chairman, Pharmaceuticals, Johnson & Johnson; and, Scott White, Company Group Chairman, North American Pharmaceuticals, Johnson & Johnson. *See* https://www.janssen.com/about/our-leadership (last visited on April 24, 2019).

37. J&J made payments to thousands of physicians nationwide, ostensibly for activities including participating on speakers' bureaus, providing consulting services, assisting in post-marketing safety surveillance and other services, but in fact, aimed to deceptively promote and maximize the use of opioids. In addition, J&J made payments to front groups, discussed herein, who perpetuated and disseminated Defendants' misleading marketing messages regarding the risks and benefits of opioids.[9]

38. In this suit Janssen Pharmaceuticals, Inc., Ortho-McNeil-Janssen Pharmaceuticals, Inc., Janssen Pharmaceutica, Inc., and J&J are collectively referred to as "Janssen".

39. Janssen manufactures, promotes, sells, and distributes opioids in the U.S. and in and around the County, including the opioid Duragesic. Before 2009, Duragesic accounted for at least $1 billion in annual sales., Janssen developed, marketed and sold the opioids Nucynta and Nucynta ER until January 2015. Together, Nucynta and Nucynta ER accounted for $172 million in sales in 2014.

40. Janssen's opioid business impacts County.

41. Endo Health Solutions, Inc. is a Delaware corporation with its principal place of business in Malvern, Pennsylvania, and may be served through its registered agent for service of process, The Corporation Trust Company, Corporation Trust Center, 1209 Orange St., Wilmington, DE 19801. Endo Pharmaceuticals, Inc. is a wholly-owned subsidiary of Endo Health Solutions Inc. and is a Delaware corporation with its principal place of business in Malvern, Pennsylvania. It may be served through its registered agent for service of process, The

[9] U.S. Senate Homeland Security & Governmental Affairs Committee, Ranking Member's Office, Staff Report, Fueling an Epidemic, Report Two, Exposing the Financial Ties Between Opioid Manufacturers and Third Party Advocacy Groups, n. 23 ("Payments from Janssen include payments from Johnson & Johnson, Health Care Systems, Inc.".)

Corporation Trust Company, Corporation Trust Center 1209 Orange St, Wilmington, DE 19801.

42. In this suit Endo Health Solutions Inc. and Endo Pharmaceuticals, Inc. are collectively referred to as "Endo".

43. Endo develops, markets, and sells prescription drugs in the U.S., including the opioids Opana/Opana ER, Percodan, Percocet, and Zydone, in the U.S. and in and around County. Opioids made up roughly $403 million of Endo's overall revenue of $3 billion in 2012. Opana ER yielded $1.15 billion in revenue from 2010 and 2013, and it accounted for 10% of Endo's total revenue in 2012. Endo also manufactures and sells generic opioids such as oxycodone, oxymorphone, hydromorphone, and hydrocodone products in the U.S. and in and around the County, by itself and through its subsidiary, Qualitest Pharmaceuticals, Inc.

44. On July 6, 2017, in response to an FDA request that Endo voluntarily withdraw the product from the market, the company announced that it would stop marketing and selling a reformulated version of Opana ER that it had marketed as an abuse-deterrent.

45. Endo's opioid business impacts County.

46. Abbvie, Inc. (hereafter, "Abbvie") is a Delaware corporation with its principal place of business in North Chicago, Illinois, and may be served through its registered agent for service of process; The Corporation Trust Company, Corporation Trust Center 1209 Orange St, Wilmington, DE 19801. Knoll Pharmaceutical Company (hereafter, "Knoll") has been a wholly-owned subsidiary of Abbvie from January 1, 2013. Knoll is a New Jersey corporation with its principal place of business in Parsippany, New Jersey, and may be served through its registered agent for service of process; The Corporation Trust Company, 820 Bear Tavern Rd, West Trenton, NJ 08628.

47. Abbvie began manufacturing, developing, promoting, marketing, and selling the opioid drug, Vicodin, in the U.S. and in County. Knoll irresponsibly marketed narcotics, such as Vicodin through toys and souvenirs and did so to boost the sales of opioids. Taking advantage of the fact that Vicodin was not regulated as a Schedule II controlled substance for many years, and the fact that physicians and consumers did not fully appreciate the highly addictive nature of Vicodin, Knoll advertised Vicodin with tag lines such as "The Highest Potency Pain Relief You Can Still Phone In." This tag line came as part and parcel of souvenirs like a "Vicodin" fanny pack and water bottle, both bearing the name of Vicodin, the opioid Knoll was promoting. This irresponsible marketing of a narcotic drug caused doctors and patients to believe Vicodin was safer than it really was.

48. Abbvie and Knoll's opioid business has been to the detriment of people in County.

49. Allergan PLC is a public limited company incorporated in Ireland with its principal place of business in Dublin, Ireland. Actavis PLC acquired Allergan PLC in March 2015, and the combined company changed its name to Allergan PLC in January 2013. Before that, Watson Pharmaceuticals, Inc. acquired Actavis, Inc. in October 2012, and the combined company changed its name to Allergan Finance, LLC as of October 2013.

50. Allergan Finance, LLC is a Nevada Corporation with its principal place of business in Parsippany, New Jersey, and may be served through its registered agent for service of process, The Corporation Trust Company of Nevada, 701 S. Carson St., Suite 200, Carson City, NV 89701. Watson Laboratories, Inc. is a Nevada corporation with its principal place of business in Corona, California, and is a wholly-owned subsidiary of Allergan PLC (f/k/a Actavis, Inc., f/k/a Watson Pharmaceuticals, Inc.), and may be served through its

registered agent for service of process, Corporate Creations Network, Inc., 8275 South Eastern Ave., #200, Las Vegas, NV 89123. Actavis Pharma, Inc. (f/k/a Actavis, Inc.) is a Delaware corporation with its principal place of business in New Jersey and was formerly known as Watson Pharma, Inc., and may be served through its registered agent for service of process, Corporate Creations Network Inc., 3411 Silverside Road, Tatnall Building Ste 104, Wilmington, DE 19810. Actavis LLC is a Delaware limited liability company with its principal place of business in Parsippany, New Jersey, and may be served through its registered agent for service of process, Corporate Creations Network, Inc., 3411 Silverside Rd., Tatnall Building, Suite 104, Wilmington, DE 19810.

51. Each of the Defendants identified in Paragraph 49 above is owned by Allergan PLC, which uses them to market and sell its drugs in the U.S.. Upon information and belief, County alleges that Allergan PLC exercises control over these marketing and sales efforts, and profits from the sale of Allergan/Actavis products ultimately inure to its benefit.

52. In this suit Allergan PLC, Actavis PLC, Actavis, Inc., Allergan Finance, LLC, Actavis LLC, Actavis Pharma, Inc., Watson Pharmaceuticals, Inc., Watson Pharma, Inc., and Watson Laboratories, Inc. are collectively referred to as "Actavis".

53. Actavis manufactures, promotes, sells, and distributes opioids in the U.S. and its opioid business impacts the County.

54. Actavis acquired the rights to Kadian from King Pharmaceuticals, Inc. on December 30, 2008 and began marketing Kadian in 2009.

55. Mallinckrodt, PLC, is an Irish public limited company headquartered in Staines-upon-Thames, United Kingdom, with its U.S. headquarters in St. Louis, Missouri. Mallinckrodt, LLC is a limited liability company organized and existing under the laws of the State of

Delaware with its principal place of business in St. Louis, Missouri. Since June 28, 2013, it has been a wholly owned subsidiary of Mallinckrodt, PLC. Prior to June 28, 2013 Mallinckrodt, LLC, was a wholly-owned subsidiary of Covidien PLC. Mallinckrodt Brand Pharmaceuticals is a Delaware Corporation which is wholly owned by Mallinckrodt PLC. Defendant SpecGx, LLC, is a Delaware limited liability company with its headquarters in Clayton, Missouri, and is a wholly-owned subsidiary of Mallinckrodt PLC.

56. SpecGX currently manufactures and sells certain opioids which were previously manufactured by Mallinckrodt, LLC.

57. Mallinckrodt, PLC., Mallinckrodt Brand Pharmaceuticals, Covidien PLC., and SpecGx, LLC., are collectively referred to as "Mallinckrodt."

58. Mallinckrodt manufactures and markets two branded opioids: Exalgo, which is extended-release hydromorphone, sold in 8, 12, 16 and 32 mg dosage strengths, and Roxicodone, which is oxycodone, sold in 15 and 30mg dosage strengths. In 2009, Mallinckrodt Inc. acquired the U.S. rights to Exalgo. The FDA approved Exalgo for treatment of chronic pain in 2012. Mallinckrodt further expanded its branded opioid portfolio in 2012 by purchasing Roxicodone from Xanodyne Pharmaceuticals. In addition, Mallinckrodt developed Xartemis XR, an extended-release combination of oxycodone and acetaminophen, which the FDA approved in March 2014, and which Mallinckrodt has since discontinued.

59. Mallinckrodt promoted its branded opioid products with its own direct sales force.

60. Mallinckrodt is also a leading manufacturer of generic opioids. In 2015, Mallinckrodt estimated, based on IMS Health data, that its generics claimed an approximately 23% market share of DEA Schedules II and III opioid and oral solid dose medications.

61. In 2017, Mallinckrodt paid a $35 million fine to the Department of Justice for its failure to report suspicious orders of its opioids.

b. Distributor Defendants

62. The following pharmaceutical distributors are hereafter collectively referred to as "Distributor Defendants": Cardinal Health Inc., McKesson Corporation; AmerisourceBergen Drug Corporation, Walgreens Boots Alliance d/b/a Walgreen Co., Wal-Mart Stores Inc., CVS Health, Rite Aid Corporation, and the Kroger Company.

63. Cardinal Health, Inc. (hereafter, "Cardinal") is an Ohio corporation and is headquartered in Dublin, Ohio. It may be served through its registered agent for service of process, CT Corporation System, 4400 Easton Commons, Suite 125, Columbus, OH 43219.

64. Cardinal describes itself as a "global, integrated health care services and products company," and is the 15th largest company by revenue in the U.S., with annual revenue of $121 billion in 2016. Based on Cardinal's own estimates, 1 of every 6 pharmaceutical products dispensed to U.S. patients travels through the Cardinal Health network.

65. Cardinal distributes pharmaceutical drugs, including opioids, throughout the U.S. including in Kentucky. Upon information and belief County alleges that Cardinal distributes pharmaceuticals to retail pharmacies and institutional providers in the County.

66. McKesson Corporation (hereafter, "McKesson") is incorporated in Delaware, with its principal place of business in San Francisco, California. It may be served through its registered agent for service of process, Corporation Service Company, 251 Little Falls Drive, Wilmington, DE 19808.

67. McKesson is 5th on the list of Fortune 500 companies, with annual revenue of $191 billion in 2016.

68. McKesson is a wholesaler of pharmaceutical drugs that distributes opioids throughout the U.S., including in Kentucky. Upon information and belief, County alleges that McKesson distributes pharmaceuticals to retail pharmacies and institutional providers in the County.

69. Amerisourcebergen Drug Corporation (hereafter, "Amerisource") is incorporated in Delaware with its principal place of business in Chesterbrook, Pennsylvania. It may be served through its registered agent for service of process, The Corporation Trust Company, Corporation Trust Center, 1209 Orange St., Wilmington, DE 19801.

70. Amerisource is a wholesaler of pharmaceutical drugs that distributes opioids throughout the U.S., including in Kentucky. Upon information and belief, County alleges that McKesson distributes pharmaceuticals to retail pharmacies and institutional providers in the County.

71. Cardinal, McKesson and AmerisourceBergen are, at times, collectively referred to hereafter as "The Big Three."

72. Walgreens Boots Alliance, Inc., d/b/a Walgreen Co. (hereafter, "Walgreens") is incorporated in Delaware, with its principal place of business in Illinois. It may be served through its registered agent for service of process, Corporation Service Company, 251 Little Falls Drive, Wilmington, DE 19808.

73. Walgreens is registered to do business in Kentucky under the name Walgreen Co.

74. Walgreens includes a captive distributor that supplies pharmaceutical drugs and opioids to Walgreens pharmacies in Kentucky and throughout the country.

75. Walgreens has distribution centers across the U.S. which distribute medications, including opioids, to various states, including Kentucky. According to its website, Walgreens operates 9,560 retail stores with pharmacies.

76. At all relevant times, Walgreens has sold, and continues to sell prescription opioids at locations in and in close proximity to County.

77. Wal-Mart Stores, Inc. (hereafter, "Wal-Mart") is a Delaware corporation with its principal place of business in Arkansas. It may be served through its registered agent for service of process, The Corporation Trust Company, Corporation Trust Center, 1209 Orange St., Wilmington, DE 19801.

78. Wal-Mart operates 3,646 retail stores with pharmacies, including 21 retail locations in Kentucky.

79. At all relevant times, Wal-Mart has sold, and continues to sell prescription opioids at locations in and in close proximity to the County.

80. CVS Health (hereafter, “CVS”) is incorporated in Delaware with its principal place of business in Rhode Island. It may be served through its registered agent for service of process; The Corporation Trust Company, Corporation Trust Center, 1209 Orange St., Wilmington, DE 19801.

81. CVS operates approximately 9,800 retail stores with pharmacies, including 77 retail locations in Kentucky.

82. At all times relevant to this complaint, CVS has sold, and continues to sell prescription opioids in the U.S. and at locations in and in close proximity to County.

83. The Distributor Defendants dominate the Pharmaceutical wholesale distribution market, including in Kentucky. In order to increase their revenue, increase their profits, and grow

their share of the prescription painkiller market, each of the Distributor Defendants distributed, supplied, sold, and placed into the stream of commerce prescription opioids, without fulfilling their fundamental duty under Kentucky statutes and common law, to detect, report, and refuse to ship suspicious orders of opioids in order to prevent diversion of these dangerous drugs for non-medical purposes.

84. Each Distributor Defendant has been cited and fined by the U.S. Drug Enforcement Administration and/or Department of Justice for failing to maintain effective controls against diversion. This unlawful conduct by the Distributor Defendants is a substantial cause for the volume of prescription opioids plaguing County.

c. Pharmacy Defendants

85. Walgreens, Wal-Mart, and CVS, Rite Aid Corporation and the Kroger Company are registered retail pharmacies across the country, and are at times collectively referred to hereafter as "Pharmacy Defendants."

86. Defendant Rite Aid Corporation (hereafter, "Rite Aid") is a Delaware corporation with its principal office located in Camp Hill, Pennsylvania.

87. At all relevant times, Rite Aid has sold and continues to sell prescription opioids at locations in and in close proximity to the County.

88. Defendant the Kroger Co. (hereafter, "Kroger") is an Ohio corporation with its principal office located in Cincinnati, Ohio.

89. At all relevant times, Kroger has sold and continues to sell prescription opioids at locations in and in close proximity to the County.

90. The Pharmacy Defendants represent 46.6%, or nearly half of all prescription drug sales in the U.S.. In order to avail themselves of rebate programs with pharmaceutical distributors,

and consequently maximize their profits, the Pharmacy Defendants incentivized employees with volume-based bonuses for filling prescriptions for opioid controlled substances. In lieu of upholding their obligations under the law, Pharmacy Defendants instead consistently chose to ignore unresolvable red flags of diversion, and thus filled prescriptions without ensuring the prescription had been issued for a legitimate medical purpose in the course of usual medical practice. As a result of Pharmacy Defendants neglecting their legal obligations, millions of pills of dangerous opioid controlled substances were diverted all over the country, including into the County.

91. The County lacks information sufficient to specifically identify the true names or capacities; whether individual, corporate or otherwise, of Defendants sued herein under the fictitious names DOES 1 through 100 inclusive. The County will amend this Complaint to show their true names and capacities if and when they are ascertained. the County is informed and believes, and on such information and belief alleges, that each of the Defendants named as a DOE has engaged in conduct that contributed to cause events and occurrences alleged in this Complaint and, as such, shares liability for at least some part of the relief sought herein.

III. VENUE AND JURISDICTION

92. Venue is proper in the U.S. District Court for the Western District of Kentucky because all or a substantial part of the events or omissions giving rise to this claim occurred in the Western District of Kentucky: 28 U.S.C. § 1391.

93. Federal subject matter jurisdiction is based upon 28 U.S.C. § 1331.

94. Additionally, pursuant to 28 U.S.C. § 1332(a), the matter in controversy exceeds $75,000, exclusive of interests and costs, and is between citizens of different states.

95. This Court also has specific jurisdiction over all Defendants as their activities were directed toward Kentucky and injuries complained of resulted from their activities. Each Defendant has a substantial connection with Kentucky and the requisite minimum contacts with Kentucky necessary to constitutionally permit the Court to exercise jurisdiction.

IV. FACTUAL ALLEGATIONS

96. Defendants, to sell more pharmaceutical drugs, changed doctors' views regarding opioids through deceptive marketing schemes. Each Defendant used direct marketing and unbranded advertising disseminated by seemingly independent third parties, to spread false and deceptive statements about the risks and benefits of long-term opioid use.

97. Generally accepted standards of medical practice prior to 1990 dictated that opioids should be used only for treating short-term acute pain, which included pain relating to recovery from surgery or for break-through cancer pain or palliative (end-of-life) care. Prescriptions for opioids to treat chronic pain was discouraged or even prohibited because there was a lack of evidence that opioids improved patients' ability to overcome pain and to function. Instead the evidence demonstrates that patients developed tolerance to opioids over time, which increased the risk of addiction and other side effects.

98. Upon information and belief, the County alleges that Defendants spread their false and deceptive statements by:

(i) marketing their branded opioids directly to doctors treating patients residing in the County and the County patients themselves; and

(ii) deploying so-called unbiased and independent third parties to County.

99. Defendants' direct marketing of opioids generally proceeded on two tracks. First, each Defendant conducted advertising campaigns touting the purported benefits of their branded

drugs. For example, Defendants spent more than $14 million on medical journal advertising of opioids in 2011, nearly triple what they spent in 2001, including $4.9 million by Janssen, and $1.1 million by Endo.

100. A number of Defendants' branded ads deceptively portrayed the benefits of opioids for treating chronic pain. For example, Endo distributed and made available on its website, www.opana.com, a pamphlet promoting Opana ER with photographs depicting patients with physically demanding jobs like a construction worker and chef, implying that the drug would provide long-term pain-relief and functional improvement. Pursuant to a settlement agreement, Endo agreed in late 2015 and 2016 to halt these misleading representations in New York, but they may continue to disseminate them in Kentucky.

101. Second, each Defendant promoted the use of opioids for treating chronic pain through "detailers" – sales representatives who visited individual doctors and medical staff in their offices– and small-group speaker programs. Defendants devoted massive resources to direct sales contacts with doctors. In 2014 alone, Defendants spent $168 million on detailing branded opioids to doctors, including $34 million by Janssen, $10 million by Endo, and $2 million by Actavis. This amount is twice as much as Defendants spent on detailing in 2000.

102. Defendants also identified doctors to serve, for payment, on their speakers' bureaus and to attend programs with speakers and meals paid for by Defendants. These speaker programs provided: (1) an incentive for doctors to prescribe a particular opioid (so they might be selected to promote the drug); (2) recognition and compensation for the doctors selected as speakers; and (3) an opportunity to promote the drug through the speaker to his or her peers. These speakers gave the false impression that they were providing unbiased and medically- accurate presentations when they were, in fact, presenting a script prepared by Defendants. On information and belief, these

presentations conveyed misleading information, omitted material information, and failed to correct Defendants' prior misrepresentations about the risks and benefits of opioids.

103. Upon information and belief, Defendants employed the same marketing plans, strategies, and messages in and around the County, as they did nationwide. Across the pharmaceutical industry, "core message" development is funded and overseen on a national basis by corporate headquarters. This comprehensive approach ensures that Defendants' messages are accurately and consistently delivered across marketing channels and in each sales territory. Defendants consider this high level of coordination and uniformity crucial to successfully marketing their drugs.

104. Upon information and belief, Defendants also deceptively marketed opioids in and around the County through unbranded advertising – i.e., advertising that promotes opioid use generally but does not name a specific opioid. This advertising was ostensibly created and disseminated by independent third parties. But by funding, directing, reviewing, editing, and distributing this unbranded advertising, Defendants controlled the deceptive messages disseminated by these third parties and acted in concert with them to falsely and misleadingly promote opioids for treating chronic pain.

105. Unbranded advertising also avoided regulatory scrutiny because Defendants did not have to submit it to the FDA, and therefore it was not reviewed by the FDA.

106. Defendants' deceptive unbranded marketing often contradicted their branded materials reviewed by the FDA. For example, Endo's unbranded advertising contradicted its concurrent, branded advertising for Opana ER:

Pain: Opioid Therapy (Unbranded)	**Opana ER Advertisement (Branded)**

"People who take opioids **as prescribed usually do not become addicted**."	"All patients treated with opioids require careful monitoring for signs of abuse and addiction, since **use of opioid analgesic products carries the risk of addiction even under appropriate medical use**."

107. Defendants spoke through a small circle of doctors who, upon information and belief, were selected, funded, and elevated by Defendants because their public positions supported using opioids to treat chronic pain. These doctors became known as "key opinion leaders" or "KOLs."

108. Defendants paid KOLs to serve as consultants or on their advisory boards and to give talks or present CMEs, and their support helped these KOLs become respected industry experts. As they rose to prominence, these KOLs touted the benefits of opioids to treat chronic pain, repaying Defendants by advancing their marketing goals. KOLs' professional reputations became dependent on continuing to promote a pro-opioid message, even in activities that were not directly funded by Defendants.

109. KOLs have written, consulted on, edited, and lent their names to books and articles, and given speeches and CMEs supportive of chronic opioid therapy. Defendants created opportunities for KOLs to participate in research studies which Defendants suggested or chose and then cited and promoted favorable studies or articles by their KOLs. By contrast, Defendants did not support, acknowledge, or disseminate publications of doctors unsupportive or critical of chronic opioid therapy.

110. Defendants' KOLs also served on committees that developed treatment guidelines that strongly encourage using opioids to treat chronic pain, and on the boards of pro-opioid advocacy groups and professional societies that develop, select, and present CMEs. Defendants were able to direct and exert control over each of these activities through their KOLs.

111. Pro-opioid doctors are one of the most important avenues that Defendants use to spread their false and deceptive statements about the risks and benefits of long-term opioid use. Defendants know that doctors rely heavily and less critically on their peers for guidance, and KOLs provide the false appearance of unbiased and reliable support for chronic opioid therapy.

112. Defendants utilized many KOLs, including many of the same ones. Two of the most prominent are described below.

113. The first, Dr. Russell Portenoy, former Chairman of the Department of Pain Medicine and Palliative Care at Beth Israel Medical Center in New York, is an example of a KOL who Defendants identified and promoted to further their marketing campaign. Dr. Portenoy received research support, consulting fees, and honoraria from Endo, and Janssen.

114. 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 1997 and again in 2009. He was also a member of the Board of the American Pain Foundation ("APF"), an advocacy organization almost entirely funded by Defendants.

115. Dr. Portenoy also made frequent media appearances promoting opioids. He appeared on Good Morning America in 2010 to discuss using opioids long-term to treat chronic pain. On this widely-watched program, broadcast in Kentucky and across the country, Dr. Portenoy claimed: "Addiction, when treating pain, is distinctly uncommon. If a person does not have a history, a personal history, of substance abuse, and does not have a history in the family of substance abuse, and does not have a very major psychiatric disorder, most doctors can feel very assured that that person is not going to become addicted."[10]

[10] Good Morning America television broadcast, ABC News (Aug. 30, 2010).

116. Dr. Portenoy later admitted that he "gave innumerable lectures in the late 1980s and '90s about addiction that weren't true."[11] These lectures falsely claimed that less 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."[12] Portenoy candidly admitted: "Did I teach about pain management, specifically about opioid therapy, in a way that reflects misinformation? Well…I guess I did."[13]

117. The second KOL, Dr. Lynn Webster, was the co-founder and Chief Medical Director of Lifetree Clinical Research, an otherwise unknown pain clinic in Salt Lake City, Utah. Dr. Webster was President in 2013 and is a current board member of AAPM, a Front Group that ardently supports chronic opioid therapy. He is a Senior Editor of Pain Medicine, the same journal that published Endo special advertising supplements touting Opana ER. Dr. Webster authored numerous CMEs sponsored by Endo while he was receiving significant funding from Defendants.

118. In 2011, Dr. Webster presented a program via webinar titled Managing Patient's Opioid Use: Balancing the Need and the Risk. Dr. Webster recommended using risk screening tools, such as urine testing and patient agreements as a way to prevent "overuse of prescriptions" and "overdose deaths," which was available to and was, upon information and belief, intended to reach doctors treating the County's residents.

119. Dr. Webster was also 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. In Dr. Webster's description, the only way to differentiate the two was to increase a patient's

[11] Thomas Catan & Evan Perez, *A Pain-Drug Champion Has Second Thoughts*, WALL ST. J., Dec. 17, 2012.
[12] *Id.*
[13] *Id.*

dose of opioids. As he and his co-author wrote in a book entitled Avoiding Opioid Abuse While Managing Pain (2007), 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." 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."[14]

120. Defendants entered into arrangements with seemingly unbiased and independent patient and professional organizations ("Front Groups") to promote opioids for treating chronic pain. Under Defendants' direction and control, the Front Groups generated:

(i) treatment guidelines;
(ii) unbranded materials; and
(iii) programs that favored chronic opioid therapy.

They also assisted Defendants by responding to:

(i) negative article by advocating against regulatory changes that would limit prescribing opioids in accordance with the scientific evidence; and
(ii) by conducting outreach to vulnerable patient populations targeted by Defendants.

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

[14] John Fauber & Ellen Gabler, *Networking Fuels Painkiller Boom*, MILWAUKEE WISC. J. SENTINEL (Feb. 19, 2012).

122. Defendants Endo and Janssen utilized many Front Groups. Some of the Front Groups include the American Pain Society ("APS"), American Geriatrics Society ("AGS"), the Federation of State Medical Boards ("FSMB"), American Chronic Pain Association ("ACPA"), American Society of Pain Education ("ASPE"), National Pain Foundation ("NPF") and Pain & Policy Studies Group ("PPSG").

123. The American Pain Foundation ("APF") received more than $10 million in funding from opioid manufacturers from 2007 until it closed its doors in May 2012. Endo alone provided more than half of that funding.

124. Over 80% of APF's operating budget in 2009 and 2010 came from pharmaceutical industry sources. First, APF's total income in 2009 was $2.85million. Of this amount, APF received about $2.3 million from industry sources including industry grants for specific projects. Second, in 2010 the APF projected receipts of about $2.9 million from drug companies, out of their total income of about $3.5 million for that year. By 2011, APF was entirely dependent on incoming grants from defendant Endo and others to avoid using its line of credit. As one of its board members, Russell Portenoy, explained the lack of funding diversity was one of the biggest problems at APF.

125. APF issued education guides for patients, reporters, and policymakers that touted the benefits of opioids for treating chronic pain and trivialized their risks, particularly the risk of addiction. 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 the programs and materials were available nationally and were, upon information and belief, intended to reach patients and consumers in the County.

126. The American Academy of Pain Medicine, with the assistance, prompting, involvement, and funding of Defendants, issued treatment guidelines and sponsored and hosted medical education programs essential to Defendants' deceptive marketing of chronic opioid therapy.

127. AAPM has received over $2.2 million in funding from opioid manufacturers since 2009. AAPM maintained a corporate relations council, whose members paid $25,000 each year (on top of other funding) to participate. The benefits included allowing members to present educational programs at off-site dinner symposia in connection with AAPM's marquee event – its annual meeting held in Palm Springs, California, or other resort locations. AAPM describes the annual event as an "exclusive venue" for offering education programs to doctors. Membership in the corporate relations council also allows drug company executives and marketing staff to meet with AAPM executive committee members in small settings. Defendants Endo and Actavis were members of the council and presented deceptive programs to doctors who attended this annual event.

128. AAPM is viewed internally by Endo as "industry friendly," with Endo advisors and speakers among its active members. – does not read well Endo attended AAPM conferences, funded its CMEs, and distributed its publications.

129. The conferences sponsored by AAPM heavily emphasized sessions on opioids 37 out of roughly 40 at one conference alone. AAPM's presidents have included top industry-supported KOLs Perry Fine, Russell Portenoy, and Lynn Webster. Dr. Webster was even elected president of AAPM while under a DEA investigation.

130. A past AAPM president, Dr. Scott Fishman, stated that he would place the organization "at the forefront" of teaching that "the risks of addiction are . . . small and can be managed."[15]

131. AAPM's staff understood they and their industry funders were engaged in a common task. Defendants were able to influence AAPM through both their significant and regular funding and the leadership of pro-opioid KOLs within the organization.

132. In 1997, AAPM and the American Pain Society jointly issued a consensus statement, The Use of Opioids for the Treatment of Chronic Pain, which endorsed opioids to treat chronic pain and claimed there was a low risk that patients would become addicted to opioids. Dr. Portenoy was the sole consultant. The consensus statement remained on AAPM's website until 2011, and was taken down from AAPM's website only after a doctor complained, though it still lingers on the internet elsewhere.

133. AAPM and APS issued their own guidelines in 2009 (hereafter, "AAPM/APS Guidelines") and continued to recommend using opioids to treat chronic pain. Fourteen of the twenty-one panel members who drafted the AAPM/APS Guidelines, including KOLs Dr. Portenoy and Dr. Perry Fine of the University of Utah, received support from Janssen and Endo.

134. The 2009 Guidelines promote opioids as "safe and effective" for treating chronic pain, despite acknowledging limited evidence, and conclude that the risk of addiction is manageable for patients regardless of past abuse histories.

135. A panel member, Dr. Joel Saper, Clinical Professor of Neurology at Michigan State University and founder of the Michigan Headache & Neurological Institute, resigned from the

[15] Interview by Paula Moyer with Scott M. Fishman, M.D., Professor of Anesthesiology and Pain Medicine, Chief of the Division of Pain Medicine, Univ. of Cal., Davis (2005), http://www.medscape.org/viewarticle/500829.

panel because he was concerned the 2009 Guidelines were influenced by contributions that drug companies, including Defendants, made to the sponsoring organizations and committee members.

136. These AAPM/APS Guidelines have been a particularly effective channel of deception and have influenced not only treating physicians, but also the body of scientific evidence on opioids. The Guidelines have been cited 732 times in academic literature, were, upon information and belief, disseminated in and around the County during the relevant time period, are still available online, and were reprinted in the Journal of Pain.

137. Upon information and belief, to convince doctors treating residents in the County and the County's patients that opioids can and should be used to treat chronic pain, Defendants had to convince them that long-term opioid use is both safe and effective. Knowing they could do so only by deceiving those doctors and patients about the risks and benefits of long-term opioid use,

138. Defendants made claims that were not supported by, or were contrary to, the scientific evidence. Even though pronouncements by and guidance from the FDA and the CDC based confirm that Defendants' claims were false and deceptive, Defendants have not corrected them, or instructed their KOLs or Front Groups to correct them. Rather they continue to spread them today.

139. To convince doctors and patients that opioids are safe, Defendants deceptively trivialized and failed to disclose the risks in long-term opioid use, particularly the risk of addiction. Defendants did this through a series of misrepresentations which 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 who were at greatest risk of addiction could be readily 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, does not pose special risks; and (4) abuse-deterrent opioids both prevent overdose and are inherently less addictive. Defendants have not only failed to correct these misrepresentations, they continue to make them today.

140. Defendants misrepresentations in paragraph 137 above have been conclusively debunked by the FDA and CDC.

141. Defendants falsely claimed that the risk of addiction is low and unlikely to develop when opioids are prescribed, as opposed to obtained illicitly, and failed to disclose the greater risk of addiction with prolonged use of opioids. For example:

a. Actavis's predecessor caused a patient education brochure to be distributed in 2007 claiming opioid addiction is possible, but "less likely if you have never had an addiction problem." Upon information and belief, based on Actavis's acquisition of its predecessor's marketing materials along with the rights to Kadian, Actavis continued to use this brochure in 2009 and beyond;

b. Endo sponsored a website, Painknowledge.com, which claimed in 2009 that "[p]eople who take opioids as prescribed usually do not become addicted." 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;"

c. 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." A similar statement appeared on the Endo website, www.opana.com;

d. Janssen reviewed, edited, approved, and distributed a patient education guide entitled *Finding Relief: Pain Management for Older Adults* (2009), which described as "myth" the claim that opioids are addictive, and asserted as fact that "[m]any studies show that opioids are rarely addictive when used properly for the management of chronic pain;"

e. Janssen currently runs a website, Prescriberesponsibly.com (last updated July 2, 2015), which claims that concerns about opioid addiction are "overestimated;" and

f. Upon information and belief, detailers for Endo and Janssen in and around

> the County minimized or omitted any discussion with doctors of the risk of addiction; misrepresented the potential for opioid abuse with purportedly abuse-deterrent formulations; and routinely did not correct the misrepresentations noted above.

142. These claims contradict longstanding scientific evidence, as the FDA and CDC have conclusively declared. As noted in the 2016 CDC Guidelines endorsed by the FDA, there is "extensive evidence" of the "possible harms of opioids (including opioid use disorder [an alternative term for opioid addiction])."[16] The Guideline points out that "[o]pioid pain medication use presents serious risks, including…opioid use disorder" and that "continuing opioid therapy for 3 months substantially increases risk for opioid use disorder."[17]

143. The FDA further exposed the falsity of Defendants' claims about the low risk of addiction when it announced changes to the labels for ER/LA opioids in 2013 and for IR opioids in 2016. In its announcements, the FDA discussed the risks related to opioid use and noted that IR opioids are associated with "persistent abuse, addiction, overdose mortality, and risk of NOWS [neonatal opioid withdrawal syndrome]."[18]

144. According to the FDA, because of the risks associated with long-term opioid use, including "the serious risk of addiction, abuse, misuse, overdose, and death,"[19] opioids should be "reserved for pain severe enough to require opioid treatment, and for which alternative treatment options (e.g., non-opioid analgesics or opioid combination products, as appropriate) are inadequate or not tolerated."[20]

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[16] *CDC Guideline for Prescribing Opioids for Chronic Pain – United States 2016*, Centers for Disease Control and Prevention (Mar. 18, 2016).

[17] *Id.*

[18] *FDA Announcement of Enhanced Warnings for Immediate-Release Opioid Pain Medications Related to Risks of Misuse, Abuse, Addiction, Overdose and Death*, Federal Drug Administration (Mar. 22, 2016).

[19] *Id.*

[20] *Id.*

145. The warnings on Defendants' own FDA-approved drug labels caution that opioids "exposes users to risks of addiction, abuse and misuse, which can lead to overdose and death"[21] and that addiction "can occur in patients appropriately prescribed"[22] opioids.

146. Defendants falsely instructed doctors and patients that signs of addiction are actually signs of undertreated pain which should be treated by prescribing more opioids. Defendants called this phenomenon "pseudoaddiction" – a term coined by Dr. David Haddox and popularized by Dr. Russell Portenoy, a KOL for Endo and Janssen – and claimed that pseudoaddiction is substantiated by scientific evidence. For example:

a. Janssen sponsored, funded, and edited the *Let's Talk Pain* website, which in 2009 stated: "pseudoaddiction . . . refers to patient behaviors that may occur when pain is under-treated . . . Pseudoaddiction is different from true addiction because such behaviors can be resolved with effective pain management;"

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

147. The 2016 CDC Guideline rejects the concept of pseudoaddiction. The Guideline nowhere recommends that opioid dosages be increased if a patient is not experiencing pain relief. To the contrary, the Guideline explains that "[p]atients who do not experience clinically meaningful pain relief early in treatment…are unlikely to experience pain relief with longer-term use,"[23] and that physicians should "reassess [] pain and function within 1 month"[24] in order to

[21] *See, e.g.*, OxyContin label and insert at *OxyContin.com.*
[22] *Id.*

[23] *CDC Guidelines for Prescribing Opioids for Chronic Pain, supra.*
[24] *Id.*

decide whether to "minimize risks of long-term opioid use by discontinuing opioids"[25] because the patient is "not receiving a clear benefit."[26]

148. Defendants falsely instructed doctors and patients that addiction risk screening tools, patient contracts, urine drug screens, and similar strategies allow them to reliably identify and safely prescribe opioids to patients predisposed to addiction. These misrepresentations were especially insidious because Defendants aimed them at general practitioners and family doctors who lack the time and expertise to closely manage higher-risk patients. Defendants' misrepresentations made these doctors feel more comfortable prescribing opioids to their patients, and patients more comfortable starting opioid therapy for chronic pain. For example:

a. Endo paid for a 2007 supplement in the *Journal of Family Practice* written by a doctor who became a member of Endo's speakers' bureau in 2010. The supplement, entitled *Pain Management Dilemmas in Primary Care: Use of Opioids*, 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.

149. The 2016 CDC Guideline confirms these representations are false. The Guideline notes that there are no studies assessing the effectiveness of risk mitigation strategies – such as screening tools, patient contracts, urine drug testing, or pill counts – widely believed by doctors to detect and deter outcomes related to addiction and overdose.[27] As a result, the Guideline recognizes that doctors should not overestimate the risk screening tools for classifying patients as high or low risk for opioid addiction because they are insufficient to rule out the risks of long-term opioid therapy.[28]

[25] *Id.*
[26] *Id.*

[27] *CDC Guidelines for Prescribing Opioids for Chronic Pain, supra.*
[28] *See id.*

150. To downplay the risk and impact of addiction and make doctors feel more comfortable starting patients on opioids, Defendants falsely claimed that opioid dependence can easily be addressed by tapering and that opioid withdrawal is not a problem thereby failing to disclose the increased difficulty of stopping opioids after long-term use.

151. For example, a CME sponsored by Endo, entitled *Persistent Pain in the Older Adult*, claimed that withdrawal symptoms can be avoided by tapering a patient's opioid dose by 10%-20% for 10 days.

152. Defendants deceptively minimized the significant symptoms of opioid withdrawal, which, as explained in the 2016 CDC Guideline, include drug cravings, anxiety, insomnia, abdominal pain, vomiting, diarrhea, sweating, tremor, tachycardia (rapid heartbeat), spontaneous abortion and premature labor in pregnant women, and the unmasking of anxiety, depression, and addiction – and grossly understated the difficulty of tapering, particularly after long-term opioid use.

153. Yet the 2016 CDC Guideline recognizes that the duration of opioid use and the dosage of opioids prescribed should be limited to "minimize the need to taper opioids to prevent distressing or unpleasant withdrawal symptoms,"[29] because "physical dependence on opioids is an expected physiologic response in patients exposed to opioids for more than a few days."[30] The Guideline further states that "tapering opioids can be especially challenging after years on high dosages because of physical and psychological dependence"[31] and highlights the difficulties, including the need to carefully identify "a taper slow enough to minimize symptoms and signs of opioid withdrawal"[32] and pausing and restarting tapers depending on the patient's response.

[29] *CDC Guidelines for Prescribing Opioids for Chronic Pain, supra.*
[30] *Id.*
[31] *Id.*
[32] *CDC Guidelines for Prescribing Opioids for Chronic Pain, supra.*

154. The CDC also acknowledges the lack of any "high-quality studies comparing the effectiveness of different tapering protocols for use when opioid dosage is reduced or opioids are discontinued."[33]

155. Defendants falsely claimed that doctors and patients could increase opioid dosages indefinitely without added risk and failed to disclose the greater risks to patients at higher dosages. The ability to escalate dosages was critical to 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. For example:

a. Actavis's predecessor created a patient brochure for Kadian in 2007 that stated, "Over time, your body may become tolerant of your current dose. You may require a dose adjustment to get the right amount of pain relief. This is not addiction." Upon information and belief, based on Actavis's acquisition of its predecessor's marketing materials along with the rights to Kadian, Actavis continued to use these materials in 2009 and beyond;

b. Endo sponsored a website, painknowledge.com, which claimed in 2009 that opioid dosages may be increased until "you are on the right dose of medication for your pain;"

c. Endo distributed a pamphlet edited by a KOL entitled *Understanding Your Pain: Taking Oral Opioid Analgesics*, which was available during the time period of this Complaint on Endo's website. In Q&A format, 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;" and

d. Janssen sponsored a patient education guide entitled *Finding Relief: Pain Management for Older Adults* (2009), which was distributed by its sales force. This guide listed dosage limitations as "disadvantages" of other pain medicines but omitted any discussion of risks of increased opioid dosages.

156. These claims conflict with the scientific evidence, as confirmed by the FDA and CDC. As the CDC explains in its 2016 Guideline, the "[b]enefits of high-dose opioids for

[33] *Id.*

chronic pain are not established"[34] while the "risks for serious harms related to opioid therapy increase at higher opioid dosage."[35]

157. 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."[36] Similarly, there is an "increased risk for opioid use disorder, respiratory depression, and death at higher dosages."[37] That is why the CDC advises doctors to avoid increasing dosages above 90 morphine milligram equivalents per day.

158. The 2016 CDC Guideline reinforces earlier findings announced by the FDA. In 2013, the FDA acknowledged that available data suggested that increasing the opioid dosage likewise increased certain adverse events. For example, the FDA noted that studies suggest a positive association between high-dose opioid use and overdoses.

159. Finally, Defendants' deceptive marketing of the so-called abuse-deterrent properties of some of their opioids has created false impressions that these opioids can curb addiction and abuse. More specifically, Defendants have made misleading claims about the ability of their so-called abuse-deterrent opioid formulations to deter addiction and overdose. 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 misuse the product. This claim was false.

[34] *CDC Guidelines for Prescribing Opioids for Chronic Pain, supra.*
[35] *Id.*
[36] *Id.*
[37] *Id.*

160. The FDA warned in a 2013 letter that there was no evidence Endo's design would provide a reduction in oral, intranasal or intravenous use.[38] Moreover, Endo's own studies, which it failed to disclose, showed that Opana ER could still be ground and chewed.

161. In a 2016, settlement with the State of New York, Endo agreed not to make statements in New York that Opana ER was designed to be or is crush resistant. The State found those statements false and deceptive because there was no difference in the ability to extract the narcotic from Opana ER as compared to other opioids.

162. Similarly, the 2016 CDC Guideline states that no studies support the notion that "abuse-deterrent technologies [are] a risk mitigation strategy for deterring or preventing abuse,"[39] noting that the technologies – even when they work – "do not prevent opioid abuse through oral intake, the most common route of opioid abuse, and can still be abused by non-oral routes."[40]

163. These numerous, long-standing misrepresentations of the risks of long-term opioid use were spread by Defendants and successfully convinced doctors and patients to discount those risks.

164. To convince doctors and patients that opioids should be used to treat chronic pain, Defendants had to persuade them that there was a significant benefit to long-term opioid use. But as the 2016 CDC Guideline makes clear, there is "insufficient evidence to determine the long-term benefits of opioid therapy for chronic pain."[41]

165. In fact, the CDC found no evidence showing "a long-term benefit of opioids in pain and function versus no opioids for chronic pain with outcomes examined at least 1 year later

[38] *See FDA Statement: Original Opana ER Relisting Determination* (May 10, 2013).
[39] *CDC Guidelines for Prescribing Opioids for Chronic Pain, supra.*
[40] *Id.*
[41] *Id.*

(with most placebo-controlled randomized trials ≤ 6 weeks in duration)"[42] and that other treatments were more or equally beneficial and less harmful than long-term opioid use. The FDA, too, has recognized the lack of evidence to support long-term opioid use.

166. In 2013, the FDA stated that it was unaware of any studies demonstrating the safety and efficacy of opioids for long-term use.[43] Despite this lack of studies, Defendants falsely and misleadingly touted the benefits of long-term opioid use and suggested that these benefits were supported by scientific evidence. Not only have Defendants failed to correct these false and deceptive claims, they continue to make them today. For example:

a. Actavis distributed an advertisement that claimed 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;

b. Endo distributed advertisements that claimed that the use of Opana ER for chronic pain would allow patients to perform demanding tasks like construction work or work as a chef and portrayed seemingly healthy, unimpaired subjects;

c. Janssen sponsored and edited a patient education guide entitled *Finding Relief: Pain Management for Older Adults* (2009) – which states as "a fact" that "opioids may make it easier for people to live normally." The guide lists expected functional improvements from opioid use, including sleeping through the night, returning to work, recreation, sex, walking, and climbing stairs;

d. Endo's NIPC website *painknowledge.com* claimed in 2009 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 NIPC's intent to make misleading claims about function, and Endo closely tracked visits to the site;

e. Endo was the sole sponsor, through NIPC, of a series of CMEs titled *Persistent Pain in the Older Patient*, which claimed that chronic opioid

[42] *Id.*

[43] 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).

therapy has been "shown to reduce pain and improve depressive symptoms and cognitive functioning." The CME was disseminated via webcast;

f. Janssen sponsored, funded, and edited a website, *Let's Talk Pain*, in 2009, which featured an interview edited by Janssen claiming that opioids allowed a patient to "continue to function." This video is still available today on YouTube;

g. Endo's and Janssen's sales representatives have conveyed and continue to convey the message that opioids will improve patient function.

167. These claims find no support in the scientific literature. Most recently, the 2016 CDC Guideline, approved by the FDA, concluded, "There is no good evidence that opioids improve pain or function with long-term use"[44] and "complete relief of pain is unlikely."[45] (Emphasis added.) The CDC reinforced this conclusion throughout its 2016 Guideline:

a. "No 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 . . ."[46]

b. "Although opioids can reduce pain during short-term use, the clinical evidence review found insufficient evidence to determine whether pain relief is sustained and whether function or quality of life improves with long-term opioid therapy;"[47] and

c. "[E]vidence is limited or insufficient for improved pain or function with long-term use of opioids for several chronic pain conditions for which opioids are commonly prescribed, such as low back pain, headache, and fibromyalgia."[48]

168. The CDC also noted that the risks of addiction and death "can cause distress and inability to fulfill major role obligations."[49] As a matter of common sense (and medical evidence), drugs that can kill patients or commit them to a life of addiction or recovery do not improve their function and quality of life.

[44] *CDC Guidelines for Prescribing Opioids for Chronic Pain, supra.*
[45] *Id.*
[46] *Id.*
[47] *Id.*
[48] *Id.*
[49] *Id.*

169. The 2016 CDC Guideline was not the first time a federal agency repudiated Defendants' claim that opioids improved function and quality of life. In 2010, the FDA warned Actavis that "[w]e 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."[50]

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

171. Consequently, the FDA changed the labels for extended release and long acting opioids in 2013 and immediate release opioids in 2016 to state that opioids should be used only as a last resort where alternative treatments 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.

172. The State of New York found that Endo failed to require sales representatives to report signs of addiction, diversion, and inappropriate prescribing; paid bonuses to sales representatives for detailing prescribers who were subsequently arrested or convicted for illegal

[50] Warning Letter from Thomas Abrams, Dir., FDA Div. of Mktg., Adver., & Commc'ns, to Doug Boothe, CEO, Actavis Elizabeth LLC (Feb. 18, 2010), http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/EnforcementActivitiesbyFDA/WarningLettersandNoticeofViolationLetterstoPharmaceuticalCcompanies/ucm259240.htm.

prescribing; and failed to prevent sales representatives from visiting prescribers whose suspicious conduct had caused them to be placed on a no-call list.

173. As a part of their deceptive marketing scheme, Defendants identified and targeted susceptible prescribers and vulnerable patient populations in the U.S. and, upon information and belief, in and around County. For example, Defendants focused their deceptive marketing on primary care doctors, who were more likely to treat chronic pain patients and prescribe opioids but were less likely to be educated about treating pain and the risks and benefits of opioids.

174. Defendants also targeted vulnerable patient populations like the elderly and veterans, who tend to suffer from chronic pain. Defendants targeted these vulnerable patients even though the risks of long-term opioid use were significantly greater for them.

175. For example, the 2016 CDC Guideline observes that existing evidence shows that elderly patients taking opioids suffer from elevated fall and fracture risks, greater risk of hospitalization, and increased vulnerability to adverse drug effects and interactions. The Guideline therefore concludes that there are "special risks of long-term opioid use for elderly patients" and recommends that doctors use "additional caution and increased monitoring" to minimize the risks of opioid use in elderly patients.

176. Defendants, both individually and collectively, made, promoted, and profited from their misrepresentations about the risks and benefits of opioids for chronic pain even though they knew their misrepresentations were false and deceptive. The history of opioids, as well as research and clinical experience over the last 20 years, established that opioids were highly addictive and responsible for a long list of very serious adverse outcomes.

177. Not only did the FDA and other regulators warn Defendants, but Defendants had access to scientific studies, detailed prescription data, and reports of adverse events, including

reports of addiction, hospitalization, and deaths – all of which made clear the harms from long-term opioid use, including the suffering from addiction, overdoses, and death in alarming numbers in patients using opioids.

178. More recently, the FDA and CDC have issued pronouncements based on the medical evidence that conclusively expose the known falsity of Defendants' misrepresentations, and Endo has recently entered an agreement prohibiting it from making some of the same misrepresentations described herein in New York.

179. Moreover, Defendants took steps to avoid detection of and to fraudulently conceal their deceptive marketing and unlawful, unfair, and fraudulent conduct. For example, Defendants disguised their role in the deceptive marketing of chronic opioid therapy by funding and working through third parties like Front Groups and KOLs.

180. Finally, Defendants manipulated their promotional materials and the scientific literature to make it appear that these items were accurate, truthful, and supported by objective evidence, when they were not. Thus, Defendants successfully concealed from the medical community and patients' facts sufficient to arouse suspicion of the claims the County now asserts. The County did not know of the existence or scope of Defendants' industry-wide fraud and could not have acquired such knowledge earlier through the exercise of reasonable diligence.

181. Defendants' misrepresentations deceived doctors and patients about the risks and benefits of long-term opioid use. Studies reveal that many doctors and patients are unaware of or do not understand the risks or benefits of opioids. Indeed, patients often report that they were not warned they might become addicted to opioids prescribed to them. As reported in January 2016, a

2015 survey of more than 1,000 opioid patients found that 4 out of 10 were not told opioids were potentially addictive.[51]

182. While Defendants may claim the federal government authorized the amount of annual prescription opioids sold, they know in truth that several Defendants have successfully used their organized money and influence to render the federal government's enforcement agency, the Drug Enforcement Administration, virtually powerless to interrupt the over-supply of prescription opioid drugs.

183. Upon information and belief, Defendants' deceptive marketing scheme caused and continues to cause doctors in and around County to prescribe opioids for chronic pain conditions such as back pain, headaches, arthritis, and fibromyalgia. Absent Defendants' deceptive marketing scheme, these doctors would not have been able to over prescribe opioids or become embroiled in pill mills that negatively impacted residents of County.

184. Defendants' deceptive marketing scheme also caused and continues to cause patients to purchase and use opioids for their chronic pain believing they are safe and effective. Absent Defendants' deceptive marketing scheme, fewer patients would be using opioids long-term to treat chronic pain, and those patients using opioids would be using less of them.

185. Defendants' deceptive marketing has caused and continues to cause the prescribing and use of opioids to explode. Indeed, this dramatic increase in opioid prescriptions and use corresponds with the dramatic increase in Defendants' spending on their deceptive marketing scheme. Defendants' spending on opioid marketing totaled approximately $91 million in 2000. By 2011, that spending had tripled to $288 million.

[51] Hazelden Betty Ford Foundation, *Missed Questions, Missed Opportunities* (Jan. 27, 2016), *available at* http://www.hazeldenbettyford.org/about-us/news-and-media/pressrelease/doctors-missing-questions-that-could-prevent-opioid-addiction.

186. The escalating number of opioid prescriptions written by doctors who were deceived by Defendants' deceptive marketing scheme is the cause of a correspondingly dramatic increase in opioid addiction, overdose, and death throughout the U.S. and County.

187. Scientific evidence demonstrates a strong correlation between opioid prescriptions and becoming addicted to opioids. In a 2016 report, the CDC explained that prescribing opioids has quadrupled since 1999, which has resulted in a parallel increase in opioid overdoses.[52] Indeed, there has been a two-third increase in overdose deaths from using opioids since 2000.[53] For these reasons, the CDC concluded that efforts to rein in the prescribing of opioids for chronic pain are critical "to reverse the cycle of opioid pain medication misuse that contributes to the opioid overdose epidemic."[54]

188. Due to the increase in opioid overdoses, first responders such as police officers, have been and will continue to be in the position to assist people experiencing opioid-related overdoses.[55] In 2016, "over 1,200 law enforcement departments nationwide carried naloxone in an effort to prevent opioid-related deaths."[56]

189. Upon information and belief, Defendants' deceptive marketing scheme has also detrimentally impacted children in County. Overprescribing opioids for chronic pain has made the drugs more accessible to school-aged children, who come into contact with opioids after they have been prescribed to friends or relatives in the same household.

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[52] CDC. National Vital Statistics System, Mortality. CDC WONDER. Atlanta, GA: US Department of Health and Human Services, CDC; 2016. https://wonder.cdc.gov/; Rudd RA, Seth P, David F, Scholl L. Increases in Drug and Opioid-Involved Overdose Deaths — United States, 2010–2015. MMWR Morb Mortal Wkly Rep. ePub: 16 December 2016.

[53] *National Vital Statistics System*, Mortality file and appearing *Center for Disease Control and Prevention* Morbidity and Mortality Weekly Report, January 1, 2006 / 64(50); 1378-82, Increases in Drug and Opioid Deaths – United States, 2000-2014.

[54] *CDC Guideline for Prescribing Opioids for Chronic Pain, supra; see also* Rudd RA, Seth P, David F, Scholl L. Increases in Drug and Opioid-Involved Overdose Deaths — United States, 2010–2015. MMWR Morb Mortal Wkly Rep. ePub: 16 December 2016.

[55] Opinion of the Attorney General of Texas, KP-0168 (Oct. 4, 2017).

[56] *Id. citing* http://www.nchrc.org/law-enforcement/us-law-enforcement-who-carry-naloxone/.

190. Upon information and belief, Defendants' conduct has adversely affected County's child protection agencies in the number of children in foster care driven by parental drug addiction. Children with parents addicted to drugs tend to stay in foster care longer, and they often enter the system having experienced significant trauma, which makes these cases more expensive for counties like County.

191. Upon information and belief, opioid addiction is a significant reason that County's residents seek treatment for substance dependence. A significant number of admissions or drug addiction were associated with a primary diagnosis of opiate addiction or dependence.

192. Upon information and belief, Defendants' creation, through false and deceptive advertising and other unlawful and unfair conduct, of a virtually limitless opioid market has significantly harmed County's communities. Defendants' success in extending the market for opioids to new patients and chronic pain conditions has created an abundance of drugs available for non-medical and criminal use and fueled a new wave of addiction and injury. It has been estimated that 60% of the opioids to which people are addicted come, directly or indirectly, through doctors' prescriptions.[57]

193. Law enforcement agencies have increasingly associated prescription drug addiction with violent and property crimes. Despite strict federal regulation of prescription drugs, local law enforcement agencies are faced with increasing diversion from legitimate sources for illicit purposes, including doctor shopping, forged prescriptions, falsified pharmacy records, and employees who steal from their place of employment. The opioid epidemic has prompted a

[57] Nathaniel P. Katz, *Prescription Opioid Abuse: Challenges and Opportunities for Payers*, Am. J. Managed Care (Apr. 19 2013), at 5 ("The most common source of abused [opioids] is, directly or indirectly, by prescription."), http://www.ajmc.com/publications/issue/2013/2013-1-vol19-n4/Prescription-Opioid-Abuse-Challenges-and-Opportunities-for-Payers.

growing trend of crimes against pharmacies including robbery and burglary. This ongoing diversion of prescription narcotics creates a lucrative marketplace.

194. The rise in opioid addiction caused by Defendants' deceptive marketing scheme has also resulted in an explosion in heroin use. For example, heroin use has more than doubled in the past decade among adults aged 18 to 25 years.[58] Moreover, heroin-related overdoses in the U.S. has more than quadrupled since 2010.[59]

195. The costs and consequences of opioid addiction are staggering. For example, in 2007, the cost of healthcare due to opioid addiction and dependence was estimated at $25 billion, the cost of criminal justice was estimated at $5.1 billion, and the cost of lost workplace productivity was estimated at $25.6 billion.

196. Consequently, prescription opioid addiction and overdose have an enormous impact on the health and safety of individuals, as well as communities at large, because the consequences of this epidemic reach far beyond the addicted individual.

197. Upon information and belief, some of the repercussions for residents of County include job loss, loss of custody of children, physical and mental health problems, homelessness and incarceration, which result in instability in communities often already in economic crisis and contributes to increased demand on community services such as hospitals, courts, child services, treatment centers, and law enforcement.

198. Defendants knew and should have known about these harms that their deceptive marketing has caused and continues to cause and will cause in the future. Defendants closely monitored their sales and the habits of prescribing doctors. Their sales representatives, who

[58] Centers for Disease Control and Prevention. Vital Signs: Today's Heroin Epidemic – More People at Risk, Multiple Drugs Abused. (https://www.cdc.gov/vitalsigns/heroin/index.html). MMWR 2015.
[59] https://www.cdc.gov/vitalsigns/heroin/index.html

visited doctors and attended CMEs, knew which doctors were receiving their messages and how they were responding.

199. Defendants also had access to and carefully watched government and other data that tracked the explosive rise in opioid use, addiction, injury, and death. Defendants not only knew but intended that their misrepresentations would persuade doctors to prescribe and encourage patients to use their opioids for chronic pain.

200. Defendants' actions are neither permitted nor excused by the fact that their drug labels may have allowed, or did not exclude, the use of opioids for chronic pain. FDA approval of opioids for certain uses did not give Defendants license to misrepresent the risks and benefits of opioids. Indeed, Defendants' misrepresentations were directly contrary to pronouncements by, and guidance from, the FDA based on the medical evidence and their own labels.

201. Nor is Defendants' causal role broken by the involvement of doctors. Defendants' marketing efforts were ubiquitous and highly persuasive. Their deceptive messages tainted virtually every source doctors could rely on for information and prevented them from making informed treatment decisions. Defendants also hijacked what doctors wanted to believe – namely, that opioids represented a means of relieving their patients' suffering and of practicing medicine more compassionately.

202. Upon information and belief, Defendants' actions and omissions were each a cause-in-fact of County's past and future damages. Upon information and belief, Defendants' wrongful conduct caused injuries to County in the past, continues to cause injuries to County, and will continue to cause injuries to County in the future. Future damages include, but are not limited to, additional resources for counseling and medication assisted treatment of addicts, medical treatment for overdoses, life skills training for adolescents, increased law enforcement, and additional

resources to treat the psychological effects of opioids and the underlying conditions that make people susceptible to opioid addiction.

203. While using opioids has taken a toll on County and its residents, Defendants have realized blockbuster profits. In 2014 alone, opioids generated $11 billion in revenue for drug companies like Defendants. Indeed, financial information indicates that each Defendant experienced a material increase in sales, revenue, and profits from the false and deceptive advertising and other unlawful and unfair conduct described above.

V. CAUSES OF ACTION

COUNT I
PUBLIC NUISANCE
(Against All Defendants)

204. County re-alleges and incorporates by reference each of the allegations contained in the preceding paragraphs of this Complaint as though fully alleged herein.

205. Under Kentucky law, a Public Nuisance is, "a condition that endangers safety or health, is offensive to the senses, or obstructs the free use of property so as to interfere with the comfortable enjoyment of life or property by a community or neighborhood or by any considerable number of persons." Ky. Rev. Stat. § 241.010(46).

206. "A public nuisance is a condition that is prejudicial to the health, comfort, safety, property, sense of decency, or morals of the citizens at large, resulting either from an act not warranted by law or from neglect of a duty imposed by law." *Nuchols v. Commonwealth*, 226 S.W.2d 796, 798 (Ky. 1950). *See also Maum v. Commonwealth*, 490 S.W.2d 748, 749 (Ky. 1973).

207. Upon information and belief, Defendants knowingly encouraged doctors in and around County to prescribe, and residents to use, highly-addictive opioids for chronic pain even though Defendants knew using opioids had a high risk of addiction and reduced quality of life.

208. Upon information and belief, County alleges that by doing so, Defendants purposefully interfered with its public health, public safety, public peace, public comfort, and public convenience.

209. Upon information and belief, County further alleges that Defendants, individually and in concert with each other, have contributed to and/or assisted in creating and maintaining a condition that is harmful to the health and safety of County residents and/or unreasonably interferes with the peace and comfortable enjoyment of life in violation of Kentucky law.

210. The public nuisance created by Defendants' actions is substantial and unreasonable – it has caused and continues to cause significant harm to County – and the harm inflicted outweighs any offsetting benefit.

211. The staggering rates of opioid use resulting from Defendants' marketing efforts have caused, and continues to cause, harm to County including, but not limited to:

a. Upwards of 30% of all adults use opioids. These high rates of use have led to unnecessary opioid addiction, overdose, injuries, and deaths;

b. Children have been exposed to opioids prescribed to family members or others resulting in injury, addiction, and death. Upon information and belief, easy access to prescription opioids has made opioids a recreational drug of choice among County's teenagers; opioid use among teenagers is only outpaced by marijuana use. Even infants have been born addicted to opioids due to prenatal exposure causing severe withdrawal symptoms and lasting developmental impacts;

c. Upon information and belief, residents of the County, who have never taken opioids, 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, become addicted to, overdosed on, or been killed by opioids;

d. Upon information and belief, more broadly, opioid use and addiction have driven the County residents' health care costs higher;

e. Employers have lost the value of productive and healthy employees

who have suffered from adverse consequences from opioid use;

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

g. This demand has created additional illicit markets in other opiates, particularly heroin. The low cost of heroin has led some of those who initially become addicted to prescription opioids to migrate to cheaper heroin, fueling a new heroin epidemic in the process;

h. Upon information and belief, diverting opioids into secondary, criminal markets and increasing the number of individuals who are addicted to opioids has increased the demands on emergency services and law enforcement in the County;

i. All of Defendants' actions have caused significant harm to the County in lives lost; addictions endured; the creation of an illicit drug market and all its concomitant crime and costs; unrealized economic productivity; and broken families and homes;

j. Upon information and belief, these harms have taxed the human, medical, public health, law enforcement, and financial resources of County; and

k. Defendants' interference with the comfortable enjoyment of life of a substantial number of people is entirely unreasonable because there is limited social utility to opioid use and any potential value is outweighed by the gravity of harm inflicted by Defendants' actions.

212. Defendants knew, or should have known, that promoting opioid use would create a public nuisance in the following ways:

a. Upon information and belief, Defendants have engaged in massive production, promotion, and distribution of opioids for use by the citizens of the County;

b. Defendants' actions created and expanded the market for opioids, promoting its wide use for pain management;

c. Defendants misrepresented the benefits of opioids for chronic pain and fraudulently concealed, misrepresented, and omitted the serious

adverse effects of opioids, including the addictive nature of the drugs; and

d. Defendants knew or should have known that their promotion would lead to addiction and other adverse consequences that the larger County would suffer as a result.

213. Upon information and belief, Defendants' actions were, at the least, a substantial factor in doctors and patients not accurately assessing and weighing the risks and benefits of opioids for chronic pain thereby causing opioids to become widely available and used in County.

214. Without Defendants' actions, opioid use would not have become so widespread and the enormous public health hazard of opioid addiction would not have existed and could have been averted.

215. Upon information and belief, the health and safety of the citizens of the County, including those who use, have used, or will use opioids, as well as those affected by opioid users, is a matter of great public interest and legitimate concern to County's citizens and residents.

216. The public nuisance created, perpetuated, and maintained by Defendants can be abated and further reoccurrence of such harm and inconvenience can be prevented.

217. Upon information and belief, Defendants' conduct has affected and continues to affect a considerable number of people within County and is likely to continue to cause significant harm to patients who take opioids, their families, and the County at large.

218. Each Defendant created or assisted in creating the opioid epidemic, and each Defendant is jointly and severally liable for its abatement. Furthermore, each Defendant should be enjoined from continuing to create, perpetuate, or maintain said public nuisance in County.

COUNT II
COMMON LAW FRAUD
(Against All Defendants)

219. The County re-alleges and incorporates by reference each of the allegations contained in the preceding paragraphs of this Complaint as though fully alleged herein.

220. At all relevant and material times, Defendants expressly and/or impliedly warranted that opioids were safe, of merchantable quality, and fit for use.

221. Defendants' superior knowledge and expertise, their relationship of trust and confidence with doctors and the public, their specific knowledge regarding the risks and dangers of opioids, and their intentional dissemination of promotional and marketing information about opioids for the purpose of maximizing sales, each gave rise to the affirmative duty to meaningfully disclose and provide all material information about the risks and harms associated with opioids.

222. At all times herein mentioned, Defendants, individually and acting through their employees and agents, and in concert with each other, fraudulently represented to physicians who Defendants knew would justifiably rely on Defendants' representations that opioids were safe and effective for treating chronic pain.

223. Upon information and belief, Defendants' false representations were fraudulently made, with the intent or purpose that healthcare providers and patients would justifiably rely upon them, leading to the prescription, administration, filling, purchasing, and consumption of opioids in the County.

224. Defendants' deliberate misrepresentations and/or concealment, suppression, and omission of material facts as alleged herein include, but are not limited to:

a. Making false and misleading claims regarding the known risks of the addictive nature of opioids and suppressing, failing to disclose, and mischaracterizing the addictive nature of opioids and in concomitant costs, such as overdoses, deaths, and heroin addiction;

b. Making false and misleading written and oral statements that opioids are more effective than traditional pain killers for chronic pain, or effective at all and/or omitting material information showing that opioids are no more

effective than other non-addictive drugs for chronic pain;

c. Issuing false and misleading warnings and/or failing to issue adequate warnings concerning the risks and dangers of using opioids;

d. Making false and misleading claims downplaying the risk of addiction when using opioids and/or setting forth guidelines that would purportedly identify addictive behavior; and

e. Making false and misleading misrepresentations concerning the safety, efficacy and benefits of opioids without full and adequate disclosure of the underlying facts which rendered such statements false and misleading.

225. Defendants willfully, wantonly, and recklessly disregarded their duty to provide truthful representations regarding the safety and risk of opioids.

226. Defendants made these misrepresentations with the intent that the healthcare community and patients located wherever these opioid drugs were sold or consumed would rely upon them.

227. Defendants' misrepresentations were made with the intent of defrauding and deceiving the medical community and consumers to induce and encourage the sale of opioids.

228. Upon information and belief, Defendants' fraudulent representations evidence their callous, reckless, willful, and depraved indifference to the health, safety, and welfare of consumers living in the County.

229. Defendants omitted, misrepresented, suppressed and concealed material facts concerning the dangers and risk of injuries associated with the use of opioids, as well as the fact that the product was unreasonably dangerous.

230. Upon information and belief, Defendants' purpose was willfully blind to, ignored, downplayed, avoided, and/or otherwise understated the serious nature of the risks associated with the use of opioids.

231. Upon information and belief, the treating medical community and consumers in the County did not know that Defendants' representations were false and/or misleading and justifiably relied on them.

232. Defendants had sole access to material facts concerning the dangers and unreasonable risks of opioids, which they intentionally concealed.

233. Upon information and belief, the medical community did rely on the specific false representations made by defendants when prescribing opioids and when monitoring their patients' opioid use, and such reliance is the proximate cause of damages suffered.

234. Upon information and belief, as a direct and proximate result of Defendants' fraudulent misrepresentations and intentional concealment of facts, upon which the medical community and consumers in the County reasonably relied, the County suffered actual damages.

COUNT III
NEGLIGENCE
(Against All Defendants)

235. County re-alleges and incorporates by reference each of the allegations contained in the preceding paragraphs of this Complaint as though fully alleged herein.

236. Manufacturing Defendants have a duty to exercise reasonable care in marketing their opioids to physicians treating residents of County. Manufacturing Defendants have breached their duty by knowingly and fraudulently misrepresenting the benefits of, and downplaying the risks of, opioids for chronic pain.

237. Manufacturing Defendants have used deceitful marketing ploys, KOLs, Front Groups, and other schemes to increase profits at the cost of public health causing an opioid epidemic. Manufacturing Defendants have acted willfully, wantonly, and maliciously.

238. Likewise, Distributor Defendants have a duty to exercise ordinary care in distributing opioids. Distributor Defendants have breached their duty by failing to prevent or reduce the distribution of opioids, or to report the increase in the distribution and/or sale of opioids.

239. Distributor Defendants have intentionally failed to prevent or reduce the distribution of opioids, or to report any increases in the sale of opioids, so that they could increase profits and receive rebates or kick-backs from Manufacturing Defendants. Distributor Defendants have acted willfully, wantonly, and maliciously.

240. Upon information and belief, as a proximate result, Manufacturing and Distributor Defendants and their agents have caused the County to incur excessive costs to treat the opioid epidemic in its county, including but not limited to increased costs of social services, health systems, law enforcement, judicial system, and treatment facilities.

241. The County and its residents are therefore entitled to damages.

COUNT IV
GROSS NEGLIGENCE
(Against All Defendants)

242. The County incorporates the allegations within all prior paragraphs within this Complaint as if they were fully set forth herein.

243. Defendants' marketing scheme to optimize profits by misrepresenting and falsely touting opioids as the panacea to chronic pain was done intentionally.

244. Defendants' hiring of KOLs, Front Groups, and others to spread their fraudulent message that opioids were useful and beneficial for chronic pain was grossly negligent and done with conscious indifference to the rights, safety, and welfare of others.

245. Each Defendant's actions and omissions as described herein, singularly or in combination with each other, involved an extreme degree of risk, considering the probability and

magnitude of the potential harm to others. Each Defendant's actions and omissions described herein was done with actual and subjective awareness of the risk involved, but nevertheless demonstrated a conscious indifference to the rights, safety, and welfare of others.

246. Upon information and belief, at every stage, Defendants knew or should have known that their conduct would create an unreasonable risk of physical harm to others, including County and its residents, and should be held liable in damages to County.

COUNT V
UNJUST ENRICHMENT
(Against All Defendants)

247. County re-alleges and incorporates by reference each of the allegations contained in the preceding paragraphs of this Complaint as though fully alleged herein.

248. Upon information and belief, as an expected and intended result of their conscious wrongdoing as set forth in this Complaint, Defendants have profited and benefited from opioid purchases made by the County and its residents.

249. Upon information and belief, when County and its residents purchased opioids, they expected that Defendants had provided necessary and accurate information regarding those risks. Instead, Defendants had misrepresented the material facts regarding the risks and benefits of opioids.

250. Upon information and belief, Defendants have been unjustly enriched at the expense of County, and County is therefore entitled to damages to be determined by the jury.

COUNT VI
VIOLATIONS OF THE RACKETEER INFLUENCED AND CORRUPT ORGANIZATIONS ACT ("RICO")
18 U.S.C. § 1961, et seq.
(Against All Defendants)

251. County re-alleges and incorporates by reference each of the allegations contained in the preceding paragraphs of this Complaint as though fully alleged herein.

252. This claim is brought by the County against each Defendant for actual damages, treble damages, and equitable relief under and for violations of 18 U.S.C. § 1961, et seq.

253. Section 1962(c) makes it "unlawful for any person employed by or associated with any enterprise engaged in, or the activities of which affect, interstate or foreign commerce, to conduct or participate, directly or indirectly, in the conduct of such enterprise's affairs through a pattern of racketeering activity . . ." 18 U.S.C. §1962(c).

254. Each Defendant conducted the affairs of an "Enterprise" through a pattern of racketeering activity, in violation of 18 U.S.C. §1962(c) and §1962(d).

255. Each Defendant herein participated in an Enterprise for purposes of 18 U.S.C. §1961(3) that created and maintained systematic links for a common purpose: to sell and distribute drugs, specifically opioids, that have little or no demonstrated efficacy for the pain they are purported to treat in the majority of persons that obtain prescriptions for them.

256. To accomplish this purpose, the Enterprise engaged in a sophisticated, well developed, and fraudulent marketing scheme designed to increase the prescription rate for the sale and distribution of Defendants' opioids and popularize the misunderstanding that opioids are effective for chronic pain and the risk of addiction is low (hereafter, "the Scheme").

257. At all relevant times, each Defendant was aware of the Enterprise's conduct, was a knowing and willing participant in that conduct, and reaped profits from that conduct in the form of increased sales, distributions, and prescriptions of opioids.

258. In fact, Front Groups and KOLs received direct payments from Manufacturer Defendants in exchange for their role in the Enterprise, and to advance the Enterprise's

fraudulent marketing scheme whereas Distributor Defendants received kick-backs from Manufacturing Defendants if they reached particular monthly goals. The Enterprise engaged in, and its activities affected, interstate and foreign commerce because it involved commercial activities across state boundaries, including but not limited to: (1) marketing, promotion, and advertisement of Defendants' opioid medicines; (2) advocacy at the state and federal level for change in the law governing the use, prescription, and distribution of Defendants' opioids; (3) issuing prescriptions and prescription guidelines for Defendants' opioids; and (4) issuing fees, bills, and statements demanding payment for prescriptions of Defendants' opioids.

259. The persons engaged in the Enterprise are systematically linked through contractual relationships, financial ties, and continuing coordination of activities, as spearheaded by the Manufacturer Defendants.

260. The Enterprise functioned as a continuing unit for the purposes of executing the Scheme and when issues arose during the Scheme, each member of the Enterprise agreed to take actions to hide the Scheme and the existence of the Enterprise.

261. Each Defendant participated in the operation and management of the Enterprise by directing its affairs as described herein.

262. While Defendants participated in, and are members of, the Enterprise, they have an existence separate from the Enterprise, including distinct legal statuses, affairs, offices and roles, officers, directors, employees, and individual personhood.

263. Defendants, singularly or in combination with another, orchestrated the affairs of the Enterprise and exerted substantial control over the Enterprise by, at least: (1) making misleading statements about the purported benefits, efficacy, and risks of opioids to doctors, patients, the public, and others, in the form of telephonic and electronic communications, CME

programs, medical journals, advertisements, and websites; (2) employing sales representatives or detailers to promote the use of opioid medications; (3) purchasing and utilizing sophisticated marketing data (e.g., IMS data) to coordinate and refine the Scheme; (4) employing doctors to serve as speakers at or attend all-expense paid trips to programs emphasizing the benefits of prescribing opioid medications; (5) funding, controlling, and operating the Front Groups to target doctors, patients, and lawmakers and provide a veneer of legitimacy to the Manufacturer Defendants' Scheme; (6) retaining KOLs to promote the use of their opioid medicines and (7) concealing the true nature of their relationship with the other members of the Enterprise, including the Front Groups and the KOLs.

264. To carry out, or attempt to carry out, the scheme to defraud, the members of the Enterprise, each of whom is a person associated-in-fact with the Enterprise, did knowingly conduct or participate, directly or indirectly, in the affairs of the Enterprise through a pattern of racketeering activity within the meaning of 18 U.S.C. §§1961(1), 1961(5) and 1962(c), and employed the use of the mail and wire facilities, in violation of 18 U.S.C. §1341 (mail fraud) and §1343 (wire fraud).

265. Specifically, the members of the Enterprise have committed, conspired to commit, and/or aided and abetted in the commission of, at least two predicate acts of racketeering activity (i.e., violations of 18 U.S.C. §§1341 and 1343), within the past ten years.

266. The Enterprise's predicate acts of racketeering (18 U.S.C. §1961(1)) include, but are not limited to:

a. Mail Fraud: The members of the Enterprise violated 18 U.S.C. §1341 by sending or receiving, or by causing to be sent and/or received, fraudulent materials via U.S. mail or commercial interstate carriers for the purpose of selling drugs, specifically opioids, that have little or no demonstrated efficacy for the pain they are purported to treat in the majority of persons prescribed them.

b. Wire Fraud: The members of the Enterprise violated 18 U.S.C. §1343 by

> transmitting and/or receiving, or by causing to be transmitted and/or received, fraudulent materials by wire for the purpose of selling drugs, specifically opioids, that have little or no demonstrated efficacy for the pain they are purported to treat in the majority of persons prescribed them.

267. The mail and wire transmissions were made in furtherance of Defendants' Scheme and common course of conduct designed to sell drugs that have little or no demonstrated efficacy for chronic pain; increase the prescription rate for opioids; and popularize the misunderstanding that the risk of addiction is low when using opioids.

268. The members of the Enterprise aided and abetted others in violating the law. To achieve their common goals, the members of the Enterprise hid from County and its residents: (1) the fraudulent nature of Defendants' marketing scheme; (2) the fraudulent nature of statements made by Defendants and on behalf of Defendants regarding the efficacy of and risk of addiction associated with Defendants' opioids; and (3) the true nature of the relationship between the members of the Enterprise.

269. Defendants and each member of the Enterprise, with knowledge and intent, agreed to the overall objectives of the Scheme and participated in the common course of conduct. Indeed, for the conspiracy to succeed, each of the members of the Enterprise and their co- conspirators agreed to conceal their fraudulent scheme.

270. The members of the Enterprise knew, and intended that, County and its residents would rely on the material misrepresentations and omissions made by them and suffer damages and a result.

271. The pattern of racketeering activity described herein is currently ongoing and open-ended and threatens to continue indefinitely unless this Court enjoins the racketeering activity.

272. As a result of Defendants' racketeering activity, County has been injured in their business and/or property in multiple ways, including but not limited to increased health care costs,

increased human services costs, costs related to dealing with opioid related crimes and emergencies, and other public safety costs.

273. Defendants' violations of 18 U.S.C. §1962(c) and (d) have directly and proximately caused injuries and damages to the County and the public who are entitled to bring this action for three times its actual damages, as well as injunctive/equitable relief, costs, and reasonable attorney's fees pursuant to 18 U.S.C. §1964(c).

COUNT VII
KENTUCKY CONSUMER PROTECTION ACT
(Against All Defendants)

274. The County re-alleges and incorporates by reference each of the allegations contained in the preceding paragraphs of this Complaint as though fully alleged herein.

275. The Kentucky Consumer Protection Act (KCPA) is remedial legislation enacted to give consumers broad protection from illegal acts. *Naiser v. Unilever U.S., Inc.* (W.D.Ky. 2013) 975 F.Supp.2d 727. The Court of Appeals of Kentucky held that "the Kentucky Consumer Protection Act was broadly designed to curtail unfair, false, misleading or deceptive practices in the conduct of commerce and that the Attorney General is therefore not limited to prosecuting only those selected types of illegal business acts or practices which are used in the merchandising of goods or services intended for personal, family or household use." *Com. ex rel. Stephens v. N. Am. Van Lines, Inc.*, 600 S.W.2d 459, 462 (Ky. Ct. App. 1979).

276. Defendants committed repeated and willful unfair or deceptive acts or practices, in connection with the sale of their opioids.

277. Defendants' fraudulent, deceptive, and unconscionable misrepresentations, concealments, and omissions were reasonably calculated to deceive the State, the public, and the County.

278. As described more specifically above, Defendants' misrepresentations, concealments, and omissions constitute a willful course of conduct which continues to this day.

279. As alleged herein, each Defendant wrongfully represented that the opioid prescription medications they manufactured, marketed, and sold had characteristics, uses, or benefits that they do not have. These misrepresentations were made with the intent that others rely on them in furtherance of the Defendants' marketing of their opioids for sale to medical providers, patients, and consumers.

280. Specifically, Defendants' misrepresentations include, but are not limited to:

i. Manufacturing Defendants' claims that the risks of long-term opioid use, especially the risk of addiction were overblown;

ii. Manufacturing Defendants' claims that signs of addiction were "pseudoaddiction" reflecting undertreated pain, and should be responded to with more opioids;

iii. Manufacturing Defendants' claims that opioid doses can be increased until pain relief is achieved and there is no ceiling dose;

iv. Manufacturing Defendants' overstatement of the risks of NSAIDs, when compared to opioids;

v. Manufacturing Defendants' claims that evidence supports the long-term use of opioids for chronic pain;

vi. Manufacturing Defendants' claims that screening tools effectively prevent addiction;

vii. Manufacturing Defendants' claims that chronic opioid therapy would improve patients' function and quality of life;

viii. Endo's claims that abuse-deterrent opioids prevent tampering and abuse;

ix. Teva's unsubstantiated claims that Actiq and Fentora were appropriate for treatment of non-cancer pain and its failure to disclose that Actiq and Fentora were not approved for such use; and

x. Manufacturing Defendants' use of front groups, to suggest that the deceptive statements from these sources described in this Complaint came from objective, independent sources.

281. By engaging in the acts and practices alleged herein, Defendants omitted material facts, with the intent that others would rely on their omissions or suppression of information, that they had a duty to disclose by virtue of these Defendants' other representations, including, but not limited to, the following:

i. opioids are highly addictive and may result in overdose or death;

ii. no credible scientific evidence supports the use of screening tools as a strategy for reducing abuse or diversion;

iii. high dose opioids subject the user to greater risks of addiction, other injury, or death;

iv. the risks of hyperalgesia, hormonal dysfunction, decline in immune function, mental clouding, confusion, and dizziness, increased falls and fractures in the elderly, neonatal abstinence syndrome, and potentially fatal interactions with alcohol or benzodiazepines, particularly while exaggerating the risks of competing products, such as NSAIDs;

v. claims regarding the benefits of chronic opioid therapy lacked scientific support or were contrary to the scientific evidence;

vi. Endo's abuse-deterrent formulations are not designed to address, and have no effect on, the most common route of abuse (oral abuse), can be defeated with relative ease; and may increase overall abuse;

vii. Defendants failed to report suspicious prescribers and orders; and

viii. Manufacturing Defendants' failure to disclose their financial ties to and role in connection with KOLs and front groups.

282. The damages which the County seeks to recover were sustained as a direct and proximate cause of the Defendants' intentional and/or unlawful actions, misrepresentations, and omissions. Because of Defendants' omissions and deceptive misrepresentations to medical professionals, the public, and consumers, the County has experienced a dramatic increase in opioid addiction and death and has incurred significant costs in order to address opioid-related law enforcement, social services, and public health issues. In addition, the County has been damaged and continues to be damaged by paying for the costs of opioid prescriptions for chronic pain dispensed due to the Defendants' fraud, opioid addiction treatment, and other opioid related costs through its employee health plans and workers' compensation program.

283. The County seeks injunctive relief and actual damages under Ky. Rev. Stat. § 367.990, which creates a private right of action when the action would benefit the public. The present action benefits the public, both in the County, as well as all of Kentucky, by reducing the amounts of opioid drugs in the County, and providing the County the necessary resources, both monetary and non-monetary, to redress the opioid epidemic and treat its victims. Slowing the flow of opioids and providing funds to address the epidemic will help to alleviate this problem, save lives, prevent injuries and make the County a safer place to live.

WHEREFORE The County demands judgment in its favor against the Defendants for damages and equitable relief pursuant to KY. REV. STAT. § 367.990 and together with all the costs of this action, including prejudgment interest, post-judgment interest, costs and expenses, attorney fees, and such other relief as this Court deems just and equitable.

COUNT VIII
FALSE STATEMENT IN ADVERTISING

Ky. Rev. Stat. § 517.030 (Against All Defendants)

284. The County re-alleges and incorporates by reference each of the allegations contained in the preceding paragraphs of this Complaint as though fully alleged herein.

285. Ky. Rev. Stat. § 517.030 reads in pertinent part:

> A person is guilty of false advertising when, in connection with the promotion of the sale of or to increase the consumption of property or services, he knowingly makes or causes to be made a false or misleading statement in any advertisement addressed to the public or to a substantial number of persons.

286. As alleged herein, the Defendants engaged in a systematic campaign designed to promote the belief that opioid drugs could safely be used for chronic pain conditions in a non-addictive manner.

287. Specifically, Defendants' misrepresentations include, but are not limited to:

i. Manufacturing Defendants' claims that the risks of long-term opioid use, especially the risk of addiction were overblown;

ii. Manufacturing Defendants' claims that signs of addiction were "pseudoaddiction" reflecting undertreated pain, and should be responded to with more opioids;

iii. Manufacturing Defendants' claims that opioid doses can be increased until pain relief is achieved and there is no ceiling dose;

iv. Manufacturing Defendants' overstatement of the risks of NSAIDs, when compared to opioids;

v. Manufacturing Defendants' claims that evidence supports the long-term use of opioids for chronic pain;

vi. Manufacturing Defendants' claims that screening tools effectively prevent addiction;

vii. Manufacturing Defendants' claims that chronic opioid therapy would improve patients' function and quality of life;

viii. Endo's claims that abuse-deterrent opioids prevent tampering and abuse;

ix. Teva's unsubstantiated claims that Actiq and Fentora were appropriate for treatment of non-cancer pain and its failure to disclose that Actiq and Fentora were not approved for such use; and

x. Manufacturing Defendants' use of front groups, to suggest that the deceptive statements from these sources described in this Complaint came from objective, independent sources.

288. Defendants' false and deceptive advertising practices resulted in increased opioids being prescribed to the County residents, and the County employees and their dependents, increasing the incidence of opioid addiction and overdose in the County.

289. Because of Defendants' false and deceptive advertising practices to the County, its residents, and its medical professionals, the County has experienced a dramatic increase in opioid addiction and death and has incurred significant costs in order to address opioid-related law enforcement, social services, and public health. In addition, the County has been damaged and continues to be damaged by paying for the costs of opioid prescriptions for chronic pain dispensed due to the Defendants' fraud, opioid addiction treatment, and other opioid related costs through its employee health plans and workers' compensation program.

290. The County seeks injunctive relief and actual damages under Ky. Rev. Stat. § 517.030, which creates a private right of action when the action would benefit the public. The present action benefits the public, both in the County, as well as all of Kentucky, by reducing the amounts of opioid drugs in the state and County, and providing the County the necessary resources, both monetary and non-monetary, to redress the opioid epidemic and treat its victims. Slowing the flow of opioids and providing funds to address the epidemic will help to alleviate this problem, save lives, prevent injuries and make the County a safer place to live.

WHEREFORE The County demands judgment in its favor against the Defendants for damages and equitable relief pursuant to Ky. Rev. Stat. § 446.070 together with all the costs of

this action, including prejudgment interest, post-judgment interest, costs and expenses, attorney fees, and such other relief as this Court deems just and equitable.

COUNT IX
UNLAWFUL ACTS
Ky. Rev. Stat. § 367.170 (Against All Defendants)

291. The County re-alleges and incorporates by reference each of the allegations contained in the preceding paragraphs of this Complaint as though fully alleged herein.

292. Ky. Rev. Stat. § 367.170states, in pertinent part:

> Unfair, false, misleading, or deceptive acts or practices in the conduct of any trade or commerce are hereby declared unlawful.

293. Defendants are persons for purposes of this statute.

294. As alleged herein, Defendants have misrepresented the addictive quality of opioids and the appropriateness of opioids for long term treatment of chronic pain conditions. The Defendants engaged in an aggressive marketing campaign, which in part sought to downplay the dangerousness of these drugs, while promoting them for chronic pain for which they knew the drug were not safe or suitable.

295. Because of the dangerously addictive nature of these drugs, the Defendants' manufacturing, marketing, and sales practices unlawfully caused an opioid and heroin epidemic in the County.

296. As alleged herein, each of the Defendants wrongfully represented that the opioid prescription medications they manufactured, marketed, and sold had qualities that they do not have. Defendants misrepresentations include, but are not limited to:

i. Manufacturing Defendants' claims that the risks of long-term opioid use, especially the risk of addiction were overblown;

ii. Manufacturing Defendants' claims that signs of addiction were "pseudoaddiction" reflecting undertreated pain, and should be responded to with more opioids;

iii. Manufacturing Defendants' claims that opioid doses can be increased until pain relief is achieved and there is no ceiling dose;

iv. Manufacturing Defendants' overstatement of the risks of NSAIDs, when compared to opioids;

v. Manufacturing Defendants' claims that evidence supports the long-term use of opioids for chronic pain;

vi. Manufacturing Defendants' claims that screening tools effectively prevent addiction;

vii. Manufacturing Defendants' claims that chronic opioid therapy would improve patients' function and quality of life;

viii. Endo's claims that abuse-deterrent opioids prevent tampering and abuse;

ix. Teva's unsubstantiated claims that Actiq and Fentora were appropriate for treatment of non-cancer pain and its failure to disclose that Actiq and Fentora were not approved for such use; and

x. Manufacturing Defendants' use of front groups, to suggest that the deceptive statements from these sources described in this Complaint came from objective, independent sources.

297. By engaging in the acts and practices alleged herein, Defendants omitted material facts, with the intent that others rely on their omissions or suppression of information, that they had a duty to disclose by virtue of these Defendants' other representations, including, but not limited to, the following:

i. opioids are highly addictive and may result in overdose or death;

ii. no credible scientific evidence supports the use of screening tools as a strategy for reducing abuse or diversion;

iii. high dose opioids subject the user to greater risks of addiction, other injury, or death;

iv. the risks of hyperalgesia, hormonal dysfunction, decline in immune function, mental clouding, confusion, and dizziness, increased falls and fractures in the elderly, neonatal abstinence syndrome, and potentially fatal interactions with

alcohol or benzodiazepines, particularly while exaggerating the risks of competing products, such as NSAIDs;

v. claims regarding the benefits of chronic opioid therapy lacked scientific support or were contrary to the scientific evidence;

vi. Endo's abuse-deterrent formulations are not designed to address, and have no effect on, the most common route of abuse (oral abuse), can be defeated with relative ease; and may increase overall abuse;

vii. Defendants failed to report suspicious prescribers and orders; and

viii. Manufacturing Defendants' failure to disclose their financial ties to and role in connection with KOLs and front groups.

298. Defendants' false and deceptive advertising practices and unlawful trade practices resulted in increased opioids being prescribed to the County residents, and to the County employees and their dependents, increasing the incidence of opioid addiction and overdose in the County.

299. Because of Defendants' false and deceptive advertising practices in the County, its residents, and their medical professionals, the County has experienced a dramatic increase in opioid addiction and death and has incurred significant costs in order to address opioid-related law enforcement, social services, and public health. In addition, the County has been damaged and continues to be damaged by paying for the costs of opioid prescriptions for chronic pain dispensed due to the Defendants' fraud, opioid addiction treatment, and other opioid related costs through its employee health plans and workers' compensation program.

300. The County seeks injunctive relief and actual damages under Ky. Rev. Stat. § 367.990 and Ky. Rev. Stat. § 367.46967 , which creates a private right of action when the action would benefit the public. The present action benefits the public, both in the County, as well as all of Kentucky, by reducing the amounts of opioid drugs in the state and County, and providing the County the necessary resources, both monetary and non-monetary, to redress the opioid epidemic

and treat its victims. Slowing the flow of opioids and providing funds to address the epidemic will help to alleviate this problem, save lives, prevent injuries and make the County a safer place to live.

WHEREFORE The County demands judgment in its favor against the Defendants for damages and equitable relief pursuant to Ky. Rev. Stat. § 367.990 and Ky. Rev. Stat. § 367.46967 together with all the costs of this action, including prejudgment interest, post-judgment interest, costs and expenses, attorney fees, and such other relief as this Court deems just and equitable.

COUNT X
FRAUDULENT AND INTENTIONAL MISREPRESENTATION
(Against All Defendants)

301. The County re-alleges and incorporates by reference each of the allegations contained in the preceding paragraphs of this Complaint as though fully alleged herein.

302. The County incorporates the allegations within all prior paragraphs within this Complaint as if they were fully set forth herein.

303. Defendants, individually and acting through their employees and agents, knowingly and intentionally made misrepresentations and omissions of facts material to the County, its residents and employees, and health care providers to induce them to purchase, administer, and consume opioids as set forth in detail above.

304. In overstating the benefits of and evidence for the use of opioids for chronic pain and understating their very serious risks, including the risk of addiction; in falsely promoting abuse-deterrent formulations as reducing abuse; and in falsely portraying their efforts or commitment to rein in the diversion and abuse of opioids, Defendants have engaged in intentional, fraudulent misrepresentations and knowing omissions of material fact.

305. Defendants' misrepresentations include, but are not limited to:

i. Manufacturing Defendants' claims that the risks of long-term opioid use, especially the risk of addiction were overblown;

ii. Manufacturing Defendants' claims that signs of addiction were "pseudoaddiction" reflecting undertreated pain, and should be responded to with more opioids;

iii. Manufacturing Defendants' claims that opioid doses can be increased until pain relief is achieved and there is no ceiling dose;

iv. Manufacturing Defendants' overstatement of the risks of NSAIDs, when compared to opioids;

v. Manufacturing Defendants' claims that evidence supports the long-term use of opioids for chronic pain;

vi. Manufacturing Defendants' claims that screening tools effectively prevent addiction;

vii. Manufacturing Defendants' claims that chronic opioid therapy would improve patients' function and quality of life;

viii. Endo's claims that abuse-deterrent opioids prevent tampering and abuse;

ix. Teva's unsubstantiated claims that Actiq and Fentora were appropriate for treatment of non-cancer pain and its failure to disclose that Actiq and Fentora were not approved for such use; and

x. Manufacturing Defendants' use of front groups, to suggest that the deceptive statements from these sources described in this Complaint came from objective, independent sources.

306. By engaging in the acts and practices alleged herein, Defendants omitted material facts, with the intent that others would rely on their omissions or suppression of information, that they had a duty to disclose by virtue of these Defendants' other representations, including, but not limited to, the following:

i. opioids are highly addictive and may result in overdose or death;

ii. no credible scientific evidence supports the use of screening tools as a strategy for reducing abuse or diversion;

iii. high dose opioids subject the user to greater risks of addiction, other injury, or death;

iv. the risks of hyperalgesia, hormonal dysfunction, decline in immune function, mental clouding, confusion, and dizziness, increased falls and fractures in the elderly, neonatal abstinence syndrome, and potentially fatal interactions with alcohol or benzodiazepines, particularly while exaggerating the risks of competing products, such as NSAIDs;

v. claims regarding the benefits of chronic opioid therapy lacked scientific support or were contrary to the scientific evidence;

vi. Endo's abuse-deterrent formulations are not designed to address, and have no effect on, the most common route of abuse (oral abuse), can be defeated with relative ease; and may increase overall abuse;

vii. Defendants failed to report suspicious prescribers and orders; and

viii. Manufacturing Defendants' failure to disclose their financial ties to and role in connection with KOLs and front groups.

307. Defendants' statements about the use of opioids to treat chronic pain and/or non-cancer pain conditions were false and either not supported by or contrary to the scientific evidence.

308. Further, Defendants' omissions, which were false and misleading in their own right, rendered even seemingly truthful statements about opioids false and misleading and likely to mislead County prescribers and consumers.

309. Defendants knew at the time they made these representations and omissions that they were false.

310. Defendants intended that the County, its residents and employees, and health care providers would rely on their misrepresentations and omissions, knew that the County, its residents and employees, and health care providers would rely on their misrepresentations, and that such reliance would cause the County to suffer loss.

311. Health care providers, residents in the County, and County employees and their dependents reasonably relied on Defendants' misrepresentations and omissions in writing, filling, and using prescriptions for Defendants' opioids, and the County and its agents reasonably relied on these same misrepresentations and omissions in covering and paying for Defendants' opioids for chronic pain.

312. Had the County known that Defendants misrepresented the risks, benefits, and evidence regarding the use of opioids for chronic pain, the County would have undertaken efforts to avoid payments of related claims or to otherwise reduce its damages.

313. By reason of their reliance on Defendants' misrepresentations and omissions of material fact, the County suffered actual pecuniary damage.

314. Defendants' conduct was accompanied by wanton and willful disregard of persons who foreseeably might be harmed by their acts and omissions.

WHEREFORE, the County seeks all legal and equitable relief as allowed by law, including *inter alia* injunctive relief, compensatory damages, and all damages allowed by law to be paid by Defendants, attorneys fees and costs, and pre- and post-judgment interest and such other relief as this Court deems just and equitable.

VI. PUNITIVE DAMAGES

Based on Defendants' deliberate disregard of the County's rights, and of the rights and safety of County residents, employees and their dependents, the County is entitled to punitive damages. Pursuant to Ky. Rev. Stat. § 411.186 , the County will move the Court to amend the Complaint to claim punitive damages.

VII. REQUESTED RELIEF

WHEREFORE, County respectfully prays:

a. That the acts alleged herein be adjudged and decreed to be unlawful and that the Court enter a judgment declaring them to be so;

b. That Defendants be enjoined from, directly or indirectly through KOLs, Front Groups or other third parties, continuing to misrepresent the risks and benefits of the use of opioids for chronic pain, and from continuing to violate Kentucky law;

c. That Plaintiff recover all measures of damages allowable under the law, and that judgment be entered against Defendants in favor of the County;

d. That County recover restitution on behalf of the County consumers who paid for opioids for chronic pain;

e. That County recover the costs and expenses of suit, pre- and post-judgment interest, and reasonable attorneys' fees as provided by law; and

f. That Defendants be ordered to abate the public nuisance that they created in violation of Kentucky common law.

January 24, 2020

JURY TRIAL DEMANDED

Respectfully submitted,

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