No.

CITY OF NEW HAVEN, Plaintiff, vs. PURDUE PHARMA L.P., d/b/a PURDUE PHARMA (DELAWARE) LIMITED PARTNERSHIP; PURDUE PHARMA INC.; THE PURDUE FREDERICK COMPANY, INC.; TEVA PHARMACEUTICALS USA, INC.; CEPHALON, INC.; JOHNSON & JOHNSON; JANSSEN PHARMACEUTICALS, INC.; ORTHO-MCNEIL-JANSSEN PHARMACEUTICALS, INC. n/k/a JANSSEN PHARMACEUTICALS, INC.; ENDO HEALTH SOLUTIONS INC.; ENDO PHARMACEUTICALS, INC.; and INSYS THERAPEUTICS, INC., Manufacturer Defendants, - and – MCKESSON CORPORATION, CARDINAL HEALTH, INC., and AMERISOURCE BERGEN CORPORATION, Distributor Defendants.	SUPERIOR COURT JUDICIAL DISTRICT OF NEW HAVEN AT NEW HAVEN OCTOBER 25, 2017

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COMPLAINT

Plaintiff City of New Haven, Connecticut, with offices located at 165 Church Street, New Haven, CT 06510, alleges as follows:

I. PRELIMINARY STATEMENT

1. Many communities in the United States, including the City of New Haven, Connecticut, are currently experiencing a stark increase in the number of its residents who have become addicted to prescription opioids and heroin, and a stark increase in opioid overdoses. Prescription opioids are now known to be the "gateway" drug to heroin; approximately 80% of current heroin users got their start with prescription opioids.[1] Unlike any other epidemic, the opioid epidemic is largely man-made and is being fueled by the continuing unlawful conduct of the defendant pharmaceutical manufacturers ("Manufacturer Defendants") and pharmaceutical wholesale distributors ("Distributor Defendants").

2. Beginning in the mid-1990s, the Manufacturer Defendants, led by Purdue Pharma, have engaged in a scheme to boost sales for their prescription opioid products by falsely promoting their highly dangerous products for the use of chronic pain and knowingly, recklessly and negligently denying or trivializing the risk of addiction.

3. In furtherance of their scheme, each Manufacturer Defendant used the following unethical and unlawful methods to disseminate misinformation regarding the safety and efficacy of using long-term opioid use for pain management treatment, including:

(a) paying off doctors called "Key Opinion Leaders ("KOLs") to give speeches and write articles advocating the advantages of prescription opioids;

[1] Prescription Opioids and Heroin, National Institute on Drug Abuse (Dec. 16, 2015), https://www.drugabuse.gov/publications/research-reports/prescription-opioids-heroin.

(b) twisting scientific literature; most notably, transforming a five-sentence letter written to the *New England Journal of Medicine* in 1980 by Doctor Jick and his graduate assistant Porter ("Porter & Jick Letter"), regarding the relative safety of short-term opioid use by patients in a medical setting, into a false assertion (cited more than 600 times) that long-term opioid use in a non-medical setting has been proven to be "safe" and non-addictive;

(c) infiltrating medical societies and continuing medical education ("CME") programs with the false information that chronic pain can and should be safely treated with prescription opioids;

(d) using non-branded advertisements (that promote opioids generally, rather than any particular brand), which are not regulated by the U.S. Food and Drug Administration ("FDA"), to falsely promise relief from pain with no harmful side-effects from opioids; and

(e) providing front groups with tens of millions of dollars and giving them official-sounding names, such as "American Pain Foundation," to disseminate the falsehood that addiction is a very minor and easily handled risk of prescription opioids.

4. In addition to the foregoing, Manufacturer Defendants Purdue, Teva-Cephalon, and Insys, and upon information and belief, all the other Manufacturer Defendants used their sales forces to market their dangerous prescription opioids to treat conditions beyond which the drug had approval from the FDA, known as "off-label marketing," thereby violating the Federal False Claims Act ("FCA"), 31 U.S.C. §§3729-33.

5. To the huge detriment of the health of Americans, the scheme of the Manufacturer Defendants (which was well funded, well organized, and pervasive) was extremely successful.

In just a few years, the Manufacturer Defendants managed to jettison decades of well-established and sound medical orthodoxy holding that prescription opioids are far too addictive and potentially debilitating to be used to treat chronic pain. For example, they successfully introduced pain as the fifth factor along with respiration rate, body temperature, blood pressure, and pulse rate that is considered to be a "vital sign" upon which doctors assess patients.[2]

6. The profits of the Manufacturer Defendants skyrocketed. Opioid sales have steadily risen, from $3.8 billion in 2000, to $8 billion in 2010, to $9.6 billion in 2015. Purdue has sold more than $35 billion worth of opioids since 1996, including more than $3 billion in revenue in 2015 (from $800 million in 2006). Purdue's OxyContin sales rose from $45 million in 1996 to $3.1 billion in 2010. Endo Pharmaceuticals has gained a tremendous amount of revenue from opioid sales as well, reaping over $1 billion from Opana ER alone in 2010, and again in 2013.

7. The three Distributor Defendants, McKesson Corporation ("McKesson"), Cardinal Health Inc. ("Cardinal") and AmerisourceBergen Corporation ("ABC"), dominate 85-90% of the market share of the distribution of prescription opioids in the U.S.[3]

8. The 1970 Controlled Substance Act ("CSA"), 21 U.S.C. §§801 et seq., requires wholesale distributors of "controlled substances" (all the prescription opioids involved in the opioid epidemic and listed in Tables 1-6, infra, are either Schedule II or III controlled

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[2] *See* Natalia E. Morone & Deborah K. Weiner, *Pain as the 5th Vital Sign: Exposing the Vital Need for Pain Education*, 35(11) CLIN. THER. 1728, 1729 (2013). In 2016, the American Medical Association recommended removing pain as the fifth vital sign. *See* Remove Pain as 5th Vital Sign, AMA Urged, MedPage Today (June 13, 2016), https://www.medpagetoday.com/MeetingCoverage/AMA/58486?xid=nl_mpt_DHE_2016-06-14&eun=g368150d0r ("Just as we now know earth [is] not flat, we know that pain is not a vital sign.").

[3] Adam J. Fein, 2016 MDM Market Leaders / Top Pharmaceutical Distributors (MDM 2017), https://www.mdm.com/2016-top-pharmaceuticals-distributors.

substances) to register with the U.S. Drug Enforcement Administration ("DEA") to be approved as a vendor of controlled substances. 21 U.S.C. §§821-30.

9. In order to get and retain the coveted registration (without which a wholesale distributor could not lawfully sell any opioid prescriptions in the United States), the wholesale distributor has a statutory duty to discharge several binding obligations. Included among these obligations are the duties "to report to [the] DEA suspicious orders for controlled substances and to take other precautions to ensure that those medications would not be diverted into illegal schemes." Masters Pharm., Inc. v. DEA, 861 F.3d 206, 211-12 (D.C. Cir. 2017); 21 C.F.R. §1301.77.

10. Each Distributor Defendant utterly failed to discharge its statutory obligations to maintain and monitor a closed chain of distribution, and to detect, report, inspect, and halt suspicious orders so as to prevent the black market diversion of controlled substances. The direct and foreseeable result of the Distributor Defendants' unlawful conduct is that many communities, including New Haven, Connecticut, have been flooded with an excess supply of pharmaceutical opioids.

11. Each Distributor Defendant has been investigated and fined by the DEA for violation of their statutory obligation to:

(a) operate their mandatory internal oversight system in good faith;

(b) report suspicious orders to the DEA; and

(c) halt the shipment of "suspicious orders for controlled substances" when they were discovered.

12. McKesson, the largest wholesale distributor in the United States, agreed on January 17, 2017 to pay a $150 million fine to the U.S. Department of Justice ("DOJ") for its violations of the CSA.4

13. In late December 2016, Cardinal reached a $44 million settlement with the federal government for its violations. It also settled a lawsuit initiated by the State of West Virginia for $20 million, which alleged similar violations of the CSA. See State of W. Va. v. AmerisourceBergen Drug Corp., No. 12-C-141 (W. Va. Cir. Ct., Boone Cty.).

14. ABC also agreed to pay West Virginia $16 million for settlement of the same litigation. See id.

15. The explosion in opioid prescription use caused by Defendants has led to a public health crisis in the State of Connecticut, including the City of New Haven. Connecticut faces skyrocketing opioid addiction and opioid-related overdoses and deaths, as well as devastating social and economic consequences. This public health crisis is a public nuisance to the City of New Haven because it constitutes unreasonable interference with the public health, safety, peace and welfare of the City. The catastrophic effects of each Manufacturer Defendant's unlawful deceptive marketing scheme and each Distributor Defendant's wanton, willful and reckless violation of their statutory gatekeeping role to ensure that the supply of opioids into communities be maintained at safe levels are only getting worse.

16. An oversupply of prescription opioids has provided a source for illicit use or sale of opioids, while the widespread use of opioids has created a population of patients physically and psychologically dependent on them. And when those patients can no longer afford or

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4 *See* Justice News, DOJ, Office of Public Affairs (Jan. 17, 2017), *McKesson Agrees to Pay Record $150 Million Settlement for Failure to Report Suspicious Orders of Pharmaceutical Drugs*, https://www.justice.gov/opa/pr/mckesson-agrees-pay-record-150-million-settlement-failure-report-suspicious-orders.

legitimately obtain opioids, scientific studies show, they often turn to the street to buy prescription opioids, or even heroin.

17. As the profits of the Defendants have increased year after year, so too have the numbers of substance abuse treatment admissions in the State of Connecticut; Connecticut Department of Mental Health and Addiction Services, which offers various services that act as a safety net to addicts and those in recovery, reported a 150% increase in people accessing treatment services.[5] So too have the deaths increased: the number of opioid-related deaths in New Haven was 44 in 2016,[6] more than the number of opioid-related deaths in 1996 for all of Connecticut.[7]

18. Defendants' conduct has violated and continues to violate the Connecticut Unfair Trade Practices Act ("CUTPA"). Conn. Gen. Stat. §42-110a, et seq. Additionally, Defendants' conduct constitutes a common law public nuisance, common law fraud, negligent misrepresentation, negligence, and unjust enrichment.

19. To redress and enjoin Defendants' previous and continuous violations of the law, the City of New Haven brings this action seeking abatement, restitution, damages, disgorgement of unlawful profits, civil penalties, attorneys' fees and costs permitted by law and equity.

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[5] Andrew Ba Tran, What can be done to curb the drug overdose deaths, TRENDCT.ORG (Mar. 10, 2016), https://overdose.trendct.org/story/what

[6] Accidental Drug Related Deaths 2012-2016, Connecticut Open Data (last visited Oct. 13, 2017), https://data.ct.gov/Health-and-Human-Services/Accidental-Drug-Related-Deaths-2012-2016/ecj5-r2i9,

[7] CT Heroin Epidemic: Interactive Map of Deaths by Town, Patch (last updated Mar. 2, 2017), https://patch.com/connecticut/newcanaan/ct-heroin-epidemic-interactive-map-deaths-town-0.

II. JURISDICTION AND VENUE

20. Plaintiff City of New Haven is the seat of and largest city in New Haven County, Connecticut, and has a population of approximately 130,000. Plaintiff is a "municipality" within the definition of Conn. Gen. Stat. 7-148(a). Section 7-148 defines the scope of municipal powers and provides that "[a]ny municipality shall have the power to . . . sue and be sued, and institute, prosecute, maintain and defend any action or proceeding in any court of competent jurisdiction." §7-148(c)(1)(A).

21. Additionally, section §7-148(c)(7)(H) gives Connecticut municipalities the power to (1) "prohibit the carrying on within the municipality of any trade, manufacture, business or profession ... prejudicial to public health ... or dangerous to, or constituting an unreasonable annoyance to, those living or owning property in the vicinity;" (2) "[p]reserve the public peace and good order;" and (3) "do all things necessary or desirable to secure and promote the public health." Id. Generally, Conn. Gen. Stat. §52-73 states that: "[t]owns, societies, communities and corporations may prosecute and defend civil actions, may appoint agents to appear in their behalf and may employ attorneys in such actions." The jurisdiction of this action is proper in this Court, which has original jurisdiction throughout the State in all causes of action brought under the Constitution of the State of Connecticut, article 20, § 1: "Section 1 of article fifth of the constitution is amended to read as follows: The judicial power of the state shall be vested in a supreme court, an appellate court, a superior court, and such lower courts as the general assembly shall, from time to time, ordain and establish. The powers and jurisdiction of these courts shall be defined by law."

22. This Court has personal jurisdiction over Defendants because they carry on a continuous and systematic part of their general business within Connecticut, have transacted

substantial business with Connecticut entities and residents, and have caused harm in Connecticut as a result of the specific business activities complained of herein.

23. Venue is proper in this Court pursuant to Conn. Gen. Stat. §51-345.

III. PARTIES

A. Plaintiff

24. Plaintiff City of New Haven ("Plaintiff," "City," or "New Haven") provides many municipal services that are designed to foster the safety, health, and well-being of its residents, including police, fire, and first responder services, law enforcement services, judiciary services, public health, safety and assistance services for families, teenagers, and persons in need.

25. The City of New Haven also self-insures for workers compensation for its city employees. Additionally, New Haven self-insures for medical and health insurance for its city employees and retirees.

26. The City brings this action on its own behalf and as *parens patriae* in the public interest on behalf of its residents.

B. Defendants

Defendant Purdue Pharma L.P. ("Purdue")

27. Defendant Purdue Pharma L.P. ("PPL"), registered and doing business in Connecticut as Purdue Pharma (Delaware) Limited Partnership, is a limited partnership organized under the laws of Delaware with its principal place of business in Stamford, Connecticut.

28. Defendant Purdue Pharma Inc. ("PPI") is a New York corporation with its principal place of business in Stamford, Connecticut.

29. Defendant The Purdue Frederick Company, Inc. ("PFC") is a New York corporation with its principal place of business in Stamford, Connecticut.

30. PPL, PPI, and PFC (collectively, "Purdue") are engaged in the manufacture, promotion, distribution, and sale of opioids nationally and in the City of New Haven, including the following:

Table 1 - Purdue Opioids

Drug Name	Chemical Name
OxyContin	Oxycodone hydrochloride extended release
MS Contin	Morphine sulfate extended release
Dilaudid	Hydromorphone hydrochloride
Dilaudid-HP	Hydromorphone hydrochloride
Butrans	Byprenorpine
Hysingla ER	Hydrocodone bitrate
Targiniq ER	Oxycodone Hydrochloride and naloxone

31. OxyContin is Purdue's largest-selling opioid. Since 2009, Purdue's national annual sales of OxyContin have fluctuated between $2.47 billion and $3.1 billion, up four-fold from 2006 sales of $800 million. OxyContin constitutes roughly 30% of the entire market for analgesic drugs (i.e., painkillers).

32. In 2007, Purdue settled criminal and civil charges brought against it by the DOJ for misbranding OxyContin and agreed to pay the United States over $600 million – at the time, one of the largest settlements with a drug company for marketing misconduct, as well as a sweeping set of injunctive relief requiring the Defendant to cease its unlawful and deceptive marketing practices. United States of America v. Purdue Frederick Company, Inc., Plea Agreement, No. 1:07CR29 (W.D. Va. May 10, 2007). Simultaneously, Purdue settled an action brought by twenty-seven States Attorneys General for $20 million and further injunctive relief.

33. Upon information and belief, Purdue has violated most, if not all, of its commitment under its consent decrees with the Government.

Defendants Teva Pharmaceuticals and Cephalon, Inc. ("Cephalon")

34. Defendant Teva Pharmaceuticals USA, Inc. ("Teva USA") is a Delaware corporation with its principal place of business in North Wales, Pennsylvania. Teva USA is a wholly owned subsidiary of Teva Pharmaceutical Industries, Ltd. ("Teva Ltd."), an Israeli corporation.

35. Defendant Cephalon, Inc. is a Delaware corporation with its principal place of business in Fraser, Pennsylvania. In 2011, Teva Ltd. acquired Cephalon, Inc.

36. Teva USA and Cephalon, Inc. (collectively, "Cephalon") work together to manufacture, promote, distribute and sell both brand name and generic versions of opioids nationally and in the City of New Haven, including the following:

Table 2 – Cephalon Opioids

Drug Name	Chemical Name	Form
Actiq	Fentanyl citrate	Lollipop or lozenge
Fentora	Fentanyl citrate	Buccal tablet, like a smokeless tobacco plug

37. In September 2008, Cephalon pled guilty to a criminal violation of the Federal Food Drug and Cosmetic Act for its misleading promotion of Actiq (and two other drugs) and agreed to pay $425 million in fines, damages, and penalties.

Defendants Johnson & Johnson and Janssen Pharmaceuticals ("Janssen")

38. Defendant Johnson & Johnson ("J&J") is a New Jersey corporation with its principal place of business in New Brunswick, New Jersey.

39. Defendant Janssen Pharmaceuticals, Inc. ("Janssen Pharmaceuticals") is a Pennsylvania corporation with its principal place of business in Titusville, New Jersey, and is a wholly owned subsidiary of J&J.

40. Defendant Ortho-McNeil-Janssen Pharmaceuticals Inc. ("OMP"), now known as Janssen Pharmaceuticals, Inc., is a Pennsylvania corporation with its principal place of business in Titusville, New Jersey.

41. Janssen Pharmaceuticals, Inc. was formerly known as Ortho-McNeil-Janssen Pharmaceuticals, Inc., which in turn was formerly known as Janssen Pharmaceutica, Inc.

42. Janssen Pharmaceutica, Inc. ("Janssen Pharmaceutica"), now known as Janssen Pharmaceuticals, Inc., is a Pennsylvania corporation with its principal place of business in Titusville, New Jersey.

43. J&J is the only company that owns more than 10% of Janssen Pharmaceuticals stock. Upon information and belief, J&J controls the sale and development of Janssen Pharmaceuticals drugs, and Janssen Pharmaceuticals' profits inure to J&J's benefit.

44. J&J, Janssen Pharmaceuticals, OMP, and Janssen Pharmaceutica (collectively, "Janssen") are or have been engaged in the manufacture, promotion, distribution, and sale of opioids nationally and in the City of New Haven, including the following:

Table 3 – Janssen Opioids

Drug Name	Chemical Name	Form
Duragesic	Fentanyl	Transdermal Patch
Nucynta (prior to 2015)	Tapentadol ER	Tablet
Nucynta ER (prior to 2015)	Tapentadol	Tablet

45. Together, Nucynta and Nucynta ER accounted for $172 million in sales in 2014. Prior to 2009, Duragesic accounted for at least $1 billion in annual sales.

Defendant Endo Pharmaceuticals ("Endo")

46. Defendant Endo Health Solutions Inc. ("EHS") is a Delaware corporation with its principal place of business in Malvern, Pennsylvania.

47. Defendant Endo Pharmaceuticals, Inc. ("EPI") is a wholly owned subsidiary of EHS and is a Delaware corporation with its principal place of business in Malvern, Pennsylvania.

48. EHS and EPI (collectively, "Endo") manufacture, promote, distribute, and sell opioids nationally and in the City of New Haven, including the following:

Table 4 – Endo Opioids

Drug Name	Chemical Name	Form
Opana ER	Oxymorphone hydrochloride extended	Tablet
Opana	Oxymorphone hydrochloride and aspirin	Tablet
Percodan	Ocycodone hydrochloride and acetaminophen	Tablet release
Percocet	Oxycodone and acetaminophen	Tablet

49. Opioids comprise approximately $403 million of Endo's overall revenues of $3 billion in 2012. Opana ER yielded revenue of $1.15 billion from 2010 to 2013, and it accounted for 10% of Endo's total revenue in 2012. Endo also manufactures and sells generic opioids, both directly and through its subsidiary, Qualities Pharmaceuticals, Inc., including generic oxycodone, oxymorphone, hydromorphone, and hydrocodone products.

50. A reformulated Opana ER that had been approved in 2012 was removed from the market in June 2017, at the request of the FDA, which found that "the benefits of the drug may no longer outweigh its risks." The FDA stated, "the FDA determined that the data did not show that the reformulation could be expected to meaningfully reduce abuse and declined the company's request to include labeling describing potentially abuse-deterrent properties for Opana ER."[8]

[8] News release, FDA, FDA requests removal of Opana ER for risks related to abuse (June 8, 2017), https://www.fda.gov/newsevents/newsroom/pressannouncements/ucm562401.htm.

Defendant Insys Therapeutics ("Insys")

51. Defendant Insys Therapeutics, Inc. ("Insys") is a Delaware corporation with its principal place of business in Chandler, Arizona.

52. Since 2012, Insys has been manufacturing and selling the following opioid:

Table 6 – Insys Opioids

Drug Name	Chemical Name	Form
Subsys	Fetanyl	Sublingual Spray Absorbed through mucous in the mouth

53. Subsys is a highly addictive synthetic opioid mouth-spray approved for treatment of cancer pain in patients who are tolerant of other opioids. Subsys is a form of fentanyl - a narcotic up to 50 times more powerful than heroin and 100 times more powerful than morphine.

54. According to Insys's 2016 annual report, Subsys was the most prescribed transmucosal immediate-release fentanyl, with 42% market share, which translates to nearly $300 million in annual U.S. product sales for Insys – an increase of 270% in sales over just a year. See Insys Annual Report filed on Form 10-K on April 3, 2017 at 1.

55. The broad sales of Subsys raised suspicion over Insys's sales practices, especially because it appeared that only 1% of Subsys sales were generated by oncologists. Subsequent investigations revealed rampant off-label marketing and sales practices resulting in widespread prescriptions of the drug for unapproved uses.

56. The United States Federal Bureau of Investigations ("FBI"), as well as Colorado, Florida, Illinois, Massachusetts, Maryland, Minnesota, New Hampshire, New Jersey, New York, Oregon, Pennsylvania and Washington have issued subpoenas to Insys in regards to its marketing campaign for Subsys. These investigations ended in many criminal indictments of sales persons, executives, and outside physician groups that took bribes.

57. In 2013, The Department of Health and Human Services Office of Inspector General (DHHS-OIG) began investigating Insys for possible illegal off-label marketing of Subsys.

58. In 2015, the Oregon Department of Justice cited Insys for misrepresenting, among other things, that Subsys should be used to treat migraine, neck pain, back pain, and other off-label uses. Insys paid $1.1 million to settle the matter.

59. In 2017, Insys agreed to pay New Hampshire $2.9 million to settle allegations of aggressive and deceptive marketing.

60. In 2015, Insys paid $4.5 million to Illinois over allegations of deceptive marketing for off-label uses.

61. In May 2017, former Insys manager Elizabeth Gurrieri pled guilty to wire fraud conspiracy in connection with Subsys sales. In July 2017, two former Insys sales representatives pled guilty to federal kickback charges. One of them, Natalie Levine, is the wife of indicted former CEO of Insys Michael Babich.

62. In addition, at least three civil suits have been brought against Insys for unethical marketing by estates of persons who overdosed as a result of being prescribed Subsys.

63. The Senate Homeland Security and Government Affairs Committee, led by Senator Claire McCaskill (D-MO) ("McCaskill Investigation"), is investigating the involvement of opioid manufacturers in the current crisis. The conclusion to McCaskill's initial report, Fueling an Epidemic, states that Insys "has repeatedly employed aggressive and likely illegal

techniques to boost prescriptions of its fentanyl product Subsys. . . . [that] included actions to undermine critical safeguards in the prior authorization process[.]"[9]

64. For ease of reference, the following is a table of all Manufacturer Defendants and their opioid products:

Table 7

Purdue Opioids

Drug Name	Chemical Name
OxyContin	Oxycodone hydrochloride extended release
MS Contin	Morphine sulfate extended release
Dilaudid	Hydromorphone hydrochloride
Dilaudid-HP	Hydromorphone hydrochloride
Butrans	Byprenorpine
Hysingla ER	Hydrocodone bitrate
Targiniq ER	Oxycodone Hydrochloride and naloxone

Cephalon Opioids

Drug Name	Chemical Name	Form
Actiq	Fentanyl citrate	Lollipop or lozenge
Fentora	Fentanyl citrate	Buccal tablet, like a smokeless tobacco plug

Janssen Opioids

Drug Name	Chemical Name	Form
Duragesic	Fentanyl	Transdermal Patch
Nucynta (prior to 2015)	Tapentadol ER	Tablet
Nucynta ER (prior to 2015)	Tapentadol	Tablet

Endo Opioids

Drug Name	Chemical Name	Form
Opana ER	Oxymorphone hydrochloride extended	Tablet
Opana	Oxymorphone hydrochloride and aspirin	Tablet
Percodan	Ocycodone hydrochloride	Tablet release

[9] Minority Report, U.S. HSGAC (Sept. 6, 2017), Fueling an Epidemic: Insys Therapeutics and the Systemic Manipulation of Prior Authorization, available at https://www.hsdl.org/?view&did=803959.

	and acetaminophen	
Percocet	Oxymorphone hydrochloride and acetaminophen	Tablet

Insys Opioids

Drug Name	Chemical Name	Form
Subsys	Fetanayl	Sublingual Spray Absorbed through mucous in the mouth

Defendant McKesson Corporation ("McKesson")

65. Defendant McKesson Corporation is registered with the Connecticut Secretary of State as a company incorporated under the laws of Delaware with its principal place of business located in San Francisco, California. McKesson is the largest pharmaceutical distributor in North America; it delivers approximately one-third of all pharmaceuticals used in North America. McKesson conducts business in the State of Connecticut by distributing prescription opioids to hospitals, retail pharmacies, practitioners, mid-level practitioners, and teaching institutions ("Retail End Users"). McKesson is subject to federal reporting obligations with respect to the distribution of controlled substances to the State of Connecticut.

Defendant AmerisourceBergen Corporation ("ABC")

66. Defendant AmerisourceBergen Corporation is registered with the Connecticut Secretary of State as a company incorporated under the laws of Delaware with its principal place of business located in Chesterbrook, Pennsylvania. ABC is the second largest pharmaceutical distributor in North America. ABC conducts business in the State of Connecticut by distributing prescription opioids to Retail End Users. ABC is subject to federal reporting obligations with respect to the distribution of controlled substances to the State of Connecticut.

Defendant Cardinal Health, Inc. ("Cardinal")

67. Defendant Cardinal Health, Inc. is registered with the Connecticut Secretary of State as a company incorporated under the laws of Ohio with its principal place of business

located in Dublin, Ohio. Cardinal is the third largest distributor of pharmaceuticals in North America. Cardinal conducts business in the State of Connecticut by distributing prescription opioids to Retail End Users. Cardinal is subject to federal reporting obligations with respect to the distribution of controlled substances to the State of Connecticut.

IV. FACTUAL ALLEGATIONS

A. The Scientific Basis for Pain-Relieving and Addictive Properties of Opioids

1. Similarity between prescription opioids and heroin

68. The medicinal effects of an extract from the flowering poppy plant, to relieve pain and often cause euphoria, has been known for thousands of years.

69. In the early 1800s a German pharmacist, Freidrich Sertürner, isolated the substance from the poppy plant and named it "morphine" for its ability to cause hypnotic as well as analgesic properties.

70. The late 1800s and early 1900s saw a plethora of semi-synthetic morphines that were easily derived by manipulating the basic morphine structure.

71. One of the first semi-synthetic opiates, heroin, began being manufactured in 1914. In 1914 the Harrison Narcotics Tax Act imposed a tax on those making, importing or selling any derivative of opium. By the 1920s, physicians were aware of the highly addictive nature of opioids and tried to avoid treating patients with them. Heroin became illegal in 1924.

72. Other semi-synthetic opioids such as oxycodone, hydrocodone, oxymorphone and hydromorphone continued to be designed in labs and approved for restricted medical uses. All the opioids sold by Manufacturer Defendants Purdue and Endo fall within these categories. (See Table 7, ¶64, supra).

73. In 1960 a totally synthetic opiate acting drug, named fentanyl, was synthesized by Dr. Paul Janssen in Belgium.

74. Fetanyl has been produced in various forms, including lollipops (Actiq) and a spray absorbed through the mouth (Subsys). All the products of Cephalon, Janssen and Insys (listed on Table 7, ¶64, supra) are fentanyl or fentanyl-based synthetic opioids.

75. All these opioids, semi-synthetic opioids and the fully synthetic opioids work on a patient in very similar ways. They react with specific opioids in the brain of the patient and are considered "agonists." "Agonists interact with a receptor to produce a maximal response from that receptor."10

76. The reaction with the opioid receptor sets off sharp increases in the release of dopamine in the brain. New England Journal of Medicine, Neurobiologic Advances from the Brain Disease Model of Addiction, NEJM 374:4 January 28, 2016.

77. The surge of dopamine gives the subject the pain relief and euphoric feeling that has been described for millennia as a property of the poppy plant.

78. However, a known result of the physiological process for all the opioids (just as it has been for millennia with the morphine from the poppy plant) is that, with repeated exposure to the same reward, dopamine cells stop firing as strongly. This factor helps explain why people on morphine or other opioids experience cravings for the drug.

79. The charts below show the chemical compositions of all the drugs described above: morphine, heroin, semi-synthetic opioids (oxycodone, hydrocodone, oxymorphone and hydromorphone), and fentanyl.

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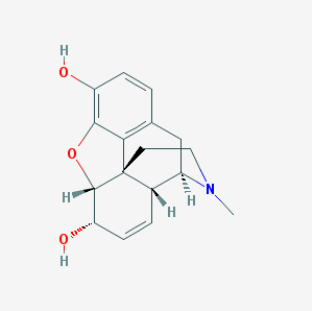
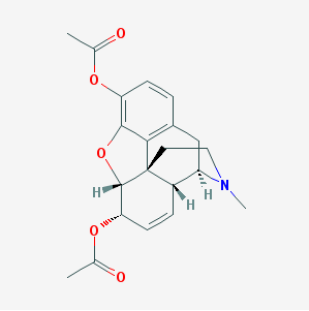
10 Hasan Path and John Williams, *Basic opioid pharmacology: an update*, 6(1) BR J PAIN 11-16 (2012), https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4590096/.

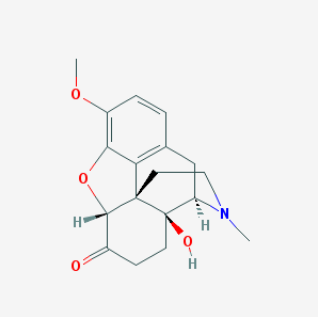
Morphine[11]



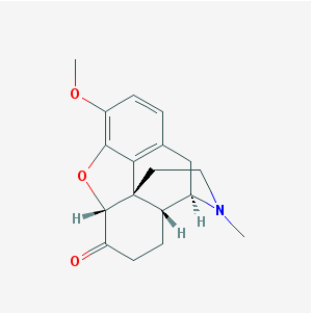
Heroin[12]



Oxycodone[13]
(sold as Percocet, OxyContin)



Hydrocodone[14]
(sold as Vicodin)



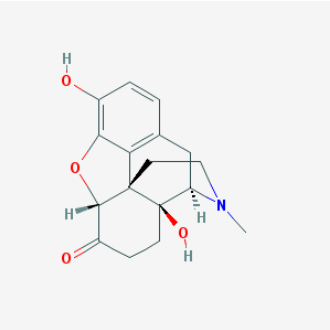
[11] National Center for Biotechnology Information. PubChem Compound Database; CID=5288826, https://pubchem.ncbi.nlm.nih.gov/compound/5288826 (accessed Oct. 3, 2017).

[12] National Center for Biotechnology Information. PubChem Compound Database; CID=5462328, https://pubchem.ncbi.nlm.nih.gov/compound/5462328 (accessed Oct. 3, 2017).

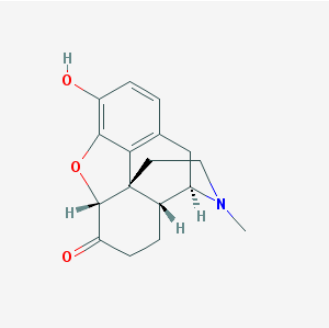
[13] National Center for Biotechnology Information. PubChem Compound Database; CID=5284603, https://pubchem.ncbi.nlm.nih.gov/compound/5284603 (accessed Oct. 3, 2017).

[14] National Center for Biotechnology Information. PubChem Compound Database; CID=5284569, https://pubchem.ncbi.nlm.nih.gov/compound/5284569 (accessed Oct. 3, 2017).

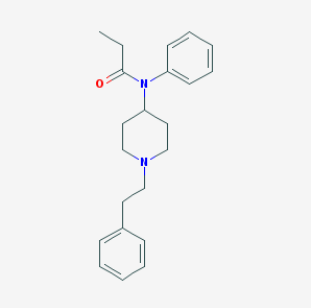
Oxymorphone[15]
(sold as Opana, Percocet)



Hydromorphone[16]
(sold as Dilaudid)



Fentanyl[17]
(sold as Subsys)



80. It is simple to see from these charts how chemically similar to one another the natural morphine, heroin and the semi-synthetic opioids are to one another. They all share the same five-ring structure that allows for them to react with opioid receptors in the brain. While Fetanyl and other synthetic opioids do not share the same five-ring structure, they nevertheless interact with opioid receptors in the brain the same way.

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[15] National Center for Biotechnology Information. PubChem Compound Database; CID=5284604, https://pubchem.ncbi.nlm.nih.gov/compound/5284604 (accessed Oct. 3, 2017).

[16] National Center for Biotechnology Information. PubChem Compound Database; CID=5284570, https://pubchem.ncbi.nlm.nih.gov/compound/5284570 (accessed Oct. 3, 2017).

[17] National Center for Biotechnology Information. PubChem Compound Database; CID=3345, https://pubchem.ncbi.nlm.nih.gov/compound/3345 (accessed Oct. 3, 2017).

81. All the prescription opioids have the same pain-relieving, euphoria-inducing, intensely addictive qualities of morphine and heroin.

2. Why a person with a prescription opioid addiction frequently turns to street drugs.

82. As recent addiction science shows, once an individual is addicted to any of these products, there is a series of biochemical reactions and physiological changes in the brain that make it very difficult to break the addiction, even if the patient desperately wants to. These known brain changes in addicted persons also explain why addiction is a relapsing disease.

83. As the New England Journal of Medicine explains:

> This attenuated release of dopamine renders the brain's reward system much less sensitive to stimulation by both drug-related and non-drug-related rewards. As a result, persons with addiction no longer experience the same degree of euphoria from a drug as they did when they first started using it. It is for this same reason that persons with addiction often become less motivated by everyday stimuli (e.g., relationships and activities) that they had previously found to be motivating and rewarding. Again, it is important to note that these changes become deeply ingrained and cannot be immediately reversed through the simple termination of drug use (e.g., detoxification).

Nora D. Volkow et al., Neurobiologic Advances from the Brain Disease Model of Addiction, 374(4) N. ENGL. J. MED. 363-371 (2016).

84. As addiction deepens, the changes in the brain of the addict become more profound. The deadened mood affect and pre-occupation with getting the next hit of dopamine to the exclusion of previously pleasurable activities gets aggravated by a lessened ability to control impulses.

> The changes that occur in the reward and emotional circuits of the brain are accompanied by changes in the function of the prefrontal cortical regions, which are involved in executive processes. Specifically the down-regulation of dopamine signaling that dulls the reward circuits' sensitivity to pleasure also occurs in prefrontal brain regions and their associated circuits, seriously impairing executive processes, among which are the capacities for self-regulation, decision making, flexibility in the selection and initiation of action, attribution of salience (the assignment of relative value), and the monitoring of error.

Id.

85. Recent research on the brains of addicted individuals makes clear why that person would substitute heroin for prescription opioids, and further why the changes in the individual's brain caused by the addiction to prescription opioids makes it almost impossible to resist the need for continued use, even to the point of death.

86. In short, the progression of addiction is the initial pain relief and feeling of well-being or euphoria experienced by the patient. Next is the craving for more and more of the substance since the dopamine rewards system has been hijacked and the patient is incapable of experiencing everyday joys. Even greater and more frequent amounts of the opioid do not work since the patient's dopamine reward system is broken. As addiction proceeds, the patient becomes increasingly incapable to think through the situation, since his prefrontal cortical regions have become affected. Therefore, a person who has become addicted to opioid prescriptions may have substantial brain chemistry impelling him to use street drugs as a substitute.

C. Campaign of Misinformation and Unlawful Conduct by Manufacturer Defendants

1. Summary of Manufacturer Defendants' Disinformation Campaign

87. Manufacturer Defendants, through a sophisticated and highly deceptive and unfair marketing campaign that began in the late 1990s, deepened from around 2006, and continues to the present, set out to and succeeded in reversing the popular and medical understanding of opioids. Chronic opioid therapy – the prescribing of opioids to treat chronic pain long-term – is now a commonplace and highly dangerous practice in the United States.

88. Before Defendants began their marketing campaign, prevailing medical knowledge dictated that opioids should only be used short-term, where the risks of addiction are

low or of little significance. Literature from the 1980s and earlier made the reasons to avoid opioids for long-term therapy clear: opioids' mixed record in reducing pain long-term and failure to improve patients' function; greater pain complaints as most patients developed tolerance to opioids; opioid patients' diminished ability to perform basic tasks; their inability to make use of complementary treatments like physical therapy due to the side effects of opioids; and the most dangerous side-effect, addiction. Leading authorities discouraged or prohibited the use of opioid therapy for chronic pain.

89. To accomplish this reversal, Manufacturer Defendants spent hundreds of millions of dollars: (a) developing and disseminating seemingly truthful scientific and educational materials and advertising that misrepresented the risks, benefits, and superiority of opioids for treating chronic pain; (b) funding, assisting, encouraging, and directing a small group of doctors, known as "key opinion leaders" ("KOLs"), to deliver scripted talks, publish misleading studies, present continuing medical education programs ("CMEs") that disseminated false and incomplete information to medical practitioners, and infiltrating the boards and committees of professional societies and patient advocacy groups that delivered messages and developed guidelines supporting chronic opioid therapy; (c) funding, assisting, directing, and encouraging seemingly neutral and credible professional societies and patient advocacy groups (referred to as "Front Groups") that developed misleading educational materials and treatment guidelines that were then distributed by Defendants, urging doctors to prescribe, and patients to use, opioids long-term to treat chronic pain; (d) deploying sales representatives who visited doctors and other prescribers who marketed their opioids for "non-indicated" or off-label purposes, not approved by the FDA, thereby violating 21 U.S.C. §§331(a)-(b), 352(a); and (e) targeting public ads to vulnerable populations such as the elderly and veterans.

90. Manufacturer Defendants: (a) overstated the benefits of chronic opioid therapy, promised improvement in patients' function and quality of life, and failed to disclose the lack of evidence supporting long-term use; (b) trivialized or obscured opioids' serious risks and adverse outcomes, including the risk of addiction, overdose, and death; (c) overstated their superiority compared with other treatments, such as other non-opioid analgesics, physical therapy, and other alternatives; and (d) mischaracterized the difficulty of withdrawal from opioids and the prevalence of withdrawal symptoms. There is, and has never been, reliable scientific evidence to support Manufacturer Defendants' marketing claims. There is now and always has been substantial scientific evidence that these claims are false.

2. False Messaging

a. Falsehood: Opioids Not Addictive for Long-Term Use

91. Manufacturer Defendants long maintained that prescription opioids carry little to no risk of addiction, when they knew that not to be true. For example, Purdue claimed that the risk of addiction was negligible even though its own studies had shown that between 8% and 13% of OxyContin patients became addicted.

92. Manufacturer Defendants have said that specific characteristics of their drugs made them less addictive, when there was no evidence to support their assertions. For example, Endo marketed Opana ER as being crush-resistant, and as a result, hard to abuse, and harder to become addicted to. In fact, Endo knew that there was no evidence to support this assertion.

93. Cephalon-sponsored Treatment Options: A Guide for People Living with Pain (American Pain Foundation, 2007) stated that addiction is limited to extreme cases of unauthorized dose escalations, getting opioids from multiple sources, or theft. In truth, Cephalon knew there was no basis for this depiction that addiction occurred only in rare cases.

94. Manufacturer Defendants have maintained that addiction risk can be managed by the prescribing physician by asking patients to fill out a questionnaire to assess their risk of addiction (known as "screening"). However, there is not and never has been evidence to suggest that such screening is reliable.

95. Contrary to Defendants' assertions, opioids have been found time and again to be addictive. Dr. Andrew Kolodny, Chief Medical Officer for Phoenix House, a national addiction treatment program, has likened the effect of opioids to "hijack[ing] the brain's reward system," in turn convincing a user that "the drug is needed to stay alive."18 A patient's fear of the unpleasant effects of discontinuing opioids, combined with the negative reinforcement during a period of actual withdrawal, can push a patient to seek further opioid treatment – even where ineffective or detrimental to quality of life – simply to avoid the deeply unpleasant effects of withdrawal.

b. Falsehood: No Upper Limit on Amount of Opioids to Consumer

96. Manufacturer Defendants have misrepresented and even denied entirely the dangers posed by large doses of opioids. Manufacturer Defendants claimed that dosages could be escalated continuously to match high pain tolerance, even though studies show that such escalation could be deadly. This false advice has been disseminated even though the Manufacturer Defendants, their executives, researchers, and sales staff have knowledge that increasing a dosage or starting a patient with a high dosage may be fatal. See ¶¶235-36, infra.

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18 David Montero, *Actor's death sows doubt among O.C.'s recovering opioid addicts*, ORANGE CNTY. REG. (Feb. 4, 2014), http://www.ocregister.com/articles/heroin-600148-shaffer-hoffman.html.

97. This falsehood is particularly of concern because none of the Manufacturer Defendants' opioids have a cap on dosage. Thus, the guidance of manufacturers (and the medical community, informed by manufacturers) has a critical role to play in preventing overdose.

98. There is not now and never has been any scientifically based support for the Manufacturer Defendants' statements that there are no upper limits for opioids.

99. High doses pose real risk. The 2016 Guidelines issued by the Centers for Disease Control and Prevention ("CDC"), Guideline for Prescribing Opioids for Chronic Pain, is a peer-reviewed guideline that is based on scientific evidence. It states in pertinent part: "[b]enefits of high-dose opioids for chronic pain are not established," while the "risks for serious harms related to opioid therapy increase at higher opioid dosage." It further states there are "increased risks for opioid use disorder, respiratory depression, and death at higher dosages[.]" As a result the CDC advised doctors to "avoid increasing dosage" above 90 morphine milligram equivalents per day.

100. When under the continuous influence of opioids over time, patients grow tolerant to their analgesic effects. As tolerance increases, a patient typically requires progressively higher doses to obtain the same levels of pain reduction to which he or she has become accustomed – up to and including doses that are "frighteningly high."[19] At higher doses, the effects of withdrawal are more substantial, thus leaving a patient at a much higher risk of addiction. A patient can take the opioids at the continuously escalating dosages to match pain tolerance and still overdose at recommended levels.

c. Falsehood: Opioids Are the Best Solution

101. Manufacturer Defendants have consistently exaggerated the benefits and downplayed the side effects of opioids as compared to other analgesics. Specifically,

[19] M. Katz, Long-term Opioid Treatment of Nonmalignant Pain: A Believer Loses His Faith, 170(16) ARCHIVES OF INTERNAL MED. 1422 (2010).

Manufacturer Defendants have ignored the effects of long-term opioid therapy, which include addiction, hyperalgesia, hormonal dysfunction, decline in immune function, increased bone fractures in the elderly, neonatal abstinence syndrome, and potentially fatal interaction with other medication taken to treat disorders frequently coexisting with chronic pain. At the same time, Manufacturer Defendants have greatly exaggerated the incidence of side-effects and the risk of death from medicines such as aspirin or ibuprofen, technically known as non-steroidal anti-inflammatory drugs ("NSAIDs"). Defendants have suggested 10,000-20,000 annual deaths are attributable to NSAIDs when the real number is approximately 3,200 and shrinking.[20]

102. On the contrary, there is evidence that opioid drugs are less effective at treating chronic pain, and may worsen patients' health. A 2006 study-of-studies found that opioids as a class did not demonstrate improvement in functional outcomes over other non-addicting treatments. Notably, it stated: "[f]or functional outcomes, the other analgesics were significantly more effective than were opioids." Andrea D. Furlan, et al., Opioids for chronic noncancer pain: a meta-analysis of effectiveness and side effects, 174(11) Can. Med. Ass'n J. 1589 (2006). The above study and similar ones that were antithetical to the position of the Manufacturer Defendants were not presented by the KOLs in their speeches to practitioners, in the lectures presented at CMEs controlled by the Manufacturer Defendants, or in the Front Groups used to disseminate the Manufacturer Defendants' false message that opioids are a superior pain treatment.

103. The Manufacturer Defendants knew their disparagement of NSAIDs and other analgesics was untrue. Endo's own research shows that patients taking opioids, as opposed to

[20] *See* Ask the Expert: Do NSAIDs Cause More Deaths than Opioids?, Practical Pain Management (Nov./Dec. 2013), https://www.practicalpainmanagement.com/treatments/pharmacological/opioids/ask-expert-do-nsaids-cause-more-deaths-opioids.

other prescription pain medicines, report higher rates of obesity (30% to 39%); insomnia (9% to 22%); and self-described fair or poor health (24% to 34%).

d. Falsehood: The Promise of a Pain-Free Life and Vigorous Existence

104. Manufacturer Defendants misrepresented that opioids improve functioning over time. For example, Janssen sponsored a patient education guide in 2009, Finding Relief: Pain Management for Older Adults, which states as a fact that "opioids may make it easier for people to live normally."

105. There is not, and has never been, any data to support the claim that they do so; in fact, there is data to suggest that long-term opioid usage reduces functioning. Data from workers' compensation claims indicates that there is a negative correlation between opioid prescriptions and a person returning to work. See, e.g., Cindy L. Kidner, et al., Higher Opioid Doses Predict Poorer Functional Outcome in Patients with Chronic Disabling Occupational Musculoskeletal Disorders, 91(4) J. Bone Joint Surg. Am. 919-27 (Apr. 1, 2009).

106. The 2016 CDC Guidelines (¶99, *supra*) state that "[a]lthough 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." The CDC further found that "evidence 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."

e. Falsehood: Tapering Is an Effective Way to Manage Any Withdrawal

107. Manufacturer Defendants also falsely represent that withdrawal is easily managed, for example by tapering off a patient's dosage. For example, Endo's CME Persistent

Pain in the Older Adult taught that withdrawal can be avoided by tapering off dosage by 10-20% daily for ten days.

108. Janssen's training materials asserted that Nucynta ER has a low incidence of withdrawal symptoms, based on a study of withdrawal symptoms two to four days after discontinuing use (when in fact the symptoms peak earlier than that).

109. On its current website, PrescribeResponsibly.com, Janssen states that opioid addiction "can usually be managed" with such tools such as Opioid Agreements between the prescribing physician and patient.

110. There is no reliable data, nor has there ever been, supporting the statements made by each Manufacturer Defendant that gradual tapering would alleviate the risk of withdrawal.

f. Falsehood: Pseudo-Addiction

111. Pharmaceutical manufacturers tried to dismiss signs of addiction in patients by using the term "pseudoaddiction," invented by Dr. David Haddox, later Vice President of Health Policy at Purdue. Pseudoaddiction was a term used for patients showing signs of addiction; defendants explained that what these patients were actually exhibiting was "under-treated pain."

112. With no reliable data, the Manufacturer Defendants (other than Insys) grabbed hold of the concept of pseudoaddiction with the intent and result that treating physicians would ignore signs of actual addiction in their patients (such as seeking early refills, agitation), etc. Instead of advising the treating physician that the patient is likely in the throes of addiction, the Manufacturer Defendants advocated that the patient is still undertreated and should be prescribed a higher potency of the opioid.

113. Janssen sponsored, funded and edited a website publication entitled, Let's Talk Pain, which 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."

114. While the term "pseudoaddiction" is no longer prevalent and is not currently posted on any of the Manufacturer Defendants' websites, it was in common use and widely disseminated to physicians through at least 2012. Upon information and belief, as a result of the Defendants' false information campaign, the signs of addiction in opioid-treated patients are still being misconstrued as pseudoaddiction in the community of practicing physicians, including those physicians in Connecticut who serve the population of the City of New Haven.

115. There never was any scientifically valid evidence for the concept of pseudoaddiction. The Manufacturer Defendants knew there was no scientific basis for the concept. The statements about it by the Manufacturer Defendants were false when made.

3. Means of Disinformation

116. Manufacturer Defendants strengthened the effects of their misinformation by disseminating it through varied sources in a number of settings, targeting both doctors and patients.

117. Manufacturer Defendants have poured significant resources into branded advertisements for their own particular opioids. In 2011, Manufacturer Defendants spent over $14 million advertising in medical journals, including $8.3 million by Purdue, $4.9 million by Janssen, and $1.1 million by Endo.

118. Since Insys entered the opioid pain market in 2012 after many of those means to disseminate false information were already under way, it is not known at this time to what extent Insys participated in these means of dissemination. Upon information and belief, Insys was able to effectively sell Subsys off-label due to the wide dissemination of misinformation propagated by the other Manufacturer Defendants.

119. These advertisements have been run in publications aimed at pain specialists (e.g., Journal of Pain, Clinical Journal of Pain) as well as those aimed at the entire medical community (e.g., Journal of the American Medical Association).

120. These advertisements have contained misleading claims about their opioid products. For example, a 2005 Purdue advertisement in the Journal of Pain described OxyContin as an "around-the-clock analgesic . . . for an extended period of time." The advertisement featured a man and boy fishing and proclaimed that "*There Can Be Life With Relief*," falsely suggesting (on both counts) that OxyContin provides effective long-term pain relief and functional improvement. Endo's Opana ER was advertised with photos of people engaged in demanding jobs, suggesting that the drug could provide long-term relief and functional improvement.

a. Unsupported research

121. Manufacturer Defendants have misrepresented scientific research and evidence surrounding the addictiveness of their pharmaceutical products.

122. Defendants led people to reasonably believe that they had tested the safety and efficacy of opioids for long-term use, by creating a body of false, misleading, and unsupported literature about opioids that appeared to be the result of independent, objective research, and was thus more likely to shape the perceptions of prescribers, patients and payors.

123. Defendants coordinated the timing and publication of manuscripts, abstracts, posters and oral presentations, and educational materials in peer-reviewed journals and other publications to support the launch and sales of their drugs. Defendants' internal documents show plans to submit research papers and "studies" to long lists of journals, including back-up options and last resort, "fast-track" application journals, that they could use if the pending paper was rejected everywhere else.

124. Defendants worked to ensure that favorable articles were disseminated and cited widely in medical literature, even where references distorted the significance or meaning of the underlying study. One of the most frequently used distortions is the instance of a five-sentence letter written to the New England Journal of Medicine (NEJM) in 1980 by Dr. Jick and his assistant Ms. Porter.

125. In 1980 Dr. Hershel Jick, and his assistant Jane Porter, who both worked at the Boston University Medical Center, sent the following letter to the prestigious NEJM:

> ADDICTION RARE IN PATIENTS TREATED WITH NARCOTICS
>
> To the Editor: Recently, we examined our current files to determine the incidence of narcotic addiction in 39,946 hospitalized medical patients who were monitored consecutively. Although there were 11,882 patients who received at least one narcotic preparation, there were only four cases of reasonably well documented addiction in patients who had no history of addiction. The addiction was considered major in only one instance. The drugs implicated were meperidine in two patients, Percodan in one, and hydromorphone in one. We conclude that despite widespread use of narcotic drugs in hospitals, the development of addiction is rare in medical patients with no history of addiction.
>
> Jane Porter
> Hershel Jick, M.D.
> Boston Collaborative Drug
> Surveillance Program
> Waltham, MA 02154 Boston University Medical Center.

J. Porter and H. Jick, Addiction Rare in Patients Treated with Narcotics, 302(2) NEW ENG. J. MED. 123 (1980).

126. Manufacturer Defendants and their Front Groups have twisted this letter and misused it as scientific confirmation for their assertion that widespread and long-term opioid use does not pose a substantial threat of addiction. The Manufacturer Defendants knew, but failed to disclose, the material information that undermined the validity of the five-sentence letter for the sweeping proposition for which it was cited.

127. Manufacturer Defendants knowingly misrepresented the findings and scientific value of the letter in several ways:

(a) By omitting the fact that the Porter/Jick observations were made in a letter to the editor, and implying – or outright stating – that the results were the published results of a peer-reviewed scientific clinical trial study, they misrepresented the scientific validity of its findings.

(b) Based on when the letter is written, in 1980, the use of opioids being described in the letter could only have been for acute pain or for end-of-life care because medical practice at the time prohibited opioids from being used to treat chronic pain. Nevertheless Manufacturer Defendants cited the Porter/Jick Letter as evidence for the proposition that opioids pose a low risk of addiction in all contexts, including long-term use for chronic pain.

(c) Since the Porter/Jick Letter is not based on a clinical trial, there is no level of confidence that patients were regularly being monitored for signs of addiction. Thus, there may have been false negatives.

(d) The letter is written about patients who were being ***monitored in a hospital***, rather than those who were given prescriptions to take home. Nonetheless, it was trumpeted by Defendants as scientific evidence that opioids pose a low risk of addiction in all contexts.

(e) There is no evidence that these patients were followed up with after leaving the hospital regarding the presence of any addiction. But it was cited by Defendants as showing that opioids pose no long-term risk of addiction.

128. Manufacturer Defendants mis-cited the Porter/Jick Letter again and again as evidence of the minimal risk of addiction from using opioids as a treatment for chronic pain despite its limited credibility, and despite the existence of much more significant evidence to the contrary.

129. Two papers funded by Purdue in 1998 showed that between 8% and 13% of patients studied subsequently became addicted to opioids. Ignoring this study, the Porter/Jick Letter was cited and relied upon in two CME courses put on by Purdue and Endo in 2012 to support the assertion that opioids are not addictive.

130. The Porter/Jick Letter was not extensively cited as evidence of opioids' low risk of addiction until it first appeared in a 1986 paper by the American Pain Society, one of Defendants' Front Groups. From there its use as a tool of misinformation mushroomed. It has been cited over 600 times, in contrast to the other 11 letters to the editor published in the NEJM contemporaneously, which were cited a median of 11 times.

131. Dr. Hershel Jick, the primary author, later stated that his own letter had been misused and distorted. He has said that he is "mortified that that letter to the editor was used as an excuse to do what these drug companies did," referring to the fact that "they used this letter to spread the word that these drugs were not very addictive."21

132. A 2017 statement in the NEJM (probably the first of its kind) was published as a meta-study on the misuse of the letter. It says that the letter "was heavily and uncritically cited as

[21] Derek Hawkins, WASHINGTON POST, How a short letter in a prestigious journal contributed to the opioid crisis (June 2, 2017), https://www.washingtonpost.com/news/morning-mix/wp/2017/06/02/how-the-opioid-crisis-traces-back-to-a-five-sentence-scholarly-letter-from-1980/?utm_term=.836d02c52301.

evidence that addiction was rare with long-term opioid therapy," which statement "contributed to the North American opioid crisis[.]"22

133. The 2017 study reports that 80.8% of articles citing the 1980 letter did not mention that it was limited to the hospital setting, and 72.2% of articles citing it used it to support the conclusion that addiction is rare in patients treated with opioids.

134. Manufacturer Defendants also worked to discredit or bury negative information. Defendants – often with the help of third-party consultants – targeted a broad range of media to disseminate their message, including negative review articles, letters to the editor, commentaries, case-study reports, and newsletters disparaging reports of the link between opioids and addiction.

135. Manufacturer Defendants' strategies were intended to, and did, knowingly and intentionally distort the truth regarding the risks, benefits and superiority of opioids for chronic pain relief, resulting in distorted prescribing patterns.

b. Key Opinion Leaders

136. Manufacturer Defendants used Key Opinion Leaders ("KOLs") (who are generally distinguished physicians and neutral sources of guidance in their medical field), as sources of pro-opioid misinformation for regular practicing doctors, including those in the State of Connecticut who treat residents of the City of New Haven.

137. The KOLs have been central to the Manufacturer Defendants' diffuse marketing efforts. KOLs have written, consulted on, edited, and lent their names to books and articles, and given speeches and CMEs supportive of chronic opioid therapy. They have served on committees that developed treatment guidelines strongly encouraging the use of opioids to treat chronic pain and on the boards of pro-opioid advocacy groups and professional societies that

22 NEW ENG J MED, A 1980 Letter on the Risk of Opioid Addiction (June 1, 2017), http://www.nejm.org/doi/full/10.1056/NEJMc1700150#t=article.

develop, select, and present CMEs. Defendants were able to exert control of each of these modalities through their KOLs.

138. In exchange for these services of the KOLs, Manufacturer Defendants provided KOLs with money, prestige, recognition, research funding, and avenues to publish. This positioned the KOLs to exert even more influence in the medical community.

139. Opioid-makers were not the first to mask their deceptive marketing efforts in purported science. The tobacco industry also used KOLs in its effort to persuade the public and regulators that tobacco was not addictive or dangerous. For example, tobacco companies funded a research program at Harvard and chose as its chief researcher a doctor who had expressed views in line with industry's views. He was dropped when he criticized low-tar cigarettes as potentially more dangerous, and later described himself as a pawn in the industry's campaign.

140. Defendants cultivated and promoted only those KOLs who could be relied upon to help broaden the chronic pain opioid therapy market. Defendants selected, funded, and elevated those doctors whose public positions were unequivocally supportive of using opioids to treat chronic pain. These doctors' professional reputations were then dependent on continuing to promote a pro-opioid message, even in activities not directly funded by the drug companies.

141. Defendants cited and promoted favorable studies or articles by these KOLs. By contrast, Defendants did not disseminate the publications of doctors critical of the use of chronic opioid therapy. One prominent KOL sponsored by many of the Defendants, Dr. Russell Portenoy, stated that he was told by a drug company that research critical of opioids (and the doctors who published that research) would never obtain funding.

142. Some KOLs have even gone on to become direct employees and executives of Defendants, like Dr. Haddox, Purdue's Vice President of Health Policy, or Dr. Bradley Galer, Endo's former Chief Medical Officer.

143. Defendants provided substantial opportunities for KOLs to author articles or research studies on topics Defendants suggested or chose, with the predictable effect of ensuring that many favorable studies appeared in the academic literature. As described by Dr. Portenoy, drug companies would approach him with a study that was well under way and ask if he would serve as the study's author. Dr. Portenoy regularly agreed.

144. Defendants also paid KOLs to serve as consultants or on their advisory boards and give talks or present CMEs, often over meals or at conferences. Since 2000, Cephalon, for instance, has paid doctors more than $4.5 million for programs relating to its opioids.

145. Defendants kept close tabs on the content of the misleading materials published by these KOLs. In many instances they also scripted what these KOLs said—as they did with all their recruited speakers.

146. Dr. Portenoy received research support, counseling fees, and honoraria from Defendants Purdue, Cephalon, Janssen and others.

147. Dr. Lynn Webster was the author of numerous CMEs sponsored by Purdue, Cephalon and Endo.

148. Dr. Scott Fishman was a KOL who authored Responsible Opioid Prescribing, a publication sponsored by Defendants Purdue and Cephalon. Dr. Fishman was also a board member of the Front Group American Pain Foundation ("APF").

149. Dr. Perry Fine was a KOL who received funding from Defendants Purdue, Cephalon, Janssen and Endo.

c. Continuing Medical Education

150. Physicians are required to attend continuing medical education ("CME") courses in order to keep their medical licenses. Manufacturer Defendants sponsored CME courses and made sure that the content supported their position on opioids. They were thereby able to promulgate their teaching to a large number of doctors that they should be prescribing more opioids.

151. Because CMEs are typically delivered by KOLs who are highly respected in their fields, and are thought to reflect these physicians' medical expertise and "cutting edge" practices, they can be especially influential to doctors.

152. The countless doctors and other healthcare professionals who participate in accredited CMEs constitute an enormously important audience for opioid reeducation. Defendants targeted general practitioners, who were especially susceptible to Defendants' deceptions because of their lack of specialized training in pain management, and the likelihood that they would treat patients who seek medical treatment for pain management issues.

153. These CMEs, often with names related to treatment of chronic pain, inflated the benefits of opioids, omitted or downplayed their risks, and focused on them to the exclusion of alternative treatments.

154. The influence of Defendants' funding on the content of these CMEs is clear. One study by a Georgetown University Medical Center professor compared the messages retained by medical students who reviewed an industry-funded CME article on opioids versus another group who reviewed a non-industry-funded CME article. The industry-funded CME did not mention opioid-related death once; the non-industry-funded CME mentioned opioid-related death 26 times.

155. Students who read the industry-funded article more frequently noted the impression that opioids were underused in treating chronic pain. The "take-aways" of those reading the non-industry-funded CME mentioned the risks of death and addiction much more frequently than those of the other group.

156. Neither group could accurately identify whether the article they read was industry-funded, making clear the difficulty medical practitioners (the audience for CMEs) have in screening and accounting for source bias. Adriane Fugh-Berman, Marketing Messages in Industry-Funded CME, PharmedOUT.org (June 25, 2010), available at http://pharmedout.galacticrealms.com/conferencematerials.htm.

157. By sponsoring CME programs presented by Front Groups like the American Academy of Pain Medicine ("AAPM"), APF, and others, Defendants could expect messages to be favorable to them, as these organizations were otherwise financially dependent on Defendants for other projects. The sponsoring organizations honored this principle by hiring pro-opioid KOLs to give talks that supported chronic opioid therapy. Defendant-driven content in these CMEs had a direct and immediate effect on prescribers' views on opioids.

d. Treatment Guidelines

158. Manufacturer Defendants produced treatment guidelines for doctors. Such guidelines were crucial for giving legitimacy to extensive opioid prescriptions and providing a framework within which doctors would feel comfortable prescribing them. These guidelines are also cited throughout the scientific literature and referenced by third-party payors in determining whether they should cover treatments for specific indications.

(i) Federation of State Medical Boards

159. The Federation of State Medical Boards ("FSMB") is a trade organization representing the various state medical boards in the United States, including those in

Connecticut, which have the power to license doctors, investigate complaints, and discipline physicians. The FSMB finances opioid- and pain-specific programs through grants from Manufacturer Defendants.

160. In 1998, the FSMB developed its Model Guidelines for the Use of Controlled Substances for the Treatment of Pain ("FSMB Guidelines"), which FSMB conceded was produced "in collaboration with pharmaceutical companies." The FSMB Guidelines taught that opioids were "essential" for treatment of chronic pain, including as a first prescription option. The FSMB Guidelines failed to mention risks relating to respiratory depression and overdose, and discussed addiction only in the sense that "inadequate understanding" of addiction can lead to "inadequate pain control."

161. The publication of Responsible Opioid Prescribing, a book adapted from these guidelines, was backed largely by Manufacturer Defendants, including Cephalon, Endo, and Purdue. The FSMB financed the distribution of Responsible Opioid Prescribing by its member boards by contracting with drug companies, including Endo and Cephalon, for bulk sales and distribution to sales representatives (for distribution to prescribing doctors). 163,131 copies of Responsible Opioid Prescribing were distributed to state medical boards, including the State of Connecticut Medical Examining Board (and through the boards, to practicing doctors), and the FSMB earned approximately $250,000 in revenue and commissions from their sale.

162. The FSMB guidelines conveyed the message that "inadequate pain control" would result in official discipline, but no discipline would result if opioids were prescribed as part of an ongoing patient relationship and prescription decisions were documented.

163. Through the FSMB guidelines, the Manufacturer Defendants were able to turn doctors' fear of discipline on its head—doctors, who used to believe that they would be

disciplined if their patients became addicted to opioids, were taught that they would be punished instead if they failed to prescribe opioids to their patients with pain.

(ii) AAPM/APS Guidelines

164. AAPM and the American Pain Society ("APS") are professional medical societies, each of which received substantial funding from Manufacturer Defendants from 2009 to 2013 (with AAPM receiving over $2 million).

165. AAPM issued a consensus statement in 1997, The Use of Opioids for the Treatment of Chronic Pain, which endorsed opioids for treating chronic pain and claimed that the risk of addiction to opioids was low.[23] The co-author of the statement, Dr. Haddox, was at the time a paid speaker for Purdue, and subsequently became Vice President of Health Policy at Purdue. Dr. Portenoy, one of the main KOLs who received funding from Manufacturer Defendants Janssen, Cephalon, Endo, and Purdue, was the sole consultant. The consensus statement formed the foundation of the FSMB Guidelines.

166. AAPM and APS issued their own guidelines in 2009 ("AAPM/APS Guidelines"), continuing to recommend the use of opioids to treat chronic pain.[24] Fourteen of the 21 panel members who drafted the AAPM/APS Guidelines, including KOLs Dr. Portenoy and Dr. Fine of the University of Utah, received support from Janssen, Cephalon, Endo, and Purdue.

167. The AAPM/APS 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.

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[23] Consensus statement, APS & AAPM, *The Use of Opioids for the Treatment of Chronic Pain*, (1997), http://www.jpain.org/article/S1082-3174(97)80022-0/pdf.

[24] Roger Chou et al., *Clinical Guidelines for the Use of Chronic Opioid Therapy in Chronic Noncancer Pain*, 10(2) The Journal of Pain: Official Journal of the American Pain Society 113-130 (2009).

168. One panel member, Dr. Joel Saper, Clinical Professor of Neurology at Michigan State University and founder of the Michigan Headache & Neurological Institute, resigned from the panel because of his concerns that the AAPM/APS Guidelines were influenced by contributions that drug companies, including Manufacturer Defendants, made to the sponsoring organizations and committee members.

169. The 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, are still available online, and were reprinted in the Journal of Pain.

170. Defendants widely referenced and promoted the AAPM/APS Guidelines without disclosing the acknowledged lack of evidence to support them.

(iii) American Geriatrics Society

171. The American Geriatrics Society ("AGS"), a nonprofit organization serving healthcare professionals who work with the elderly, disseminated guidelines regarding the use of opioids for chronic pain in 2002 (The Management of Persistent Pain in Older Persons, hereinafter "2002 AGS Guidelines") and 2009 (Pharmacological Management of Persistent Pain in Older Persons, hereinafter "2009 AGS Guidelines").

172. The 2009 AGS Guidelines recommended that "[a]ll patients with moderate to severe pain . . . should be considered for opioid therapy" and stated that "the risks [of addiction] are exceedingly low in older patients with no current or past history of substance abuse."[25]

[25] Pharmacological Management of Persistent Pain in Older Persons, 57 J. AM. GERIATR SOC 1331, 1339, 1342 (2009), *available at* http://onlinelibrary.wiley.com/doi/10.1111/j.1526-4637.2009.00699.x/full.

These recommendations are not supported by any study or any other reliable scientific evidence. Nevertheless, they have been cited 278 times in Google Scholar since their 2009 publication.

173. AGS contracted with Defendants Endo, Purdue, and Janssen to disseminate the 2009 AGS Guidelines, and to sponsor CMEs based on them. The Manufacturer Defendants were aware of the content of the 2009 AGS Guidelines when they agreed to provide funding for these projects.

174. The 2009 AGS Guidelines were first published online on July 2, 2009. AGS submitted grant requests to Defendants, including Endo and Purdue beginning July 15, 2009. Internal AGS discussions in August 2009 reveal that AGS did not want to receive up-front funding from Manufacturer Defendants, which would suggest drug company influence, but would instead accept commercial support to disseminate the publication. However, by drafting the guidelines knowing that pharmaceutical company funding would be needed, and allowing these companies to determine whether to provide support only after they had approved the message, AGS effectively ceded significant control to these companies. Endo, Janssen, and Purdue all agreed to provide support to distribute the guidelines.

175. Five of ten of the experts on the guidelines panel disclosed financial ties to Defendants, including serving as paid speakers and consultants, presenting CMEs sponsored by Defendants, receiving grants from Manufacturer Defendants, and investing in Defendants' stock.

176. As noted in ¶¶194-95, *infra*, the recommendations (in this case, treatment guidelines) of those organizations not financed by Manufacturer Defendants stood in marked contrast to those financed by the Defendants.

e. Front Groups and Unbranded Advertising

177. Marketing Defendants Purdue, Endo, Janssen, and Cephalon collectively used unbranded, third-party marketing (through KOLs and Front Groups) as part of their national

marketing strategies for their branded drugs. Unbranded advertising had the dual advantage of having an appearance of independence and credibility, and not being subject to the regulations promulgated by the FDA for branded advertising. The purpose of the FDA regulations on branded advertising, 21 U.S.C. § 352(a); 21 C.F.R. §§ 1.21(a), 202.1(e)(3), 202.1(e)(6), is to encourage truthful advertising.

178. Defendants Purdue, Cephalon, Janssen, and Endo engaged in a series of actions designed to thwart federal advertising guidelines, market themselves by way of seemingly neutral third parties, and appear distanced from these organizations while simultaneously funneling large amounts of money into them. By doing so, they were able to engage in a multi-pronged effort to misrepresent the risks and overstate the benefits of using opioids. These Defendants were also able to change prescribing practices through materials that appeared not to be marketing.

179. One part of this approach was to influence the stances of Front Groups by heavily contributing to the organizations' income. Manufacturer Defendants then turned around and cited materials produced by these groups as evidence of their positions.

180. One such Front Group was APF. The group's name is meant to sound official and impartial, but in fact this organization was a front for promotional material and advocacy on behalf of manufacturers.

181. APF submitted amicus briefs in defense of opioids: in one case, in support of Purdue Pharma; in another, in support of a doctor on trial for over-prescribing pain medication (who was subsequently found guilty of 16 counts of drug trafficking).

182. Between 2007 and 2012, APF received upwards of $10 million from Manufacturer Defendants. In 2009 and 2010, it received from them more than 80% of its operating budget). In 2010, for example, APF received more than $1 million from Endo.

183. APF issued materials recommending the use of opioids to doctors, policymakers, and reporters. Its Board included KOLs otherwise responsible for encouraging the prescription of opioids and an employee of a public relations firm working for APF and Purdue. APF members attended conferences for Front Groups, where they received suggestions from Manufacturer Defendants about strategies to pursue and publications to produce.

184. The publications available from APF extolled the benefits of opioids, and these publications were underwritten by Purdue, Cephalon, Janssen, and Endo. For example, one board member published a study in 2010 sponsored by Cephalon, finding that Cephalon's drug Fentora was "generally safe and well-tolerated" in non-cancer patients, even though it was only approved for severe cancer pain.

185. APF also targeted the public on behalf of manufacturers. Its name was misleading because it suggested that the group's principal concern was patient pain when in truth its interests lay in making money for the manufacturers of pain medication.

186. APF targeted the public, through a multimedia campaign, expressing people's "right" to pain medication. The patient guide on its website discouraged the use of non-opioid pain relievers, citing harmful side-effects; at the same time, it encouraged the use of opioids, minimizing risks of addiction and downplaying side effects.

187. APF also represented itself as a patient advocacy organization by lobbying against legislation obstructive to manufacturer interests and by providing "patient representatives" for manufacturers' promotional activities.

188. A 2012 U.S. Senate Finance Committee investigation between manufacturers and APF resulted in an abrupt halt to this funding. APF's Board dissolved the group within days of this investigation.

189. AAPM similarly has received more than $2 million from opioid manufacturers since 2009. This group issues treatment guidelines and hosts CME courses, while espousing positions consistent with opioid manufacturers. Presidents of this organization include many of the KOLs mentioned above. A yearly meeting in Palm Springs, California, put on by AAPM allows the group to interface with opioid manufacturers, who pay to present "medical education programs" to AAPM and attending doctors.

190. Other Front Groups include the Pain & Policy Studies Group, which received $2.5 million from opioid manufacturers to lobby and otherwise promote opioid use; and APS, incorporated in 1977, whose primary corporate supporter is pharmaceutical manufacturer Mallinckrodt Pharmaceuticals.

191. These Front Groups provided important services for the Manufacturer Defendants. They prepared and disseminated unbranded materials, promoting the use of opioids, to doctors and the public, including by conducting CME courses and issuing treatment guidelines for doctors, and by outreach targeting particularly vulnerable groups such as veterans and elderly people. They also advocated against regulatory guidelines that would limit opioid prescription, and responded negatively to journal articles not supporting the use of opioids. The significant funding and regular interfacing between these sets of organizations ensured that the Front Groups would issue messages supporting the position(s) of the opioid manufacturers.

192. Defendants Purdue, Endo, Janssen, and Cephalon collectively exercised substantial control over the content of the messages third parties generated and disseminated, and

distributed certain of those materials themselves. Defendants took an active role in guiding, reviewing, and approving many of the misleading statements issued by these third parties, ensuring that Defendants were consistently aware of their content. By funding, directing, editing, and distributing these materials, Defendants exercised control over their deceptive messages and acted in concert with these third parties to fraudulently promote the use of opioids for the treatment of chronic pain.

193. The behavior and positions of those groups that did not accept funding from manufacturers contrasts significantly with that of the Front Groups. The American Society of Interventional Pain Physicians only recommends high doses of long-acting opioids "in specific circumstances with severe intractable pain" along with "continuous adherence monitoring, in well-selected populations, in conjunction with or after failure of other modalities of treatments with improvement in physical and functional status and minimal adverse effects."[26]

194. The American College of Occupational and Environmental Medicine similarly discourages "routine use of opioids in the management of patients with chronic pain," though conceding that for some patients it may be appropriate.[27] The U.S. Department of Veteran

[26] Laxmaiah Manchikanti, et al., American Society of Interventional Pain Physicians (ASIPP) *Guidelines for Responsible Opioid Prescribing in Chronic Non-Cancer Pain: Part 1 -- Evidence Assessment*, 15 PAIN PHYSICIAN (Special Issue) S1-S66; *Part 2 — Guidance,* 15 Pain Physician (Special Issue) S67-S116 (2012).

[27] *ACOEM's Guidelines for the Chronic Use of Opioids*, American College of Occupational and Environmental Medicine (2011), *available at* https://www.nhms.org/sites/default/files/Pdfs/ACOEM%202011-Chronic%20Pain%20Opioid%20.pdf.

Affairs and Department of Defense note risks of abuse and misuse, and "the lack of solid evidence-based research on the efficacy of long-term opioid therapy."[28]

f. Direct-to-Consumer Marketing

195. Defendants targeted patients so that they would ask doctors for those medications specifically. Endo's research, for example, found that such direct-to-consumer communications resulted in greater patient "brand loyalty," with longer durations of Opana ER therapy and fewer discontinuations.

196. Defendants marketed to consumers through patient-focused "education and support" materials. These took the form of pamphlets, videos, or other publications that patients could view in their physicians' offices. Endo also targeted employer and workers' compensation plan initiatives.

197. Defendants also recognized the obstacle of out-of-pocket costs. They overcame this obstacle by providing patients financial assistance with their insurance co-payments, through vouchers and coupons distributed by Defendant's sales representative when they visited with prescribers. For example, in 2012, Janssen planned to distribute 1.5 million savings cards worth $25 each.

198. Defendant Insys brought the effort to get insurance to pay for their product to an entirely new level of fraud. As the Fueling an Epidemic Senate report describes, Insys created a separate department, the Insys Reimbursement Center ("IRC"), that was designed to obtain quick approvals for insurance reimbursement for Insys's product Subsys, which is an orally administered spray of fentanyl. The IRC unit exercised fraud and deception (such as pretending

[28] Management of Opioid Therapy for Chronic Pain Working Group, VA/DoD Clinical Practice Guideline for Opioid Therapy for Chronic Pain (Feb. 2017), *available at* http://www.healthquality.va.gov/guidelines/Pain/cot/.

to be calling from a physician's office, and falsely representing that the prescription was for a cancer patient, which was the only FDA-approved indication for Subsys). The head of the IRC unit, Elizabeth Gurrieri, along with quite a few other executives, pled guilty to "having conspired to defraud insurers" (wire fraud) in June 2017 in the District Court for the District of Massachusetts (¶61, supra).

199. Manufacturer Defendants' marketing experts agree that direct-to-consumer marketing is particularly valuable in "increas[ing] market share . . . by bringing awareness to a particular disease that the drug treats."[29]

(i) The Elderly

200. Defendants have promoted the unfounded notion that the elderly are particularly unlikely to become addicted to opioids. The 2009 AGS Guidelines, for example, which Purdue, Endo, and Janssen publicized, described the risk of addiction as "exceedingly low in older patients with no current or past history of substance abuse." There is not now and has never been any scientifically based evidence to support this statement.

201. On the contrary, a 2010 study examining overdoses among long-term opioid users found that patients 65 or older were among those with the largest number of serious overdoses.

202. Elderly patients taking opioids have been found to be exposed to elevated fracture risks, greater risk for hospitalizations, increased vulnerability to adverse drug effects and interactions, such as respiratory depression, significantly higher rate of death, heart attacks, and strokes than users of NSAIDs.

[29] Kanika Johar, An Insider's Perspective: Defense of the Pharmaceutical Industry's Marketing Practices, 76 Albany L. Rev. 299, 308 (2013).

203. Defendants' targeted marketing to the elderly and the absence of cautionary language in their promotional materials flies in the face of scientific evidence and their own labels, and creates a heightened risk of serious injury to elderly patients.

204. Defendants' efforts have paid off. Since 2007, prescriptions for the elderly have grown at twice the rate of prescriptions for adults between the ages of 40 and 59.

(ii) Veterans

205. Veterans, too, were specifically targeted for Defendants' misleading marketing. A 2008 survey showed that prescription drug abuse among military personnel had doubled from 2002 to 2005, and then nearly tripled again over the next three years.

206. In 2009, military doctors wrote 3.8 million prescriptions for narcotic pain pills – four times as many as they had written in 2001. Further, one-third of veterans prescribed opioids as of 2012 remained on take-home opioids for more than 90 days. Although many of these veterans are returning from service with traumatic injuries, the increase in opioid prescribing is disproportionate to the population and, in far too many cases, unsuited for their treatment.

207. Among former service members receiving VA services nationally in a single year (2005), 1,013 had died of an accidental drug overdose – double the rate of the civilian population.

208. Opioids are particularly dangerous to veterans. According to a study published in the 2013 Journal of American Medicine, veterans returning from Iraq and Afghanistan who were prescribed opioids have a higher incidence of adverse clinical outcomes, such as overdoses and self-inflicted and accidental injuries; 40% of veterans with post-traumatic stress disorder received opioids and benzodiazepines (anti-anxiety drugs) that, when mixed with alcohol, can cause respiratory depression and death.

209. According to a VA Office of Inspector General report, despite the risks, 92.6% of veterans who were prescribed opioid drugs were also prescribed benzodiazepines.[30]

210. As with elderly patients, Defendants both purposefully sought to increase opioid prescribing to this vulnerable group and omitted from their promotional materials the known, serious risks opioids pose to them.

211. Exit Wounds, a 2009 publication sponsored by Purdue, distributed by APF with grants from Janssen and Endo, and written as if a personal narrative of one veteran, describes opioids as "underused" and the "gold standard of pain medications" and fails to disclose the risk of addiction, overdose, or injury.

212. Exit Wounds notes that opioid medications "increase a person's level of functioning" and that "[l]ong experience with opioids shows that people who are not predisposed to addiction are unlikely to become addicted to opioid pain medications."

213. The publication also asserts that "[d]enying a person opioid pain medication because he or she has a history of substance abuse or addiction is contrary to the model guidelines for prescribing opioids, published by the U.S. Federation of State Medical Boards." As laid out above, the FSMB itself received support from Defendants during the time it created and published its guidelines.

214. Exit Wounds minimizes the risks of chronic opioid therapy and does not disclose the risk that opioids may have fatal interactions with benzodiazepines, which were taken by a

[30] Rept. No. 14-00895-163, Dept. of Veterans Affairs, Office of Inspector General, *Healthcare Inspection – VA Patterns of Dispensing Take-Home Opioids and Monitoring Patients on Opioid Therapy* (May 14, 2014), https://www.va.gov/oig/pubs/VAOIG-14-00895-163.pdf (accessed Oct. 12, 2017).

significant number of veterans.[31] The deceptive nature of Exit Wounds is obvious when compared to guidance on opioids published by the VA and DOD in 2010 and 2011. The VA's Taking Opioids Responsibly describes opioids as "dangerous." It cautions against taking extra doses and mentions the risk of overdose and the dangers of interactions with alcohol. The list of side effects from opioids includes decreased hormones, sleep apnea, hyperalgesia, addiction, immune system changes, birth defects and death – none of which is mentioned in *Exit Wounds*.

4. Purdue-Specific Misrepresentation: The 12-Hour Dosing Lie

215. In the late 1980s, Purdue (a relatively small pharmaceutical company at the time) was facing a serious revenue threat. Its main drug was a morphine pill for cancer patients with the trade name MS Contin. The patent on MS Contin was about to expire which meant the drug would face serious downward pricing pressure from generics that were likely to enter the market of an opioid treatment for cancer patients.

216. To solve Defendant's "vulnerability of the . . . generic threat," Defendant decided to devote a huge effort and funding into the launch of another opioid product that it tradenamed OxyContin. OxyContin was classified as an oxycodone similar to Percocet (that was already on the market) but Purdue combined the oxycodone with a time release technique and claimed that the new drug, OxyContin, would control pain for up to 12 hours.

217. Purdue's claim that its opioid could provide 12 hours of pain relief was a primary selling point for its new drug, OxyContin. In its 1992 submission to the United States Patent Office, Purdue touted that OxyContin was a medical breakthrough that controlled pain for 12 hours "in approximately 90% of patients."

[31] FDA guidance states that materials designed to target a particular audience should disclose risks particular to that audience. *See* FDA Notice, Guidance for Industry, "Brief Summary and Adequate Directions for Use: Disclosing Risk Information in Consumer-Directed Print Advertisements and Promotional Labeling for Prescription Drugs," August 6, 2015.

218. Armed with its new product, Purdue launched OxyContin in 1996 after obtaining FDA approval in 1995. A Purdue marketing executive stated in a 1995 internal memo (that was obtained by the LA Times and reported on in a May 5, 2016 expose), "[w]e do not want to niche OxyContin just for cancer pain."

219. However, the promise of 12-hour pain relief was not true, which Purdue knew. The effects of OxyContin (both the pain relief and the euphoria) wore off for most of the patients in Purdue's clinical trials well before 12 hours. Many patients would start to crave another dose within eight hours, or even less time.

220. Theodore Cicero, a neuropharmacologist at Washington University School of Medicine explained that requiring OxyContin to be taken at 12-hour intervals is "the perfect recipe for addiction." He explained that patients for whom the drug doesn't last 12 hours suffer both a return of their underlying pain plus the beginning stages of acute opioid withdrawal, which generally includes body aches, nausea, and anxiety. "That becomes a very powerful motivator for people to take more drugs."[32]

221. Although Purdue was well aware of the shorter duration of the drug's effects for many patients, they withheld this information from prescribing physicians and, to the contrary, instructed its sales force (which had ballooned to over 200 by 1997, one year after launch), to recommend to the prescribers that they increase the strength of the dose rather than its frequency.

222. By use of this falsehood, Purdue kept its competitive advantage of being able to claim that OxyContin gives a full 12 hours of relief, allowing the convenience of twice-a-day dosing.

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[32] Harriet Ryan, Lisa Girion and Scott Glover, 'You Want a Description of Hell?' OxyContin's 12-Hour Problem, L.A. TIMES (May 5, 2016), available at: http://www.latimes.com/projects/oxycontin-part1/.

223. This strategy was a triple win for Purdue. First, the maximum strength 80 milligrams of OxyContin netted Purdue more than $630 rather than the $97 for a 10-milligram bottle. Second, if the patient in the throes of opioid withdrawal started to take the drug at shorter intervals, Purdue could claim it was "not their problem." Third, the increased dose made the drug even more addictive, thereby making it likely that Purdue would have a customer for life.

224. To this day, Purdue still continues to misrepresent Oxycontin to doctors as a 12-hour drug.[33]

225. The Los Angeles Times exposé stated that as of 2014, more than 52% of patients taking OxyContin longer than three months were prescribed doses greater than 60 milligrams a day. Dr. Debra Houry of the CDC stated in 2017 that those doses were "really concerning" because "the higher you go, the more likely you are to die."

5. Insys-Specific Misrepresentation

226. Insys is the last entrant into the prescription opioid market among the Manufacturer Defendants, having acquired FDA approval for its drug tradenamed Subsys in 2012.

227. Subsys is a highly addictive synthetic opioid mouth-spray approved by the FDA for a very limited indication: treatment of breakthrough cancer pain only in patients who have already been administered other opioids. Subsys is a form of fentanyl – a narcotic up to 50 times more powerful than heroin and 100 times more powerful than morphine.

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[33] OxyContin, Purdue Pharma, http://www.purduepharma.com/healthcare-professionals/products/oxycontin/; (OxyContin prescription information), http://app.purduepharma.com/xmlpublishing/pi.aspx?id=o; (medication guide), http://app.purduepharma.com/xmlpublishing/pi.aspx?id=o&medguide=1; Setting the Record Straight on OxyContin's FDA-Approved Label, Purdue Pharma (May 5, 2016) (responding to L.A. TIMES article by doubling down on its claims), available at http://www.purduepharma.com/news-media/get-the-facts/setting-the-record-straight-on-oxycontins-fda-approved-label/.

228. Insys has mounted an aggressive and unlawful off-label marketing strategy for Subsys in violation of the Food, Drug, and Cosmetic Act, 21 U.S.C. §301, et seq., knowingly marketing products for use that were not approved by the FDA, which led to the submission of false and improper payment requests to government programs Medicare and Medicaid.

229. There is a limited customer base for cancer patients who are already taking an opioid to manage cancer pain, but still need an additional boost to treat breakthrough cancer pain. Accordingly, Insys determined to sell its potent and dangerous opioid to a wider class of patients. Their sales force, whose pay was largely dependent on commissions, visited dentists, chiropractors, general practitioners, and others throughout the country to market Subsys for a wide variety of ailments from root canal to back pain.

230. Insys's business plan was profitable. According to the company's 2016 annual report, Subsys was the most prescribed transmucosal immediate-release fentanyl, with 42% market share, which translates to nearly $300 million in annual U.S. product sales for Insys – an increase of 270% in sales in just one year. See Insys Annual Report filed on Form 10-K on April 3, 2017 at 1.

231. The reckless marketing practices of Insys triggered many federal and state civil and criminal investigations, including the McCaskill Investigation (¶63, supra).

232. The McCaskill Investigation revealed, among other things, how the Insys sales force was incentivized and indoctrinated to sell Subsys as a safe treatment for many conditions far afield from breakthrough cancer pain. Moreover – and at least as dangerously – the sales staff was instructed to induce their physicians to write prescriptions for higher, more expensive doses.

233. The McCaskill Investigation revealed that, in March of 2016, a 32-year-old woman, Sarah Fuller, was killed by an overdose of Subsys that was prescribed by a physician for

treatment of fibromyalgia. The Estate of Sarah Fuller has initiated a lawsuit against Insys in Middlesex County Court. Deborah Fuller & David Fuller, as Administrators Ad Prosequendum for the Estate of Sarah R. Fuller v. Vivienne Matalon, M.D., TLC Healthcare 2, LLC, Linden Care and Insys Therapeutics, Inc., Case No. L1859-17, filed in the Superior Court of New Jersey Law Division, Middlesex County, March 23, 2017.

234. The McCaskill Investigation revealed a chilling quote from a sales representative that was uncovered from the facts surrounding the overdose of Sarah Fuller. An unnamed sales representative advised the Senate Committee that a common mantra at Insys was "start them high, hope they don't die."

235. Insys executives knew that the off-label use of Subsys could be fatal, and, at the very least, could lead to addiction in the user. Despite this knowledge, the Defendant unlawfully, recklessly, and with wanton and willful and criminal intent continued to market their product for the use on innocent persons for whom it was foreseeable that it would cause grave and perhaps fatal harm.

236. Connecticut physicians were among the physicians who received false and unlawful marketing by Insys. Connecticut residents, including residents of the City of New Haven, were among the persons who were within the foreseeable zone of injury from Insys's illegal acts.

237. On July 11, 2017, the U.S. Attorney's Office for the District of Connecticut announced that a former Insys sales representative had pleaded guilty to a count of engaging in a kickback scheme to defraud federal healthcare programs.34 The former employee admitted that

[34] Drug Company Sales Rep Admits Role in Kickback Scheme Related to Fentanyl Spray Prescriptions, Department of Justice (July 11, 2017), https://www.justice.gov/usao-ct/pr/drug-company-sales-rep-admits-role-kickback-scheme-related-fentanyl-spray-prescriptions.

she had induced certain medical practitioners to prescribe Subsys by paying them to participate in hundreds of sham "Speaker Programs" that were usually just a gathering of friends and co-workers, most of whom did not have the ability to prescribe Subsys, and where there was no educational component to the event. This recent plea follows an earlier plea in June 2015 by a pain clinic nurse in Connecticut, who pleaded guilty to accepting $83,000 in kickbacks in the form of payments for "speaking engagements" that were part of these alleged sham "Speaker Programs."

6. Manufacturer Engaged in Medicare and Medicaid Fraud by Their Off-Label Marketing

238. While it is legal for doctors to prescribe any medication for any medical indication, the FDA prohibits pharmaceutical manufacturers from *marketing* or *promoting* drugs for medical diagnoses, called "indications," not expressly approved by the FDA. This includes any attempts by pharmaceutical sales representatives to solicit off-label use of their Company's drugs. *See* 21 U.S.C. §§ 331(a)-(b), 352(a).

239. Such off-label marketing is prohibited because it evades the FDA's strict review and approval process and undercuts the incentive to obtain definitive clinical study data showing the efficacy, safety, and medical necessity of a drug.

240. Medicare and Medicaid are not permitted to pay for medications that are not prescribed for a medically accepted indication or that are prescribed as a result of false or misleading information disseminated by pharmaceutical manufacturers to payors or healthcare providers.

241. The Federal False Claims Act, which contemplates civil and criminal penalties, provides that any person who knowingly presents or causes another to present a false or fraudulent claim for payment or approval is liable for a civil penalty of up to $10,000 for each

such claim, plus three times the amount of the damages sustained by the government. 31 U.S.C. §§3729(a)(l)(A), (B).

242. Off-label marketing by a pharmaceutical company that results in Medicare or Medicaid paying the cost of a prescription drug for use by a patient for an indication that was not FDA-approved, constitutes a violation of the Federal False Claims Act. This conduct is sometimes referred to as Medicaid or Medicare fraud.

243. Upon information and belief, each of the Manufacturer Defendants engaged in Medicare and Medicaid fraud.

244. In May 2007, Purdue pled guilty, inter alia, to violation of the Federal False Claims Act because of its unlawful off-label marketing of OxyContin.

245. In 2008, Teva/Cephalon pled guilty to violation of the Federal False Claims Act resulting from their off-label marketing of Actiq, a fentanyl lollipop approved for use only by cancer patients whose pain was not controlled by morphine, for use for migraines, sickle cell pain, and other injuries.

246. Insys settled claims by the Oregon Department of Justice and the New Hampshire Department of Justice for aggressive off-label marketing of Subsys.

D. Unlawful Conduct of Distributor Defendants

247. Under the statutory scheme set out in the Controlled Substances Act ("CSA") enacted by Congress in 1970, wholesale distributors were given the statutory obligation to have in place "effective controls" to prevent the "diversion" of controlled substances. 21 C.F.R. §13201.74(a). Once a pharmaceutical distributor detects a "suspicious order" of the controlled substance, it is obligated to take several mandatory steps. It must report the "suspicious order" to the DEA. Additionally, the wholesaler must investigate the suspicious order, document the result of the investigation, and if not reasonably satisfied that the suspicious order is for the

legitimate sale of the controlled substance by the retail pharmacy, hospital, practitioner, mid-level practitioner, or teaching institution ("Retail End User") it must immediately halt the sale. See Masters Pharm., Inc. v. DEA, 861 F.3d 206 (D.C. Cir. 2017).

248. A database known as the "Automation of Reports and Consolidated Orders System" ("ARCOS") was set up under the 1970 Controlled Substances Act. ARCOS is a comprehensive reporting system that shows the flow of every controlled substance from its point of manufacture, through the distributor, and on to the Retail End User.

249. All the Manufacturer Defendants and Distributor Defendants have access to ARCOS and each is under an obligation to enter any transaction with which it is involved for any controlled substance.

250. The ARCOS database is part of the architecture of a "closed system" assuring that every entity that touches a controlled substance is a DEA registrant. The Distributor Defendants have been tasked with a statutory obligation to serve as a gatekeeper or monitor to ensure that controlled substances are not allowed to flow into a community for illegitimate uses, referred to as "diversion."

251. The ARCOS system shows distribution of controlled substances to Retail End Users on the basis of their zip code. Therefore, one would be able to learn through the ARCOS database every time that a distributor made a sale to a Retail End User within the zip code of the City of New Haven that appeared to be suspicious, and which specific prescription opioid was shipped.

252. If the Distributor Defendants would permit access to such information, the Plaintiff, City of New Haven, could document in this Complaint each suspicious sale made by each Distributor Defendant to the City of New Haven in violation of its statutory obligation.

253. The Distributor Defendants will not permit such access, even in response to a FOIA request.

254. The following chart shows the only information publicly available from the ARCOS databases, which reveals data on the basis of the first three digits of the zip code. The first three digits of the zip code ARCOS database reveals that the following grams (i.e., thousands of milligrams) were delivered to the greater New Haven area.

New Haven	2006	2007	2008	2009	2010	2011	2012	2013	2014	2015	2016
Butrans (buprenophine)	1,677	2,177	2,924	3,920	4,821	5,047	6,640	7,522	8,187	8,386	8,865
OxyContin (oxycodone)	68,526	76,021	74,986	77,849	84,610	87,773	93,497	97,204	95,357	87,362	77,863
Dilaudid (Hydromorphone)	855	1,096	1,430	1,623	1,722	1,918	2,426	3,083	2,714	2,433	2,121
Hydrocodone	7,516	8,377	9,241	9,502	8,835	9,948	9,202	8,567	8,302	6,873	6,117
MS Contin (Morphine)	25,066	26,295	24,835	23,636	23,919	24,562	25,328	23,680	22,572	20,713	18,086
Opana (Oxymorphone)	115	728	1,783	2,122	2,764	3,491	2,816	2,635	2,550	2,299	1,952
Nucynta (tapentadol)	-	-	-	317	1,800	2,069	4,219	5,032	4,227	3,653	4,100
Fentanyl Base	569	664	627	555	678	542	634	601	559	513	422

Thus, for example, the amount of oxycodone, which is the controlled substance contained in OxyContin, sent to the greater New Haven area in 2016 was 77,863 grams, the equivalent of 3,893,150 20-mg pills of OxyContin.

255. The three Distributor Defendants, McKesson, Cardinal, and ABC, control 85%-90% of the market share in the United States for the distribution of prescription opioids.

256. It is reasonable to assume, and Plaintiff alleges on information and belief, that the three Distributor Defendants have engaged in the unlawful conduct of failing to report suspicious orders, reasonably investigate such orders, and halt such orders to the City of New Haven.

257. Each Distributor Defendant has repeatedly and purposely breached its duties under federal law with knowledge that a foreseeable result of its breach would be the diversion of dangerous prescription opioids for non-medical purposes.

258. On September 26, 2006, the DEA sent a letter to each of the Distributor Defendants cautioning them to not "turn a blind eye to the suspicious circumstances." It further warned that "even just one distributor that uses its DEA registration to facilitate diversion causes enormous harm."35

259. On December 27, 2007, the DEA sent another letter to each of the Distributor Defendants warning them again of the importance of fulfilling their obligation and their role as gatekeepers for the safe distribution of opioid prescriptions. The DEA letter stated, in part:

> Registrants are reminded that their responsibility does not end merely with the filing of a suspicious order report. Registrants must conduct an independent analysis of suspicious orders prior to completing a sale to determine whether the controlled substances are likely to be diverted from legitimate channels.[36]

260. Each Distributor Defendant made the unlawful and unconscionable decision to not halt suspicious sales where it had strong reason to believe, or actually knew, that the prescription drugs were being diverted and not being used for legitimate reasons, thereby subjecting Americans to grievous harm up to, and including, death by overdose. Nevertheless each Distributor Defendant continued to permit the sales to go through because the sales enhanced the Defendants' profit.

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35 Letter from Joseph T. Rannazzisi, Deputy Assist. Admin., Office of Diversion Control, to Cardinal Health (Sept. 27, 2006) (a copy of letter is filed at Cardinal Health, Inc. v. Holder, No. 1:12-cv-00185-RBW, Doc. 14-51 (filed in U.S. D.C. on February 20, 2012)).

36 Letter from Joseph T. Rannazzisi, Deputy Assis. Admin., Office of Diversion Control, to Cardinal Health (Dec. 27, 2007) (a copy of letter is filed at Cardinal Health, Inc. v. Holder, No. 1:12-cv-00185-RBW, Doc. 14-8 (filed in U.S. D.C. on February 20, 2012)).

261. Each Distributor Defendant knowingly made the business decision that payment of whatever fines the DEA imposed was simply the cost of doing business, so long as their unlawful shipments could continue.

262. Defendant McKesson agreed to pay a $150 million civil penalty to the DOJ on January 17, 2017 for violations of the CSA.

263. The DOJ announced through its Office of Public Affairs that despite entering into the 2008 agreement, "[f]rom 2008 until 2013, McKesson supplied various U.S. pharmacies an increasing amount of oxycodone and hydrocodone pills, frequently misused products that are part of the current opioid epidemic."37

264. In December of 2016, Cardinal agreed to pay $44 million to the DOJ for its violation of the CSA.

265. On April 24, 2007, the DEA issued an order to show cause and an immediate suspension order against Defendant ABC's Orlando, Florida, distribution center, alleging failure to maintain effective controls against diversion of controlled substances. On June 22, 2007, the DEA suspended its DEA registration at that facility. ABC was allowed to continue shipments of controlled substances from its other facilities, so business was not interrupted.

266. ABC also agreed to pay $16 million to the State of West Virginia in the case captioned State of W. Va. v. Amerisource Bergen, No. 12-C-141 (W. Va. Cir. Ct., Boone Cty.), for its violation of the CSA.

267. The repeated shipments of suspicious orders, year after year, by each Distributor Defendant, demonstrated its reckless conduct and criminal indifference to its statutory

37 Press Release, McKesson Agrees to Pay Record $150 Million Settlement for Failure to Report Suspicious Orders of Pharmaceutical Drugs, United States District Attorney's Office, Middle District of Florida (Jan. 17, 2017), available at https://www.justice.gov/usao-mdfl/pr/mckesson-agrees-pay-record-150-million-settlement-failure-report-suspicious-orders.

obligations, which it knew would result in a great probability of causing substantial harm to a great many Americans.

268. The Distributor Defendants' failure to detect, report, investigate, and halt suspicious orders is a direct, foreseeable, and proximate cause of the diversion of millions of doses of opioids into the illicit market for purposes other than legitimate medical use in the State of Connecticut, City of New Haven.

269. New Haven seeks damages from the Distributor Defendants as reimbursement for the costs it undertook, and is still undertaking, to try to contain and mitigate the hazards to public health and safety caused by the Distributor Defendants. Additionally, the City of New Haven seeks injunctive relief, including payment for future costs required to eliminate the public nuisance caused by the Distributor Defendants' unlawful and unconscionable acts.

E. Damages to the City of New Haven

270. As a foreseeable, direct and proximate result of the unlawful conduct of Defendants, the City of New Haven has been subjected to a devastating public health crisis, along with many other communities in the United States.

271. The Connecticut Department of Mental Health and Addiction Services, which offers various services that act as a safety net to addicts and those in recovery, reported a 150% increase in people accessing treatment services.38

272. The number of opioid-related deaths in New Haven was 44 in 2016,39 more than the number of opioid-related deaths in 1996 for all of Connecticut.40

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38 Andrew Ba Tran, What can be done to curb the drug overdose deaths, TRENDCT.ORG (Mar. 10, 2016), https://overdose.trendct.org/story/what

39 Accidental Drug Related Deaths 2012-2016, Connecticut Open Data (last visited Oct. 13, 2017), https://data.ct.gov/Health-and-Human-Services/Accidental-Drug-Related-Deaths-2012-2016/ecj5-r2i9,

273. Connecticut has been experiencing a heroin overdose outbreak that continues to worsen despite efforts by government officials to bring it under control. For example, in 2012, Connecticut ranked 50th in the nation in terms of opioid deaths, with 2 per 100,000 people. By 2015, however, that number spiked five-and-a-half times, and Connecticut's ranking climbed to 12th,41 despite a number of legislative actions aimed at curbing the opioid crisis. According to the State's Office of the Chief Medical Examiner, a staggering 917 people in Connecticut died from drug overdoses in 2016, representing a 25% jump from 2015 when 729 people died.42 With 70 casualties in 2016, New Haven ranks second in the state in the number of opioid-related deaths.

274. To respond to the increasing demand, a number of treatment facilities opened in Hartford, New Haven, and Waterbury – areas hardest hit by the epidemic. Additionally, first responders' budgets are heavily impacted financially as they are being forced to expend thousands of dollars each month on special supplies and training of personnel. Neither is the judicial branch immune from the significant financial burdens of the opioid crisis. Indeed, on any

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[40] CT Heroin Epidemic: Interactive Map of Deaths by Town, Patch (last updated Mar. 2, 2017), https://patch.com/connecticut/newcanaan/ct-heroin-epidemic-interactive-map-deaths-town-0.

[41] Brad Drazen, America's Opioid Crisis is Magnified in Connecticut, NBCCONNECTICUT.COM (May 17, 2017, 11:10 PM EDT), http://www.nbcconnecticut.com/troubleshooters/Americas-Opioid-Crisis-is-Magnifiedin-Connecticut-422831064.html

[42] Ana Radelat, Growing number of states press opioid suits against Stamford's Purdue Pharma, CTMIRROR.ORG (July 6, 2017), https://ctmirror.org/2017/07/06/growing-number-of-states-press-opioid-suitsagainst-stamfords-purdue-pharma/

given day, "there are 400 people on the waiting list for the substance abuse treatment and detox programs" paid for by the State's Judicial Branch.[43]

275. The state of Connecticut has seen a significant rise in opioid-related deaths. The Chief Medical Examiner for the state forecasts that 1079 people are expected to die of opioid-related deaths this year, compared to 917 in 2016 and 729 in 2015. According to the Agency for Healthcare Research and Quality, Connecticut ranks among the top 25% of states for opioid-related hospital stays.[44]

276. The City of New Haven provides health insurance for its employees and retirees. Defendants' unlawful conduct has caused the City of New Haven to spend exorbitant amounts for the cost of opioid prescriptions that were written without any medical basis for City employees and insureds.

277. The City of New Haven has had to expend exorbitant amounts for the costs of opioid-related substance abuse treatment costs for its employees and insureds, due to the Defendants' unlawful conduct.

278. The City of New Haven self-insures for its workers compensation program for its City employees. Defendants' unlawful conduct has caused the City of New Haven to expend monies for the costs of opioid prescriptions written for its injured employees without any medical basis.

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[43] Jacqueline Rabe Thomas, Amid opioid crisis, substance abuse treatment programs cut, CTMIRROR.ORG (June 24, 2016), available at https://ctmirror.org/2016/06/24/amid-opioid-crisis-substance-abuse-treatment-programs-cut/.

[44] *See* State launches opioid probe, Yale Daily News (Oct. 2, 2017), https://yaledailynews.com/blog/2017/10/02/state-launches-opioid-probe/.

279. The City of New Haven has had to expend exorbitant amounts for the costs of opioid-related substance abuse treatment costs for its injured workers who are receiving workers' compensation.

280. The devastating impact of the opioid epidemic on the social fabric of the New Haven community causes tremendous economic harm to the City, including increased costs related to police, fire, and first responder services required to respond to opioid overdoses or suspected overdoses.

281. The flood of opiates into the City of New Haven has also resulted in the City's having to incur additional costs related to termination, suspension or other employment action taken against employees due to opioid addiction, lost productivity and an increasing need for drug monitoring and drug tests among City employees.

282. Due to the Defendants' unlawful conduct, the City of New Haven has had to incur the cost of purchasing and training upwards of number of employees in the use of Naloxone.

283. The City of New Haven has had to expend enormous funds in providing for rehabilitative services for its residents who have been severely damaged by the addiction brought about by the Defendants' unlawful conduct.

284. Virtually every department within the City of New Haven (including the Health Department, Social Services, and Economic Development) has been impacted, and forced to incur additional expenses year after year to try to mitigate the devastating impact of the opioid epidemic to New Haven's residents.

285. The costs of the criminal justice system have ballooned from the opioid epidemic.

286. In short, by virtue of the deceptive and fraudulent marketing campaign of the Manufacturer Defendants and the wanton and willful violation of their statutory obligations by

the Distributor Defendants, the City of New Haven, the State of Connecticut, and the nation are gripped in the throes of a drug epidemic that is causing substantial economic harm to the City and its residents.

V. CAUSES OF ACTION

Count I
Public Nuisance
(Against all Defendants)

287. Plaintiff hereby incorporates by reference all preceding paragraphs as if fully set forth herein.

288. The residents of the City of New Haven have a common right to be free from conduct that constitutes an unreasonable interference with the public health, safety, peace, and welfare. Defendants through their conduct described in this complaint have created a public nuisance that constitutes a significant, unreasonable interference with this common right. Further, this interference is continuing in nature, and has produced a long-lasting effect, and Defendants knew, or had reason to know, the devastating effects their conduct would have upon the City of New Haven and its residents.

289. Manufacturer Defendants have intentionally, recklessly, or negligently marketed their opioid products through materially false and misleading statements to physicians, pharmacists, insurers, and members of the general public that misrepresented the characteristics and safety of opioids and resulted in widespread inappropriate use of these highly addictive and dangerous pharmaceuticals. Distributing Defendants widely disseminated the Manufacturer Defendants' opioid products in the City of New Haven in suspicious quantities, in breach of federal law and with knowledge of their likely and foreseeable harm to the residents of New Haven.

290. Defendants' conduct was unlawful, intentional or reckless and has resulted in significant and unreasonable interference with the public health, safety, peace and welfare of New Haven residents. As such, Defendants' conduct constitutes a public nuisance and, if unabated, will continue to threaten the health, safety and welfare of the City's residents. The City of New Haven has a clearly ascertainable right to abate conduct that perpetuates this nuisance.

291. The public nuisance created by Defendants' conduct has directly and proximately caused harm to the City of New Haven. The special injuries suffered by the City as a result of the public nuisance created by Defendants, which are distinct from those to the general public, include expenditures for health services and law enforcement, costs related to opioid addiction treatment and overdose prevention, and payments by governmental payor programs, such as employee health insurance.

Count II
The Connecticut Unfair Trade Practices Act (CUTPA), Conn. Gen. Stat. §42-110a, *et seq.*
(as to Manufacturer Defendants)

292. Plaintiff hereby incorporates by reference all preceding paragraphs as if fully set forth herein.

293. Manufacturer Defendants violated Connecticut Gen. Stat. § 42-110b, because, in the conduct of trade or commerce, Manufacturer Defendants have engaged in unfair and deceptive acts and practices.

294. Manufacturer Defendants made, or through their control of third parties, caused to be made untrue, false, misleading, and deceptive statements of materials fact to physicians, consumers, payors, and Plaintiff, in connection with Defendants' marketing, promotion, sale, and use of prescription opioids. These untrue, false, misleading, and deceptive statements of material fact included, but were not limited to the following:

(a) Misstatements relating to the addictive nature of opioids;

(b) Misstatements relating to the high risk of overdose, death, and irreversible damage to the brain;

(c) Misstatements relating to the titration schedules of opioids;

(d) Misstatements to the treating physicians, the medical community in general, to residents of New Haven, and to New Haven relating to the risks and safety of the use of opioids for the treatment of chronic pain;

(e) Misstatements relating to and the use of unfair and deceptive practices in connection with KOLs, the creation of false fronts, infiltration of medical societies to perpetuate their false message to physicians to peddle their product to masses of persons for whom it was dangerous and caused death or permanent brain damage;

(f) Misstatements relating to the viability, risks, benefits, and superiority of alternative treatments;

(g) Purdue's and Endo false claims that abuse-deterrent opioids reduce tampering and abuse; and

(h) Purdues' false claims that OxyContin provides a full 12 hours of pain relief.

295. Manufacturer Defendants knew, or should have known, at the time of making or disseminating the false statements, that they were untrue, false, misleading and deceptive, and therefore likely to deceive the public, the physicians, the payors, and the City of Haven. Indeed, Manufacturer Defendants made these statements with the intent that the City of New Haven and its residents would rely on them, and that it was reasonably foreseeable to the Manufacturer Defendants that such reliance would result in the use of opioid prescriptions by persons in

quantities and for durations that would cause death or severe harm, and the City and its residents did rely on the Defendants' false, misleading and unconscionable statements and the City of New Haven has sustained ascertainable losses as a direct and proximate result. Further, Manufacturer Defendants intended to deceive the physicians who prescribed opioids to the residents of New Haven and the payors who purchased, or covered the purchase of, opioids for chronic pain.

296. Manufacturer Defendants' conduct, as alleged herein, offends public policy, is immoral, unethical, oppressive or unscrupulous, and caused substantial injury to consumers, including the Plaintiff.

297. The City of New Haven is a self-insured municipality, which covers medical expenses of its current and former employees and their dependents. As such, it bears a variety of expenditures, including, but not limited to:

(a) the cost of prescription drugs, including opioids;

(b) cost of governmental payor programs;

(c) health services for the treatment of addiction and overdoses;

(d) increased law enforcement and fire rescue related to overdoses, including costs of administration of Narcan;

(e) costs for social services, including, but not limited to, addiction prevention programs; and

(f) costs of governmental services intended for children, families, youth, and other residents of the City of New Haven,

which the City of New Haven would not have incurred but for the unfair and deceptive acts and practice of Manufacturer Defendants.

Count III
The Connecticut Unfair Trade Practices Act (CUTPA), Conn. Gen. Stat. §42-110a, *et seq.*
(as to Distributor Defendants)

298. Plaintiff hereby incorporates by reference all preceding paragraphs as if fully set forth herein.

299. Distributor Defendants violated Connecticut Gen. Stat. § 42-110b, because, in the conduct of trade or commerce, Distributor Defendants have engaged in unfair and deceptive acts and practices.

300. Distributor Defendants knew or should have known that controlled substances, due to their high propensity for diversion and misuse, are subject to strict reporting obligations and inventory monitoring in order to detect irregularity in buying patterns relating to the size and frequency of sale of controlled substances, as mandated by relevant state and federal law and regulations. Furthermore, Defendants knew or should have known that opioids buying patterns grossly deviated from the regular course both in quantity and frequency of purchases, yet failed to report, alert, or otherwise notify authorities of these irregular buying patterns.

301. Distributor Defendants knew, or should have known, at the time of failing to report the suspicious sales that their omissions operated to conceal the highly irregular and illegal flow of opioids into the City of New Haven. Indeed, Defendants intentionally or purposefully failed to slow down, inspect, report, alert, or otherwise limit the flow of these dangerous substances into the City of New Haven in order to generate profits that they otherwise would not generate, but for the concealment of the irregular buying patterns. Distributor Defendants knew or should have known that the City of New Haven and its residents relied on their non-disclosure of the suspicious sales, and that it was reasonably foreseeable to the Distributor Defendants that such reliance would result in the continued and increased use of opioid prescriptions by persons

in quantities, frequencies, and durations that would cause death or severe harm, and the City and its residents did rely on the Distributor Defendants' omission of the illegal and irregular buying patterns and the City of New Haven has sustained ascertainable losses as a direct and proximate result. Further, Distributor Defendants intended to deceive the physicians who prescribed opioids to the residents of New Haven and the payors who purchased, or covered the purchase of, opioids for chronic pain.

302. Distributor Defendants' conduct, as alleged herein, offends public policy, is immoral, unethical, oppressive or unscrupulous, and caused substantial injury to consumers, including the Plaintiff.

303. The City of New Haven is a self-insured municipality, which covers medical expenses of its current and former employees and their dependents. As such, it bears a variety of expenditures, including, but not limited to:

(a) the cost of prescription drugs, including opioids;

(b) cost of governmental payor programs;

(c) health services for the treatment of addiction and overdoses;

(d) increased law enforcement and fire rescue related to overdoses, including costs of administration of Narcan;

(e) costs for social services, including, but not limited to, addiction prevention programs; and

(f) costs of governmental services intended for children, families, youth, and other residents of the City of New Haven, which the City of New Haven would not have incurred but for the unfair and deceptive acts and practice of Distributor Defendants.

Count IV
Common Law Fraud
(Against the Manufacturer Defendants)

304. Plaintiff hereby incorporates by reference all preceding paragraphs as if fully set forth herein.

305. Manufacturer Defendants made untrue, false, misleading, and deceptive statements and omissions of material facts regarding the nature, risks, and benefits of opioids and their use, which statements and omissions Defendants knew were untrue, false, misleading, and deceptive.

306. By making these untrue, false, misleading, and deceptive statements and omissions, Manufacturer Defendants intended that the City of New Haven and its residents would rely on them, and that such reliance would result in the use of opioid prescriptions by persons in quantities, frequencies and for durations that would cause death or severe harm, and the City and its residents did rely on the Manufacturer Defendants' false, misleading and unconscionable statements and the City of New Haven has sustained ascertainable losses as a direct and proximate result.

307. As a direct and foreseeable consequence of the Manufacturer Defendants' fraudulent misrepresentations and omissions, Plaintiff has been damaged by incurring unnecessary expenditures, including, but not limited to:

(a) the cost of prescription drugs, including opioids;

(b) cost of governmental payor programs;

(c) health services for the treatment of addiction and overdoses;

(d) increased law enforcement and fire rescue related to overdoses, including costs of administration of Narcan;

(e) costs for social services, including, but not limited to, addiction prevention programs; and

(f) costs of governmental services intended for children, families, youth, and other residents of the City of New Haven, which the City of New Haven would not have incurred but for the fraudulent misrepresentation of Manufacturer Defendants as alleged herein.

Count V
Common Law Fraud
(Against the Distributor Defendants)

308. Plaintiff hereby incorporates by reference all preceding paragraphs as if fully set forth herein.

309. Distribution Defendants knew that opioids buying patterns grossly deviated from the regular course both in quantity and frequency of purchases, yet failed to report, alert, or otherwise notify authorities of these irregular buying patterns.

310. Distributor Defendants knew at the time of failing to report the suspicious sales that these omissions operated to conceal the highly irregular and illegal flow of opioids into the City of New Haven. Indeed, Distributor Defendants intentionally or purposefully failed to slow down, inspect, report, alert, or otherwise limit the flow of these dangerous substances into the City of New Haven in order to generate profits that they otherwise would not generate, but for the concealment of the irregular buying patterns. Distributor Defendants knew that the City of New Haven and its residents relied on their non-disclosure of the suspicious sales, and that it was reasonably foreseeable to the Distributor Defendants that such reliance would result in the continued and increased use of opioid prescriptions by persons in quantities, frequencies, and durations that would cause death or severe harm.

311. The City and its residents did in fact rely on the Distributor Defendants' omissions of the illegal and irregular buying patterns and the City of New Haven has sustained ascertainable losses as a direct and proximate result.

312. As a direct and foreseeable consequence of the Distributor Defendants' fraudulent omissions, Plaintiff has been damaged by incurring unnecessary expenditures, including, but not limited to:

(a) the cost of prescription drugs, including opioids;

(b) cost of governmental payor programs;

(c) health services for the treatment of addiction and overdoses;

(d) increased law enforcement and fire rescue related to overdoses, including costs of administration of Narcan;

(e) costs for social services, including, but not limited to, addiction prevention programs; and

(f) costs of governmental services intended for children, families, youth, and other residents of the City of New Haven, which the City of New Haven would not have incurred but for the fraudulent omissions of Distributor Defendants as alleged herein.

Count VI
Negligent Misrepresentation
(Against the Manufacturer Defendants)

313. Plaintiff hereby incorporates by reference all preceding paragraphs as if fully set forth herein.

314. The Manufacturer Defendants have failed to exercise reasonable care in the marketing of their opioid products.

315. All Manufacturer Defendants represented that prescription opioids are relatively safe for the management of chronic pain when they knew, or should have known, that opioids are

highly addictive and have a high risk of overdose, death, or life-long damage to the brain of the person who is administered the drug for a medical indication for which it is not appropriate or for a time period or dosage which is inappropriate.

316. All Manufacturer Defendants made these statements and omissions with the intent that the City of New Haven and its residents would rely on them, and that it was reasonably foreseeable to the Manufacturer Defendants that such reliance would result in the use of opioid prescriptions by persons in quantities and for durations that would cause death or severe harm.

317. The City and its residents did in fact rely on the Manufacturer Defendants' false, misleading and unconscionable statements and the City of New Haven has sustained ascertainable losses as a direct and proximate result. Further, Manufacturer Defendants intended to deceive the physicians who prescribed opioids to the residents of New Haven and the payors who purchasers, or covered the purchase of, opioids for chronic pain.

318. In justifiable reliance on these incorrect statements, which reliance was foreseeable to the Manufacturer Defendants, physicians prescribed opioids for chronic pain, insurers and third-party payors (including Plaintiff) paid for them, and patients took them to devastating effect as described herein. Additionally, the City incurred expenditures, including, but not limited to:

(a) the cost of prescription drugs, including opioids;

(b) cost of governmental payor programs;

(c) health services for the treatment of addiction and overdoses;

(d) increased law enforcement and fire rescue related to overdoses, including costs of administration of Narcan;

(e) costs for social services, including, but not limited to, addiction prevention programs; and

(f) costs of governmental services intended for children, families, youth, and other residents of the City of New Haven, which the City of New Haven would not have incurred but for the unfair and deceptive acts and practice of Manufacturer Defendants.

319. Plaintiff has thus been damaged as alleged herein, as a direct and foreseeable consequence of the Manufacturer Defendants' negligent misrepresentations.

Count VII
Negligence
(Against the Distributor Defendants)

320. Plaintiff hereby incorporates by reference all preceding paragraphs as if fully set forth herein.

321. Distributor Defendants knew or should have known that controlled substances, due to their high propensity for diversion and misuse, are subject to strict reporting obligations and inventory monitoring in order to detect irregularity in buying patterns relating to the size and frequency of sale of controlled substances, as mandated by relevant state and federal law and regulations. Furthermore, Defendants knew or should have known that opioids buying patterns grossly deviated from the regular course both in quantity and frequency of purchases, yet failed to report, alert, or otherwise notify authorities of these irregular buying patterns.

322. Distributor Defendants knew, or should have known, at the time of failing to report the suspicious sales that their omissions operated to conceal the highly irregular and illegal flow of opioids into the City of New Haven. Indeed, Defendants negligently failed to slow down, inspect, report, alert, or otherwise limit the flow of these dangerous substances into the City of New Haven.

323. Distributor Defendants knew or should have known that the City of New Haven and its residents relied on their non-disclosure of the suspicious sales, and that it was reasonably foreseeable to the Distributor Defendants that such reliance would result in the continued and increased use of opioid prescriptions by persons in quantities, frequencies, and durations that would cause death or severe harm, and the City and its residents did rely on the Distributor Defendants' omission of the illegal and irregular buying patterns and the City of New Haven has sustained ascertainable losses as a direct and proximate result. Further, Distributor Defendants intended to deceive the payors who purchased or covered the purchase of opioids for chronic pain.

324. As a result of Distributor Defendants' negligent non-compliance with the state and federal reporting obligations, the City of New Haven incurred expenditures, including, but not limited to:

(a) the cost of prescription drugs, including opioids;

(b) cost of governmental payor programs;

(c) health services for the treatment of addiction and overdoses;

(d) increased law enforcement and fire rescue related to overdoses, including costs of administration of Narcan;

(e) costs for social services, including, but not limited to, addiction prevention programs; and

(f) costs of governmental services intended for children, families, youth, and other residents of the City of New Haven, which the City of New Haven would not have incurred but for the negligence of Distributor Defendants.

Count VIII
Unjust Enrichment
(Against all Defendants)

325. Plaintiff hereby incorporates by reference all preceding paragraphs as if fully set forth herein.

326. All Defendants received a material benefit from the City of New Haven expenditure of funds for the purchase of opioid prescriptions for its insured employees and retirees under the City's workmen's compensation and medical benefits plans.

327. At the time the City of New Haven made these expenditures, it did so in reliance and under the belief that it was provided with all the necessary and accurate information regarding the risks and benefits of opioid use. The City of New Haven relied on the truthfulness and accuracy of Defendants' misrepresentations and omissions to its detriment because it agreed to confer a benefit on Defendants, which the City of New Haven would not have done but for the wrongful conduct of Defendants.

328. Retention of these benefits by each of the Defendants would be unjust.

329. Additionally, it would be inequitable to allow the City of New Haven to continue to bear the cost of expenditures it was forced to make to try to support the health and safety of its residents, in the face of the opioid epidemic in its communities created by all the Defendants without shifting the full amount of those expenditures from the City of New Haven to the Defendants.

VI. PRAYER FOR RELIEF

WHEREFORE, the Plaintiff, City of New Haven demands judgment against each Defendant, jointly and severally, awarding Plaintiff:

1. A finding that by the acts alleged herein, all Defendants violated the Connecticut Unfair Trade Practices Act (CUTPA), Conn. Gen. Stat. §42-11a, *et seq*.;

2. A finding that by the acts alleged herein the defendants have created a public nuisance;

3. Compensatory damages in an amount sufficient to compensate Plaintiff for all its damages;

4. An award of the all statutory damages, including and punitive damages, pursuant to CUTPA;

5. Disgorgement of the unjust enrichment gained by Defendants as a result of their unlawful conduct

6. All appropriate injunctive relief necessary to fully abate the public nuisance created by Defendants.

7. Attorneys' fees and costs pursuant to CUTPA.

8. For all other relief deemed to be appropriate by the Court.

VII. JURY DEMAND

Plaintiff hereby demands a trial by jury.

DATED: October 25, 2017

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