IN THE UNITED STATES DISTRICT COURT

FOR THE DISTRICT OF MINNESOTA

CITY OF DULUTH, MINNESOTA,

Plaintiff,

v.

PURDUE PHARMA L.P.; INSYS THERAPEUTICS, INC.;TEVA PHARMACEUTICAL INDUSTRIES, LTD.; TEVA PHARMACEUTICALS USA, INC.; CEPHALON, INC.; JOHNSON & JOHNSON; JANSSEN PHARMACEUTICALS, INC.; ENDO INTERNATIONAL PLC; ENDO PHARMACEUTICALS, INC.; MALLINCKRODT LLC; MALLINCKRODT PLC; ALLERGAN PLC F/K/A ACTAVIS PLC; WATSON PHARMACEUTICALS, INC. N/K/A ACTAVIS, INC.; WATSON LABORATORIES, INC.; ACTAVIS LLC; ACTAVIS PHARMA, INC. F/K/A WATSON PHARMA, INC.; MCKESSON CORPORATION; CARDINAL HEALTH, INC.; and AMERISOURCEBERGEN CORPORATION, OMNICARE DISTRIBUTION CENTER LLC; AND MASTERS PHARMACEUTICAL, INC.

Defendants.

Case No. 0:19-cv-01077

COMPLAINT AND DEMAND FOR JURY TRIAL

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**Pro Hac Vice* admission to be sought

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Plaintiff City of Duluth, Minnesota, by and through its counsel of record, HOFF BARRY, P.A., complains and states as follows.

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I. INTRODUCTION

1. The use of highly addictive narcotic drugs such as oxycodone, hydrocodone, methadone, fentanyl, codeine, and others (hereinafter, "**opioids**") has become a national epidemic of chemical addiction in the United States.[1] Across the country, Americans are addicted to prescription drugs, synthetic opioids, and heroin at levels unprecedented in U.S. history. The opioid epidemic has led to carnage and devastation—including the loss of over 33,000 lives annually, the destruction of countless families and homes, and the incarceration of hundreds of thousands of addicts who have turned to crime to support their chemical addictions. The United States comprises less than 5% of the world's population but consumes over 80% of the world's opioid products.

2. Drug overdoses are one of the leading causes of injury and death in the United States and are currently at the highest level ever recorded. Every year since 2011, fatal drug overdoses outnumbered deaths by firearms and motor vehicle crashes. In 2015, approximately 140 people died every day from drug poisoning associated with opioids.

3. The opioid epidemic is unsparing in the victims it claims. Opioids—profligately sold to treat virtually any ailment—destroy the lives of countless men and women who have the misfortune of suffering not only from severe chronic pain, but also

[1] Traditionally, the term "opiate" is used in pharmacology to refer to drugs derived from opium. Opiates are alkaloid compounds naturally found in the opium poppy plant, Papaver somniferum. These opiate alkaloid compounds include heroin, morphine, codeine, and thebaine; each has a high potential for addiction. "Opioid" is a more modern term used to refer to all substances, both natural and synthetic, that bind to opioid receptors in the human brain. Opioid is, therefore, a broader term than opiate, and it also encompasses synthetic opiates (e.g., fentanyl, meperidine, and methadone) and semi-synthetic opiates (e.g., hydrocodone, hydromorphone, oxycodone, and oxymorphone).

from relatively minor conditions, such as back pain, arthritis, workplace injuries, and a countless array of other term-limited painful conditions. Opioids devastate families whose teenaged sons and daughters were killed by accidental overdoses. America's raging opioid epidemic turbocharges the heroin trade, as people addicted to prescription opioids often end up turning to highly potent street drugs.

4. These diverse manifestations of the opioid epidemic are all rooted in a common cause: corporate greed. As patients throughout the country became addicted to opioids, manufacturers and distributors of opioids became addicted to the immense profits associated with the widespread consumption of opioids. Motivated by their own bottom lines, these corporate actors looked the other way as the epidemic unfolded.

5. Beginning in the mid-1990s, drug manufacturers aggressively over-promoted highly addictive, dangerous opioid products—falsely telling both the federal government and the medical community that the risk of opioid addiction and dependence was low. In violation of federal law, the Manufacturer Defendants, as defined below, also misled the government and the public about various aspects of the drugs, promoting opioids as miracle pills that could relieve pain without any real risk of addiction. Building upon those falsehoods, the Manufacturer Defendants launched and funded aggressive campaigns to convince doctors and the public that opioids could safely be used as a daily treatment for chronic pain.

6. The misinformation campaign worked. Across the country, doctors began prescribing highly addictive opioids for ailments ranging from neck pain to headaches. At the same time, in response to the aggressive marketing campaigns, public demand for

opioids soared. That demand, in turn, created a cottage industry of "pill mills," where unscrupulous doctors handed out opioid prescriptions for even the most minor (claimed) ailments, without any consideration of the drugs' highly addictive properties.

7. As a direct result of drug manufacturers' deceit and greed, America quickly became awash in prescription opioids. Neither the State of Minnesota nor the City of Duluth was spared from the tsunami of highly addictive opioids. Indeed, in 2012, there were 62 opioid prescriptions written for every 100 people in the State of Minnesota.[2]

8. Predictably, many of these highly addictive opioids ultimately found their way into the black market. There, they were sold to recreational users, to former pain patients suffering from addiction, and to children and teenagers, many of whom in turn became addicted. When addicted people were unable to afford prescription drugs—or when they reached a point where prescription opioids no longer satiated their withdrawal symptoms—many of them turned to an even deadlier opioid: heroin.

9. If corporate actors had only followed federal law, the torrential flow of prescription opioids into American homes, schools, towns, and cities might have been slowed to a trickle. Cognizant that opioids can have devastating effects if diverted to the black market, Congress created a system requiring any drug manufacturer or wholesale distributor to: (1) report suspicious orders of prescription opioids to the Drug Enforcement Administration ("**DEA**"); and (2) perform required due diligence prior to

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[2] CTR. FOR DISEASE CONTROL & PREVENTION, https://www.cdc.gov/vitalsigns/opioid-prescribing/infographic.html#map (last accessed April 1, 2019).

filling any suspicious orders. *See* 21 U.S.C. § 823(b)(1); 21 C.F.R. § 1301.74(b). Had those requirements been followed, manufacturers and wholesale distributors of opioids could have dramatically reduced opioid abuse.

10. Instead, manufacturers and wholesale distributors opted not to follow federal law. When presented with absurdly large opioid orders, manufacturers and wholesale distributors simply looked the other way.

11. In prioritizing profit over legal duty, the prescription drug industry wreaked havoc on the lives of countless Americans. Along the way, the industry's practices significantly and negatively impacted public funds of local governmental entities across the country, forcing municipalities to shoulder increased costs associated with the opioid epidemic.

12. As in communities across the country, the adverse effects of opioid addiction radiate through the City of Duluth. When workers in the City become addicted, it decreases their productivity and their earning power, and ultimately harms the local economy. When heads of households fall victim to the opioid epidemic, the children that rely on them fall victim as well, increasing the strain on social-service providers. The opioid epidemic has, perhaps, its most pernicious effects in neighborhoods where drugs are sold. The illegal drug trade often invites violence and decimates the quality of life for innocent families living nearby. The opioid epidemic has contributed to the destabilization of communities and neighborhoods in Duluth and elsewhere, and, in turn, has deprived the City of Duluth of tax revenue and increased the costs of delivering city services.

13. Plaintiff, the City of Duluth, accordingly brings this civil action to eliminate or, at a minimum, reduce the imminent threat to public health and safety in Duluth caused by the opioid epidemic, to abate the nuisance caused thereby, and to recoup municipal monies spent to address the harm that resulted from: (1) Defendants' false, deceptive, and unfair marketing of prescription opioids, and (2) Defendants' failure to stop plainly suspicious orders of opioids. The economic damages suffered by Plaintiff were caused by the misuse of opioid products that were foreseeable to Defendants and were sustained through Defendants' patterns of activity directly resulting from their reckless, intentional, and unlawful acts and omissions.

II. PARTIES

A. City of Duluth

14. Plaintiff City of Duluth ("**Plaintiff**," "**Duluth**," "**City**," or "**City of Duluth**") is a municipal corporation with all the powers, functions, rights, and privileges granted by the constitution and laws of the State of Minnesota to municipal corporations of the first class operating under a home rule charter. Plaintiff's offices are located at Duluth City Hall, 411 West First Street, Duluth, Minnesota 55802.

15. The City of Duluth is the county seat of St. Louis County. According to the U.S. Census Bureau estimates, the City's population grew to 86,066 by 2017.

16. Plaintiff has standing to bring the instant claims including, inter alia, claims for violations under the Racketeer Influenced and Corrupt Organizations Act ("**RICO Act**"), because Plaintiff qualifies as a "person" within the meaning of the RICO Act. *See* 18 U.S.C. § 1961(3); 18 U.S.C. § 1964(c).

17. Plaintiff directly and foreseeably sustained the economic damages alleged herein. Defendants' conduct has imposed an extraordinary financial burden on Plaintiff, for which Plaintiff seeks relief. Plaintiff has sustained, and continues to sustain, damages including, without limitation: (1) municipal costs for providing additional health care and mental-health care services to people suffering from opioid-related addiction, opioid-related diseases, and opioid dependence, overdose, and death; (2) municipal costs for providing additional law-enforcement services, additional emergency-response services, and additional judicial and public safety services relating to the opioid epidemic; and (3) municipal health care costs for providing additional treatment and care for minors affected by parents and/or guardians suffering from prescription opioid-related addiction, dependence, overdose and death.

B. Manufacturers

18. Defendant Purdue Pharma L.P. is a Delaware limited partnership with its headquarters and principal place of business located in Stamford, Connecticut. The company maintains four operational branches: Purdue Pharma L.P., the Purdue Frederick Company, Purdue Pharmaceutical Products L.P., and Purdue Products L.P. (collectively referred to herein as "**Purdue**").

19. Purdue manufactures, promotes, distributes, and sells prescription opioids such as OxyContin, MS Contin, Dilaudid/Dilaudid HP, Butrans, Hysingla ER, and Targiniq ER. These opioids are manufactured in the United States and promoted, distributed, and sold across the U.S., including in the State of Minnesota and the City of Duluth. OxyContin is Purdue's best-selling opioid. Since 2009, Purdue's annual sales of OxyContin have fluctuated between $2.47 billion and $2.99 billion, up four-fold from its

2006 sales of $800 million. OxyContin constitutes roughly 30% of the entire market for analgesic drugs, otherwise known as painkillers.

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

21. Defendant Teva Pharmaceutical Industries Ltd. ("**Teva Ltd.**") is incorporated under the laws of the State of Israel with its headquarters and principal place of business in Petah Tikva, Israel. Since Teva Ltd. acquired Cephalon, Inc., its U.S. sales and marketing activities have been conducted by Defendant Teva Pharmaceuticals USA, Inc.

22. Defendant Teva Pharmaceuticals USA, Inc. ("**Teva USA**"), a Delaware corporation, is a wholly-owned operating subsidiary of Teva Ltd. Teva USA's headquarters and principal place of business are in North Wales, Pennsylvania. Teva Pharmaceutical Industries Ltd. and Teva Pharmaceuticals USA, Inc. are collectively referred to herein as "**Teva**." Cephalon, Inc., Teva Ltd. and Teva USA are collectively referred to herein as "**Cephalon**."

23. Cephalon manufactures, promotes, distributes, and sells prescription opioids such as Actiq and Fentora. These opioids are manufactured in the United States and promoted, distributed, and sold across the U.S., including in the State of Minnesota and the City of Duluth. Actiq and Fentora have been approved by the United States Food and Drug Administration ("**FDA**") only for the "management of breakthrough cancer

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

24. Defendant Endo International PLC ("**Endo PLC**") is a public limited company organized under the laws of the State of Ireland with its headquarters and principal place of business in Dublin, Ireland.

25. Defendant Endo Pharmaceuticals Inc. ("**Endo Inc.**") (Endo International PLC and Endo Inc. are collectively referred to herein as "**Endo**") is a Delaware corporation with its headquarters and principal place of business in Malvern, Pennsylvania. Endo Pharmaceuticals Inc. is an indirectly wholly-owned subsidiary of Endo International PLC.

26. Endo manufactures, promotes, distributes, and sells prescription opioids such as Opana/Opana ER, Percodan, Percocet, and Zydone. These opioids are manufactured in the United States and promoted, distributed, and sold across the U.S., including in the State of Minnesota and the City of Duluth. In 2012, opioids made up roughly $403 million of Endo's $3 billion total revenues. Opana ER yielded $1.15 billion in revenue from 2010 and 2013, and the drug accounted for 10% of Endo's total revenue in 2012. Additionally, Endo manufactures, promotes, distributes, and sells generic opioids such as oxycodone, oxymorphone, hydromorphone, and hydrocodone products. These opioids are manufactured in the United States and promoted, distributed, and sold across the U.S., including in the State of Minnesota and the City of Duluth, by and through Endo and its subsidiary, Qualitest Pharmaceuticals, Inc.

27. Defendant Janssen Pharmaceuticals, Inc. ("**Janssen**"), formerly known as Ortho-McNeil-Janssen Pharmaceuticals, Inc. and Janssen Pharmaceutica, is a New Jersey corporation with its headquarters and principal place of business in Titusville, New Jersey and Raritan, New Jersey. Janssen is a wholly-owned subsidiary of Johnson & Johnson, a New Jersey corporation with its principal place of business in New Brunswick, New Jersey.

28. Janssen manufactures, promotes, distributes, and sells prescription opioids such as Duragesic, Nucynta, and Nucynta ER. These opioids are manufactured in the United States and promoted, distributed, and sold across the U.S., including in the State of Minnesota and the City of Duluth. Prior to 2009, Duragesic accounted for at least $1 billion in annual sales. Prior to January 2015, Janssen manufactured, promoted, distributed, and sold the prescription opioids Nucynta and Nucynta ER. In 2014, Nucynta and Nucynta ER collectively accounted for $172 million in sales.

29. Defendant Insys Therapeutics, Inc. ("**Insys**") is a Delaware corporation with its headquarters and principal place of business in Chandler, Arizona. Insys manufactures, promotes, distributes, and sells prescription opioids such as Subsys. These opioids are manufactured in the United States and promoted, distributed, and sold across the U.S., including in the State of Minnesota and the City of Duluth.

30. Defendant Mallinckrodt PLC ("**Mallinckrodt PLC**") is a public limited company organized under the law of the State of Ireland with its headquarters and principal place of business in Staines-Upon-Thames, Surrey, United Kingdom.

31. Defendant Mallinckrodt LLC ("**Mallinckrodt Pharma**") (Mallinckrodt PLC and Mallinckrodt Pharma are collectively referred to herein as "**Mallinckrodt**") is a Delaware limited liability company with its headquarters and principal place of business in Hazelwood, Missouri.

32. Mallinckrodt manufactures, promotes, distributes and sells prescription opioids such as Exalgo, Roxicodone, Xartemis XR, Methadone, Morphine sulfate extended release, and fentanyl, among other generic opioids. These opioids are manufactured in the United States and promoted, distributed, and sold across the U.S., including in the State of Minnesota and the City of Duluth. Mallinckrodt is the largest U.S. supplier of prescription opioid pain medications and is among the top ten generic pharmaceutical manufacturers of prescription opioid pain medications in the United States, based on prescriptions.

33. Defendant Allergan PLC, formerly known as Actavis PLC, is a public limited company incorporated under the laws of the State of Ireland with its headquarters and principal place of business in Dublin, Ireland.

34. Defendant Watson Pharmaceuticals, Inc., now known as Actavis, Inc., is a Delaware limited liability company with its headquarters and principal place of business in Parsippany, New Jersey.

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

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

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

38. Watson Pharmaceuticals, Inc., Watson Laboratories, Inc., Actavis LLC, and Actavis Pharma, Inc. are owned by Allergan PLC, which operates subsidiary companies to market and sell pharmaceutical drugs in the U.S. Upon information and belief, Allergan PLC exercises control over each subsidiary company, including marketing and sales efforts. Upon information and belief, profits from the sale of Allergan PLC products ultimately inure to Allergan PLC's benefit.

39. Allergan PLC, Actavis PLC, Watson Pharmaceuticals, Inc., Actavis, Inc., Watson Laboratories, Inc., Actavis LLC, Actavis Pharma, Inc., and Watson Pharma, Inc. are collectively referred to herein as "**Actavis**."

40. Actavis manufactures, promotes, distributes, and sells prescription opioids such as the brand-name drugs Kadian and Norco, a generic version of Kadian, and generic versions of Duragesic and Opana. These opioids are manufactured in the United States and promoted, distributed, and sold across the U.S., including in the State of Minnesota and the City of Duluth.

41. The manufacturer defendants listed above are all engaged in the manufacturing of opioids. The manufacturer defendants listed above are collectively referred to herein as the "**Manufacturer Defendants**."

C. Distributors

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

43. Defendant Cardinal Health, Inc. ("**Cardinal Health**") is a Delaware corporation with its headquarters and principal place of business located in Dublin, Ohio.

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

45. Defendant Omnicare Distribution Center LLC ("**Omnicare**") is a Delaware limited liability company with its headquarters and principal place of business in Cincinnati, Ohio.

46. Defendant Masters Pharmaceutical, Inc. ("**Masters**") is an Ohio limited liability company with its headquarters and principal place of business in Cincinnati, Ohio.

47. The distributor defendants listed above are all engaged in the wholesale distribution of opioids. The distributor defendants listed above are collectively referred to herein as the "**Distributor Defendants**."

48. The Manufacturer Defendants and Distributor Defendants are collectively referred to herein as the "Defendants."

III. JURISDICTION AND VENUE

49. This Court has subject matter jurisdiction over this action in accordance with 28 U.S.C. § 1332(a). Complete diversity exists between Plaintiff (a citizen of the

State of Minnesota) and Defendants (citizens of states other than Minnesota). The amount in controversy exceeds the sum or value of $75,000, exclusive of interest and costs.

50. This Court also has subject matter jurisdiction under 28 U.S.C. § 1331 based upon the federal claims asserted under the Racketeer Influenced and Corrupt Organizations Act, 18 U.S.C. § 1961, et seq. ("**RICO Act**"). This Court has supplemental jurisdiction over Plaintiff's state law claims pursuant to 28 U.S.C. § 1367, as the state law claims are so related to Plaintiff's federal law claims that the claims form part of the same case or controversy.

51. Venue is proper within this District pursuant to 28 U.S.C. § 1391, as this District is a judicial district where Defendants are subject to personal jurisdiction in accordance with 28 U.S.C. §§ 1391(a) and (c), as well as Minn. Stat. § 543.19, the Minnesota Long-Arm statute.

52. This Court has personal jurisdiction over Defendants because they conduct business in Minnesota, purposefully direct or directed their actions toward Minnesota, consented to be sued in Minnesota by registering an agent for service of process in Minnesota, consensually submitted to the jurisdiction of Minnesota when obtaining a manufacturer or distributor license, and have the requisite minimum contacts with Minnesota necessary to constitutionally permit this Court to exercise jurisdiction.

53. Defendants are non-domiciliaries of the State of Minnesota and regularly engage in business within the State of Minnesota. Defendants have committed tortious acts outside and within the State of Minnesota that have caused injury within Minnesota to the City of Duluth. Defendants expect or should reasonably have expected those acts to

have consequences in the State of Minnesota. Defendants, moreover, solicited business within the State of Minnesota, engaged in persistent courses of conduct in the State of Minnesota, and derived substantial revenue from goods used and services rendered in the State of Minnesota through interstate commerce.

54. Defendants are regularly engaged in the business of manufacturing, distributing, and dispensing prescription opioids, either directly or indirectly through third-party related entities, in the State of Minnesota and, specifically, in the City of Duluth. Defendants' activities in the City of Duluth in connection with the manufacture, distribution, and dispensation of prescription opioids was, and is, continuous and systematic, and gave rise to the causes of action alleged herein.

IV. GENERAL FACTUAL ALLEGATIONS

55. Substance-abuse addiction is generally understood as a primary, chronic disease of brain reward, motivation, memory, and related circuitry. It develops over time, has no known cure, and requires continuous monitoring and treatment if serious disability and/or death are to be avoided.

56. Rather than resulting from a moral failing or lack of willpower, substance-abuse addiction is caused by the effects of repeated substance use on neurotransmission, and on interactions within reward structures of the human brain. In turn, these effects alter motivational hierarchies and cause addictive behaviors which supplant healthy, self-care related behaviors.

57. Opioids fall in a class of drugs containing molecules that bind to naturally occurring opioid receptors in the human brain. When those molecules are in place, they block the brain's pain signalling mechanism. In addition, by blocking the brain's

dopamine-regulation mechanism, opioids cause a massive release of dopamine (in turn causing euphoria, drowsiness, and slowed breathing). Over time, a patient's dose must be increased to produce the same pain-relieving effects, and the patient will experience worsening withdrawal symptoms when the drug is not present in the body.

58. Opioids have been known to be lethally poisonous and intensely habit forming since the dawn of human civilization. Indeed, opium has been derived from the poppy plant cultivated since neolithic times and was likely mankind's first drug. Since that time, humans have derived from the poppy plant various opioids including morphine, laudanum, codeine, thebaine, hydrocodone, oxymorphone, and heroin.

59. The common denominator in most opioids is the highly addictive morphine molecule, found in the poppy plant. The lone exceptions are synthetic opioids like fentanyl. Otherwise, the opioids at issue in this case are all produced from the morphine-containing opium poppy plant.

60. For over a century, pharmaceutical companies have attempted to change the chemical composition of naturally occurring opioids to create a drug that targets pain without creating addiction. These efforts, however, have consistently resulted in unequivocal failure.

61. Heroin, for example, was invented in the nineteenth century and was derived from opium to find a non-addictive form of morphine. Now widely known as a highly addictive street drug, heroin was initially marketed as an addiction-proof pain medication. Indeed, the word "heroin" is in fact a brand name invented by the pharmaceutical company Bayer.

62. The similarities between the marketing of heroin and the marketing of prescription opioids are strikingly similar. Much like the opioids at issue in this complaint, a perverse parade of salesman and traveling promoters once claimed that heroin was non-addictive and safe in virtually every clinical context. Of course, those claims turned out to be false. And the pharmaceutical industry, having profited greatly from heroin, left a generation of addicts in its wake.

63. For much of the twentieth century (and partially because of the catastrophic failure of purportedly "addiction-proof" heroin) long-term opioid use was primarily reserved for palliative care for cancer patients in severe pain or for the terminally ill. Doctors and medical professionals understood the serious risks associated with any opioid use exceeding mere days. Those risks, including addiction, overdose, and death, significantly outweighed the benefits of the drug's pain-relieving effects.

64. Accordingly, prior to the 1990's, doctors used opioid pain relievers sparingly, and only in the short term, for cases of severe injury or illness, or during surgery.[3] Doctors' reluctance to use opioids for an extended period, despite their short-term effectiveness for pain, sprang from the legitimate fear of causing addiction.

65. In addition, Congress enacted laws which strictly regulated the marketplace for medical opioids. Pursuant to the Controlled Substances Act of 1970 ("**CSA**"), the DEA annually caps the aggregate number of opioids that could be produced in the United States. 21 U.S.C. § 826(a); 28 C.F.R. § 0.100. Under the CSA, moreover,

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[3] Meldrum ML, *Progress in Pain Research and Management*, Vol. 25 Seattle, WA: IASP Press; 2003.

opioids can be sold only through a controlled, highly regulated distribution network that requires manufacturers and wholesale distributors to act as substance-abuse watchdogs, and report any suspicious orders of opioids to the DEA. 21 C.F.R. § 1301.74(b).

66. But beginning in the late 20th century, and continuing through today, the pharmaceutical industry acted to dramatically expand the marketplace for opioids. As set forth below, pharmaceutical actors facilitated this expansion in two ways. First, pharmaceutical manufacturers engaged in a misinformation campaign that altered public perceptions of opioids, and deceived doctors, federal regulators, and the public about their addictive qualities. Second, opioid manufacturers and wholesalers flouted their federally imposed requirements to report suspicious opioid orders to the DEA. That, in turn, facilitated an explosion in the illegitimate marketplace for prescription opioids.

A. The Manufacturer Defendants' Misinformation Campaign Regarding Opioids

67. The story of the present-day opioid crisis begins with opioid manufacturers, specifically, with Manufacturer Defendants. Each of the Manufacturer Defendants produces one or more prescription opioid products. The Manufacturer Defendants, however, envisioned a bigger market for their product than mere short-term treatment for the terminally ill or severely injured.

68. In furtherance of their quest for market expansion, the Manufacturer Defendants undertook a concerted campaign to misrepresent the addictive qualities of their product, and to push opioids as a safe, effective drug which could treat a variety of non-cancer, non-terminal patients. In so doing, the Manufacturer Defendants successfully

rebranded what is essentially morphine and convinced doctors to prescribe it for bad backs, arthritis, and headaches, among other chronic conditions.

69. The Manufacturer Defendants were able to influence doctor prescribing habits by supporting "academic" physicians, funding and/or creating professional medical societies, and donating large sums to regulatory agencies. Individually, and as a group, the Manufacturer Defendants manipulated and misrepresented medical science to sell as many opioids as possible.

70. The Manufacturer Defendants, individually and as a group, encouraged doctors to prescribe opioids more liberally and reassured them, based on false evidence, that the risk of becoming addicted to prescription opioids was less than one percent. That figure was tragically wrong. Recent studies reveal that as many as 56% of patients receiving long term opioid painkillers progress to addictive opioid use, including patients with no prior history of addiction.

71. Despite knowledge that their opioid products were as dangerous as heroin, opium, or morphine, Manufacturer Defendants misrepresented these risks and fostered addiction as a central component of their business models with a total disregard for preventing addiction. The Manufacturer Defendants' goal was never to create non-addictive analgesics; if that were the case, the Manufacturer Defendants would not have used one of the most addictive substances known to man, the morphine molecule, as the primary active ingredient.

72. What the Manufacturer Defendants realized is that opioids are a perfect inelastic manufactured good. Patients treated with opioids, once they become addicted,

do not have the free will to choose not to purchase the product. Given enough time on opioids, a patient will need higher and higher doses just to stave off the ever-looming and life-threatening effects of opioid withdrawal for which the only short-term remedy is more opioids.

73. During the 1980s and 1990s, the Manufacturer Defendants introduced new opioid drugs and sought to maximize the market for them. They did so by taking advantage of, and massively taking out of context, a single letter to the editor in the New England Journal of Medicine. They then funded purportedly neutral foundations and organizations to convince doctors and the public that, contrary to what doctors and the public had previously been taught, opioids were safe and could be addiction-proof.

74. The Manufacturer Defendants' campaign of deception regarding the addictive nature of opioids was rooted in two pieces of purportedly "scientific" evidence. The first piece of evidence was a letter to the editor published in 1980 in the New England Journal of Medicine. The letter was drafted by Hershel Jick, a doctor at Boston University Medical Center, with the help of a graduate student, Jane Porter. It noted, anecdotally, that a review of "current files" did not indicate high levels of addiction among hospitalized medical patients who received narcotic preparation treatment. In full, the letter reads:

> 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.

Addiction rate in patients treated with narcotics, 302(2) NEW ENG. J. MED. 123 (Jan. 10, 1980).

75. The second major piece of "evidence" used by the Manufacturer Defendants was a 1986 study by Russell Portenoy, who was then 31 years old, in the medical journal Pain. The study, which had a patient cohort of merely 38 patients, claimed that opioids could be used for long periods of time to treat non-cancer related chronic pain without any risk of addiction. The rationale behind the study was that patients in pain would not become addicted to opioids because their pain drowned out the euphoria associated with opioids. As such, the study concluded that opioids should be freely administered to patients with fibromyalgia, headaches, finicky backs, and a host of other issues. According to Portenoy and his co-author, Dr. Kathleen Foley, "opioid maintenance therapy can be a safe, salutary and more humane alternative in those patients with intractable non-malignant pain and no history of drug abuse." Portenoy RK, Foley KM, *Chronic use of opioid analgesics in non-malignant pain: report of 38 cases*, 25 PAIN 171 (1986). Portenoy's study also cited Hershel Jick's one-paragraph letter to the New England Journal of Medicine.

76. Portenoy went on to serve as one of the pharmaceutical industry's most vocal advocates, regularly appearing at conferences and gatherings of medical professionals to promote the use of opioids for chronic, long-term pain.

77. In the years that have followed, both the New England Journal of Medicine letter and Portenoy's 1986 study have been expressly disavowed. Neither demonstrates that opioids can be safely prescribed for long-term, chronic pain.

78. In a taped interview in 2011, Portenoy admitted:

> I gave so many lectures to primary care audiences in which the Porter and Jick article was just one piece of data that I would then cite. I would cite 6 to 7 maybe 10 different avenues of thought or evidence, ***none of which represents real evidence***. And yet what I was trying to do was to create a narrative so that the primary care audience would look at this information in toto and feel more comfortable about opioids in a way they hadn't before . . . . [B]ecause the primary goal was to de-stigmatize, we often left evidence behind.
>
> . . . .
>
> It was clearly the wrong thing to do and to the extent that some of the adverse outcomes now are as bad as they have become in terms of endemic occurrences of addiction and unintentional overdose death, ***it's quite scary to think about how the growth in that prescribing driven by people like me led, in part, to that occurring***.[4]

79. As to the New England Journal of Medicine letter, Dr. Jick, in an interview with Sam Quinones decades after the letter was published, stated: "[t]hat particular letter, for me, is very near the bottom of a long list of studies that I've done. It's useful as it stands because there's nothing else like it on hospitalized patients. But if you read it carefully, it does not speak to the level of addiction in outpatients who take these drugs for chronic pain." The New England Journal of Medicine itself has since disavowed the letter, stating "[the letter] was heavily and uncritically cited as evidence that addiction was rare with long-term opioid therapy." 376 NEW ENG. J. MED. 2194,

[4] Live interview with Dr. Russell Portenoy, Physicians Responsible for Opioid Prescribing *available at* https://www.youtube.com/watch?v=DgyuBWN9D4w (last accessed October 21, 2018) (emphases added).

2194–95 (2017). "We believe," the journal continued, "that this citation pattern contributed to the North American opioid crisis by helping to shape a narrative that allayed prescribers' concerns about the risk of addiction associated with long-term opioid therapy." *Id.*

80. Indeed, the letter—because it was just a letter—did not describe how the data was gathered, the duration of the patients' treatment, or the purpose behind their treatment in the first place. But the New England Journal of Medicine is one of the premier medical journals in the country. And, given the journal's prestige, the five-sentence letter, combined with Portenoy's later study, was exactly what opioid manufacturers needed to push their products.

81. In the years following the publication of the New England Journal of Medicine letter, and the publication of Russell Portenoy's 1986 study, the Manufacturer Defendants introduced multiple new highly addictive opioid products into the market. Those new drugs included: Purdue's MS Contin (introduced in 1987) and OxyContin (1995); Janssen's Duragesic (1990), Nucynta (2008), and Nucynta ER (2011); Cephalon's Actiq (1998) and Fentora (2006); Endo's Opana and Opana ER (2006); and Insys' Subsys (2012).

82. To expand the markets for those new products, the Manufacturer Defendants engaged in a concerted push to convince doctors and the public that opioids were safe and effective for long-term pain relief. In large part, the Manufacturer Defendants turned to Russell Portenoy, the author of the 1986 Pain study. Because Portenoy's study dovetailed perfectly with the Manufacturer Defendants' marketing

strategy, within a decade, Portenoy was financed by "at least a dozen companies, most of which produced prescription opioids."[5]

83. By enlisting concept peddlers like Russell Portenoy to promote opioid analgesics, the Manufacturer Defendants successfully promoted the myth that opioids could be liberally prescribed for non-cancer related chronic pain, without any risk of addiction.

84. The Manufacturer Defendants funded these concept peddlers. In turn, these concept peddlers would speak at academic conferences to primary care physicians to de-stigmatize opioids and encouraged liberal prescription of narcotics for the treatment of non-cancer related chronic pain. Invariably, the key piece of "data" cited in support of the proposition that opioids could be safely used to treat chronic pain was the New England Journal of Medicine article.

85. In addition to funding and supporting concept peddlers like Portenoy, the Manufacturer Defendants funded multiple innocuously named front groups to convince doctors and medical professionals that opioids could safely be used as a long-term treatment for chronic pain. Those organizations included the American Pain Foundation (which received nearly 90% of its funding from the drug and medical device industry, including Manufacturer Defendants); the American Academy of Pain Management (which received funding from Manufacturer Defendants Endo, Janssen, and Purdue); and the American Pain Society.

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[5] Meier B., *Pain Killer: A Wonder Drug's Trail of Addiction and Death*, New York, NY: St. Martin's Press; 2003.

86. These purportedly neutral, industry-funded organizations took aggressive stances to convince doctors and medical professionals that America was suffering from an epidemic of untreated pain and opioids were the solution. For example, the American Pain Foundation, of which Dr. Portenoy was a director, urged tracking of what they called an epidemic of untreated pain. The American Pain Society, of which he was president, campaigned to make pain what it called the "fifth vital sign" that doctors should monitor, alongside blood pressure, temperature, heartbeat, and breathing.[6]

87. In 1996, the American Pain Society and the American Academy of Pain Management both funded almost entirely by the Manufacturer Defendants, issued a "landmark consensus," written in part by Portenoy, saying that there is little risk of addiction or overdose in pain patients. The consensus cited the "less than 1 percent" addiction figure and the Jick letter. To the contrary, the risk of addiction is as high as 56%.[7]

88. Concept peddlers including Portenoy, funded by the Manufacturer Defendants, also claimed that opioid analgesics have no "ceiling dosage" in that prescribing physicians should increase dosages for patients as high as necessary to treat non-cancer related chronic pain. Through their concept peddlers and neutral front groups, the Manufacturer Defendants also invented a term for drug seeking behavior: "pseudoaddiction." The term describes drug seeking behavior not as the result of

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[6] On June 16, 2016, at its annual meeting in Chicago, the American Medical Association ("**AMA**")—a legitimate medical organization—urged physicians to eliminate pain as the fifth vital sign.

[7] Martell BA, O'Connor PG, Kerns RD, Al E., *Systematic review: opioid treatment for chronic back pain: prevalence, efficacy, and association with addiction*, 146 ANN. INTERN. MED. 116 (2007).

addiction but as the result of under-prescribing. The solution for pseudoaddiction according to the Manufacturer Defendants is, unsurprisingly, to increase the dosage.

89. The Manufacturer Defendants' misinformation campaign worked as intended. Across the country, demand for prescription opioids exploded. Doctors and medical professionals, swayed by the Manufacturer Defendants' sophisticated propaganda machine, began prescribing prescription opioids for ailments ranging from headaches to neck pain to fibromyalgia. Over-prescription unleashed a wave of addiction, increasing the demand for opioids yet further. The Manufacturer Defendants' profits soared.

90. A key player in the Manufacturer Defendants' misinformation campaign, Russell Portenoy, has since admitted that the information the Manufacturer Defendants were pushing was false. "I gave innumerable lectures in the late 1980s and '90s about addiction that weren't true," Dr. Portenoy told a fellow doctor in 2010. "It was the wrong thing to do."[8]

91. Yet, despite the fact that 80 percent of the global opioid supply is consumed in the United States, concept peddlers, front groups, and the Manufacturer Defendants continue to maintain that pain is undertreated.

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[8] Thomas Catan and Evan Perez, *A Pain-Drug Champion Has Second Thoughts*, THE WALL STREET JOURNAL (Dec. 17, 2012).

B. The Manufacturer Defendants' Misrepresentations Regarding Their Specific Products

92. In addition to funding massive propaganda campaigns as to the safety of opioids, generally, each of the Manufacturer Defendants actively engaged in deceptive conduct with respect to their opioids. This deception, importantly, included deceiving the FDA about key qualities of their drugs.

i. Background on the FDA Approval Process

93. Pursuant to the Federal Food, Drug and Cosmetic Act ("**FDCA**"), new pharmaceutical drugs may not be marketed in the United States until the FDA determines that the drug is "safe for use" and effective for all "conditions prescribed, recommended, or suggested" on a drug's label. *See* 21 C.F.R. § 99.103; *see also* 21 C.F.R. § 201.5.

94. A company seeking to bring a new pharmaceutical drug to market in the United States must first go through a three-step FDA approval process:

> (a) First, the sponsoring company must conduct laboratory testing in animals to determine whether the drug will be relatively safe and, to some extent, effective. If animal testing indicates that the drug or compound is relatively safe, the company then submits an investigational new drug ("**IND**") application to the FDA to gain approval to test the product with human subjects;
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> (b) Second, the sponsoring company must conduct "clinical trials" on human subjects. Clinical trials are carried out sequentially in three phases—Phase I, II, and III studies. Each phase increases the number of subjects, and is designed to test for safety and efficacy of the drug for specific uses and patient populations; and
>
> (c) Third, after the clinical trials are completed, the company compiles the data and analysis into a new drug application ("**NDA**"). FDA then reviews the NDA, focusing on three major potential concerns: (i) safety and effectiveness in the drug's proposed use; (ii) appropriateness of the proposed labelling; and (iii) adequacy of manufacturing methods to assure the drug's strength, quality, and identity. After evaluating the NDA, the FDA will make the decision whether to approve or reject the drug.

95. When a drug is approved by the FDA, it means the drug manufacturer has satisfied the regulatory requirements set forth in the FDCA. It does not mean that the drug meets all state law requirements, or that it can be promoted for all uses in all populations.

96. Though the FDA plays an important role in approving drugs for use, its role is limited by the fact that it does not conduct its own clinical trials. The FDA must therefore rely heavily on the representations and reports made by the sponsoring company. For example, in the context of efficacy, the FDA can deny an application only if it finds the application lacks "substantial evidence that the drug will have the effect it purports or is represented to have [.]" 21 U.S.C. § 355(d)(5). The FDA's role is similarly circumscribed with respect to drug labelling. The FDA does not draft drug labels. Instead, the drug manufacturer submits proposed labelling and, unless the FDA finds, under FDCA standards, that the label is misleading, it must approve the label. 21 U.S.C. § 355(d).

97. Much of the FDA approval process, then, hinges on the good-faith, honest representations of the sponsoring company. And the duties of a drug company to act in good faith do not end with the approval process. To the contrary, even after the FDA approves a drug, the company manufacturing the drug continues to bear the responsibility of ensuring that the drug is manufactured, promoted, and labelled correctly.

98. Towards that end, sections 502(a) and 201(n) of the FDCA (21 U.S.C. §§ 352(a), 321(n)) impose on drug manufacturers an ongoing duty to fully and accurately disclose information in their possession relating to the efficacy of a drug—as well as

information relating to adverse events associated with that drug's use. These disclosures must appear in the drug's package insert, other labelling, and promotional materials.

99. Sections 502(a) and 201(n) of the FDCA (21 U.S.C. §§ 352(a) and 321(n)) further prohibit drug manufacturers from making misleading statements about the efficacy of a drug, from minimizing the risks of adverse events associated with that drug's use, or from making misleading claims that a drug is safer or more effective than other available medications.

100. The indications and dosages approved by the FDA are set forth in the drug's labelling, the content of which is also approved by the FDA.

101. The Food, Drug and Cosmetic Act defines "label" as "a display of written, printed, or graphic matter upon the immediate container of any article ..." See 21 U.S.C. § 321(k).

102. Furthermore, 21 C.F.R. § 202.1(l)(2) states:

> Brochures, booklets, mailing pieces, detailing pieces, file cards, bulletins, calendars, price lists, catalogs, house organs, letters, motion picture films, film strips, lantern slides, sound recordings, exhibits, literature, and reprints and similar pieces of printed, audio, or visual matter descriptive of a drug and references published (for example, the 'Physicians' Desk Reference') for use by medical practitioners, pharmacists, or nurses, containing drug information supplied by the manufacturer, packer, or distributor of the drug and which are disseminated by or on behalf of its manufacturer, packer, or distributor are hereby determined to be labeling as defined in section 201(m) of the act.

103. A manufacturer's statement that a drug is "effective" or "works" or "has been proven to . . . ." is understood to mean that well-controlled clinical studies support the use. Such a statement without clinical trial proof is misleading and a violation of a manufacturer's obligation to disclose the necessary information. *See* 21 C.F.R. § 99.205.

104. FDA also regulates the advertising and promotion of prescription drugs under the FDCA. FDA carries out this responsibility by ensuring that prescription drug advertising and promotion is truthful, balanced, and accurately communicated. FDA regulations require that promotional labeling and advertisements be submitted to the FDA at the time of initial dissemination (for labeling) and initial publication (for advertisements). The FDCA defines labeling to include all labels and other written, printed, or graphic matter accompanying an article. For example, promotional materials commonly shown or given to physicians, such as sales aids and branded promotional items, are regulated as promotional labeling.

ii. Each of the Manufacturer Defendants Flouted the FDA Approval Process for Their Respective Product(s)

105. Every Manufacturer Defendant flouted its duties under the FDCA for its particular product(s). Once Manufacturer Defendants were found to be in violation of the FDCA, the Manufacturer Defendants indirectly marketed through third parties to alter the way doctors viewed and prescribed opioids. To avoid FDA oversight, they disseminated through these third parties the unproven and deceptive messages that opioids were safe for the treatment of non-cancer related chronic pain, that opioids were virtually non-addictive, and that opioids were woefully under-prescribed to the detriment of patients who were needlessly suffering.

106. The Manufacturer Defendants did so by sponsoring pro-opioid front groups who published misleading prescription guidelines, articles, and Continuing Medical Education sessions ("**CMEs**"), and paid physicians thousands of dollars every

year to publicly opine on the safety, efficacy, and non-addictive nature of opioids for a wide variety of uses.

a. *Purdue*

107. Purdue manufactures, among other opioids, OxyContin. OxyContin is a so-called "delayed release" pill, in which doses of opioids are released into the bloodstream in specified amounts over a specified period.

108. Purdue claimed that OxyContin's "delayed release" mechanism was a game-changer, because (according to Purdue) one pill could provide the user with complete pain relief for 12 hours. That claim was front-and-center in Purdue's marketing materials. When Purdue launched OxyContin in the mid-1990s, it did so with the express claim that "[o]ne dose relieves pain for 12 hours, more than twice as long as generic medications."[9]

109. Purdue also claimed, repeatedly, that OxyContin's controlled release mechanism rendered the pill both effective and non-addictive.

110. Those claims were wrong. When evaluating the efficacy of OxyContin in Purdue's 1995 NDA, the FDA's medical review officer concluded that OxyContin had not been shown to have a significant advantage over conventional, immediate-release oxycodone taken 4 times daily other than a reduction in frequency of dosing.

111. Despite this, Purdue continued to claim that OxyContin's delayed release mechanism rendered it less addictive, less subject to abuse and to diversion into illegal

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[9] Harriet Ryan, et al., *"You Want A Description of Hell?" OxyContin's 12-Hour Problem*, THE LOS ANGELES TIMES (May 5, 2016).

channels, and less likely to build opioid tolerance and cause withdrawal symptoms than predecessor drugs.

112. Initially, OxyContin was available in 10 mg, 20 mg, 40 mg, and 60 mg tablets. 80 mg and 160 mg tablets were introduced in 1997 and 2001, respectively.

113. Any dose of OxyContin above 40mg can be deadly for a non-opioid tolerant individual.

114. Purdue spread misinformation to doctors about physical addiction, asserting that opioid seeking patients were not physically addicted, but suffered from pseudoaddiction caused by the under-treatment of pain.

115. Upon information and belief, Purdue introduced different dosage levels with the specific intent that patients would become addicted and subsequently graduate to a higher dosage level, into perpetuity. One key promotional message for OxyContin was that it was the drug "to start and to stay with."

116. Purdue claimed that OxyContin's delayed release formula would make it less susceptible to abuse, because the delayed release formula foreclosed a rapid release of oxycodone. At the same time, Purdue included directions, in the form of a safety warning on OxyContin, on how crushing OxyContin would result in a rapid release of oxycodone, thereby circumventing the delayed release formula.

117. Purdue intentionally, fraudulently, and maliciously misrepresented to consumers and doctors alike that OxyContin was an opioid that provided 12 hours of pain relief, despite explicit knowledge to the contrary.

118. Upon information and belief, even before OxyContin was approved by the FDA in 1996 for marketing and sales in the United States, Purdue had significant information indicating that OxyContin does not treat a patient's pain for 12 hours. Information in Purdue's possession included a clinical study at hospitals in Puerto Rico in 1989 during which more than a third of the study's subjects began complaining about pain in the first 8 hours, and about half required more medication before the 12-hour mark.

119. Upon information and belief, Purdue was incentivized to cling to its 12-hour claim of pain relief to protect its revenue stream because many available generic competitors successfully treated pain for less than 12-hour intervals. Without the 12-hours-of-pain-relief claim, OxyContin did not stand out from its competitors, which obviated the need for doctors to continue prescribing OxyContin over available less-expensive alternatives.

120. Upon information and belief, when Purdue began receiving reports from physicians, sales representatives, and independent researchers that OxyContin did not last 12 hours, it nevertheless clung to its 12-hour of pain relief claim. Instead of reconsidering its claims, Purdue instead recommended that doctors prescribe higher doses of OxyContin rather than more frequent doses.

121. Upon information and belief, Purdue deployed a team of hundreds of sales representatives to refocus physicians on 12-hour dosing, with company executives noting in internal documents that any consideration of more frequent dosing "needs to be nipped in the bud. NOW!"

122. As a result, patients taking OxyContin experienced higher highs, but also suffered much lower lows. Patients on whom OxyContin did not last the full 12 hours experienced agonizing pangs of acute withdrawal symptoms, and eventually became physically dependent on and addicted to opioids. That, in turn, increased patients' propensity to use opioids other than as prescribed,

123. By claiming that OxyContin offered 12 hours of relief, Purdue was able to include more oxycodone than any prescription opioids at that time. In fact, OxyContin is twice as potent as morphine.

124. From 1996 to 2001, Purdue conducted more than 40 national pain-management and speaker training conferences at lavish resorts in Florida, Arizona, and California. More than 5,000 physicians, pharmacists, and nurses attended these all-expenses-paid symposia, where they were recruited and trained for Purdue's national speaker bureau with the intent of influencing prescribing patterns towards prescribing opioids more liberally for non-cancer related chronic pain.

125. During that time, Purdue funded more than 20,000 pain-related educational programs through direct sponsorship or financial grants. In so doing, Purdue exerted enormous influence on physicians' prescribing practices throughout the country.

126. One of the cornerstones of Purdue's marketing plan was the use of sophisticated marketing data to influence physicians' prescribing patterns towards prescribing opioids more liberally for non-cancer related chronic pain.

127. Purdue (in an innovation that, on information and belief, was copied by other Manufacturer Defendants) compiled prescriber profiles on individual physicians

detailing their prescribing patterns, to influence doctors' prescribing patterns towards prescribing opioids more liberally for non-cancer related chronic pain.

128. Through these profiles, Purdue (and, on information and belief, other Manufacturer Defendants) could, and can, identify the highest and lowest prescribers of drugs in a single zip code, county, state, or the entire country.

129. One of the critical foundations of Purdue's marketing plan for OxyContin was to target the physicians who were the highest prescribers for opioids across the country.

130. Purdue's prescriber database also helped identify physicians with large numbers of chronic-pain patients and helped identify which physicians were simply the most frequent and, in some cases, the least discriminate prescribers.

131. A lucrative bonus system encouraged Purdue's sales representatives to increase sales of OxyContin in their territories, resulting in many visits by said sales representatives to physicians with high rates of opioid prescriptions, as well as a multifaceted "information" campaign aimed at high volume opioid prescribers. In 2001, in addition to the average sales representative's annual salary of $55,000, annual bonuses averaged $71,500, with a range of $15,000 to nearly $240,000.

132. Purdue paid $40 million in sales incentive bonuses to its sales representatives in 2001.

133. From 1996 to 2000, Purdue increased its internal sales force from 318 sales representatives to 671, and its total physician call list from approximately 33,400 to 44,500 to approximately 70,500 to 94,000 physicians. Through its sales representatives,

Purdue used a patient starter coupon program for OxyContin, providing patients with a free limited-time prescription for a 7-day to 30-day supply. When the program was discontinued, approximately 34,000 coupons had been redeemed nationally.

134. Purdue also distributed to health care professionals branded promotional items such as OxyContin fishing hats, stuffed plush toys, and music compact discs (''Get in the Swing With OxyContin''). That "swag" strategy was, according to the DEA, unprecedented for an opioid regulated under Schedule II of the CSA.

135. By getting more "non-pain" specialist physicians to prescribe opioids, and by equating the prescription of opioids to compassion for those in pain, Purdue pulled off a remarkably brilliant marketing campaign that was successful in removing the dangerous stigma surrounding its opioid drugs.

136. In much of its promotional campaign—in literature and audiotapes for physicians, brochures, and videotapes for patients, and its ''Partners Against Pain'' website—Purdue claimed that the risk of addiction from OxyContin was extremely small.

137. In addition, Purdue provided two promotional videos to physicians that, according to the FDA, appear to have made unsubstantiated claims and minimized the risks of OxyContin. The first video was available for about 3 years without being submitted to FDA for review.

138. In 2003, the FDA issued a warning letter to Purdue for spreading inaccurate information in OxyContin advertisements, and for failing to inform the public of important safety information about the drug. The letter found Purdue was in violation of the Food, Drug, and Cosmetic Act, 21 U.S.C. §§ 331(a) and (b), and 352 (n).

139. While Purdue did withdraw the offending promotional materials, rather than distributing a "Dear Healthcare Professional" ("**DHP"**) letter correcting the misinformation or altering the labeling for OxyContin, Purdue doubled down and instructed their sales force to "refocus" physicians if and when they learned that physicians believed their products were addictive.

140. The misinformation Purdue pushed out violated federal criminal law. On May 9, 2007, Defendant Purdue pleaded guilty, in federal court, to violations of 21 U.S.C. 331(a) and 331 (a)(2) for marketing and promoting OxyContin as less addictive, less subject to abuse and diversion, and less likely to cause tolerance and withdrawal than other pain medications.

141. Purdue thus knowingly misbranded OxyContin, and knowingly introduced misbranded OxyContin into interstate commerce, with the intent to defraud or mislead the medical community and consumers into believing OxyContin was less addictive, less subject to abuse and diversion, and less likely to cause tolerance and withdrawal than other pain medications.

142. Following its guilty plea, Purdue pivoted its promotion of OxyContin. De-emphasizing direct promotion, Purdue began to work primarily through patient advocacy organizations—or "Front Groups"—posing as neutral and credible professional organizations. In so doing, Purdue was able to deliberately mislead the medical community and the general public while avoiding FDA violations that would have been issued if it had conducted the same promotional campaigns directly.

143. The American Pain Foundation ("**APF**"), upon information and belief, received more than $10 million in funding from opioid manufacturers from 2007 through 2012. The primary opioid manufacturer contributors were Purdue and Endo. The APF, founded in 1997, described itself as the nation's largest advocacy group for pain patients.

144. APF published numerous guides and brochures for patients, doctors, and policymakers that minimized the risks of addiction and exaggerated the benefits associated with prescription opioids, including but not limited to the "Policymaker's Guide," sponsored by Purdue, which sought to dispel the "myth" that opioid pain medication leads to addiction.

145. At the heart of APF's messaging was that the risk of opioid addiction was overblown and opioids were underused as a treatment for pain. In December 2011, a ProPublica investigation found that in 2010, nearly 90% of APF's funding came from the drug and medical device community, including Manufacturer Defendants. On May 8, 2012, the U.S. Senate Finance Committee sent a letter to APF inquiring about its ties to drug manufacturers. That very same day, APF announced it was ceasing operations, effective immediately.

146. Purdue also funded "Responsible Opioid Prescribing," a guide sponsored by the Federation of State Medical Boards ("FSMB") and authored by Dr. Scott Fishman, former chairman and president of the now defunct APF in 2007. The guide was ultimately disseminated to 700,000 practicing doctors, with, upon information and belief, thousands of doctors in Minnesota receiving copies. A June 8, 2012 letter submitted by

FSMB to the Senate Finance Committee disclosed that Purdue paid $40,000 to fund the production of the guide. Purdue also paid the FSMB at least $822,400 from 1997–2012.

147. The "Responsible Opioid Prescribing" guide promoted the use of opioid pain relievers for both acute and chronic pain and severely minimized the risk of addiction, even claiming that opioids could be used safely (just with additional care) in patients assessed to have a risk of substance abuse. The guide promoted the widespread use of opioids, stating that "[p]atients should not be denied opioid medications except in light of clear evidence that such medications are harmful to the patient."

148. Additionally, the guide presented symptoms of genuine addiction as "pseudoaddiction" and taught doctors that the symptoms of addiction—such as demanding or manipulative behavior and obtaining opioid prescriptions from more than one physician—are actually pseudoaddiction, rather than addictive behavior that would necessitate the withdrawal of opioid treatment.

149. Upon information and belief, Purdue contributed funding to The American Academy of Pain Management ("**AAPM**"), a medical specialty society. AAPM issued a statement in 1997 that endorsed opioids and claimed that the risk of opioid addiction in people taking prescription opioids was low. The chairman of AAPM at that time was Dr. David Haddox. Dr. Haddox was, at the time of the statement, a paid speaker for Purdue. He later went on to become Purdue's vice president for health policy.

150. In 2009, the American Pain Society ("**APS**") and AAPM jointly issued guidelines ("**APS/AAPM Guidelines**") recommending the use of opioids to treat chronic pain. The APS/AAPM Guidelines promoted the use of opioids for the treatment of

chronic pain and concluded that the risk of opioid addiction was manageable in patients regardless of previous histories of abuse. At least fourteen of the twenty-one panel members who drafted the APS/AAPM Guidelines received funding from Manufacturer Defendants, including Purdue.

151. The APS/AAPM Guidelines have been relied upon by doctors to inform their treatment of pain. They were cited repeatedly in academic literature and were even reprinted in the monthly medical journal, Pain. Upon information and belief, pharmaceutical sales representatives employed by Purdue discussed the APS/AAPM Guidelines with doctors during sales calls.

b. *Cephalon, Inc.*

152. In 2008, the FDA found that Cephalon had promoted its fentanyl-containing lollipop, Actiq, for non-approved uses. Actiq had been "indicated" by the FDA for a specific use: to treat breakthrough pain in opioid-tolerant cancer patients who are already receiving around-the-clock opioid therapy. Cephalon, however, had been marketing Actiq for migraine headaches and other non-cancer pain, such as sickle-cell pain crises, and in anticipation of changing dressings or radiation therapy.

153. Cephalon also:

(a) had sales representatives call on doctors who would not normally prescribe such drugs in the course of their practice;

(b) trained sales representatives on techniques to prompt doctors into off-label conversations;

(c) structured its employees' compensation and bonuses in a manner that encouraged off-label marketing;

(d) had sales representatives instruct doctors how to get their patients' insurance to cover off-label uses;

(e) used grants for continuing medical education to promote off-label uses; and

(f) sent doctors to "consultant" meetings at lavish resorts to hear the company's off-label message.

154. As a result, Cephalon entered a plea agreement with the United States in which it admitted guilt to numerous violations of the FDCA and agreed to pay a record $425 million in penalties as part of a collective settlement related to the off-label market of multiple drugs, one including Actiq.

155. Cephalon was also required to: send letters to doctors about the settlement agreement to enable doctors to report questionable sales representative conduct; and post information about payments the manufacturer made to doctors on its website.

156. On March 26, 2009, Cephalon received a warning letter regarding its sponsored links on internet search engines (e.g. Google.com) for the opioid pain reliever Fentora, which made representations and/or suggestions about the efficacy of the said drug but failed to communicate any risk information.

157. The FDA found that the sponsored links omitted the most serious and frequently occurring risks associated with the Fentora, misleadingly suggesting Fentora is safer than demonstrated. The FDA also found that the sponsored link for Fentora made incomplete and misleading statements about what the drug is indicated for.

158. The FDA noted that the marketing material provided only a brief statement about what Fentora is indicated for, which was incomplete and misleading. Specifically, the marketing material suggested that Fentora is useful in a broader range of conditions or patients than was supported by substantial evidence in clinical experience. The advertisement implied that Fentora was indicated for breakthrough pain in any

patient with cancer, rather than only those who are already receiving, and already tolerant to, around-the-clock opioid therapy.

159. Additionally, the FDA found that the sponsored links did not present the full established name of said drug being promoted. Accordingly, the FDA found that Cephalon's sponsored links misbranded Fentora in violation of the Federal Food, Drug, and Cosmetic Act and FDA implementing regulations. *See* 21 U.S.C. §§ 352(a) & (n), 321(n); 21 CFR §§ 201.10(g)(1), 202.1(b)(1), (e)(3)(i), (ii) & (e)(6)(i).

160. On September 29, 2008, Cephalon pleaded guilty to violating 21 U.S.C. §§ 331(a), 331 (a) (1), and 352(f) (1) for marketing and promoting the opioid Actiq for medical indications that were not approved by the FDA.

161. Between January 1, 2001, and December 31, 2006, Cephalon thus knowingly and willfully promoted the sale and use of Actiq for certain uses which the FDA had not approved (i.e., "unapproved uses").

162. The FDA approved Actiq, a fentanyl product manufactured as a lollipop, for use only in opioid-tolerant cancer patients (meaning those patients for whom morphine-based painkillers are no longer effective).

163. Actiq is a strong and highly addictive narcotic, with significant potential for abuse. From 2001 through at least 2006, Cephalon was promoting the drug for non-cancer patients to use for such maladies as migraines, sickle-cell pain crises, injuries, and in anticipation of changing wound dressings or radiation therapy.

164. Cephalon promoted Actiq for use in patients who were not yet opioid-tolerant, and for whom it could have life-threatening complications and results.

165. Following its guilty plea, Cephalon pivoted to promoting Actiq through patient advocacy organizations or "Front Groups" posing as neutral and credible professional organizations in order to deliberately mislead the medical community and the general public while avoiding FDA violations. One such Front Group is APF.

166. At least fourteen of the twenty-one panel members who drafted the APS and AAPM Guidelines received funding from the Manufacturer Defendants, including Cephalon. The guidelines recommended the use of opioids to treat chronic pain and concluded that the risk of opioid addiction was manageable in patients regardless of previous histories of abuse.

167. Cephalon provided considerable funding to FSMB, including $180,000 from 1997 through 2012. It also funded APF before withdrawing its support due to a Senate investigation.

c. *Janssen Pharmaceuticals, Inc.*

168. On December 9, 1999, the FDA sent Janssen a letter indicating that it had reviewed a number of "homemade" marketing pieces that had been used by Janssen sales representatives for its fentanyl-based synthetic opioid, Duragesic. The FDA found those marketing pieces to be false or misleading because they contained misrepresentations regarding safety information, broadened Duragesic's indication for use, contained unsubstantiated claims, and lacked fair balance.

169. The FDA's warning letter provided the following examples of statements in the homemade marketing material that misrepresented safety information:

(a) "Significantly LESS constipation!", which suggested Duragesic had been demonstrated to be associated with less constipation than other available opioids, thus, minimizing the risk of constipation; and

(b) "Low abuse potential!", which suggested that Duragesic had less potential for abuse than other available opioids and minimized and contradicted fentanyl's status as a Schedule II controlled substance.

170. The FDA's warning letter provided the following example of a statement in the homemade marketing material that broadened Duragesic's indication for use: "It's not just for end stage cancer anymore!" That suggested that Duragesic can be used for any type of pain management and ignored the fact that Duragesic was indicated only for the management of chronic pain in patients who require continuous opioid analgesia for pain that cannot be managed by less powerful means. It also ignored the fact that use in persons other than those for whom Duragesic was indicated by FDA poses a high risk of death.

171. FDA's warning letter provided the following examples of unsubstantiated claims made in the homemade marketing material:

(a) "Preferred regimen: 2 x per week versus 2 x per day!";

(b) "Easy for Patient compliance."; and

(c) "And the #1 reason to convert your patients to the Duragesic patch: QUALITY OF LIFE," and "without pain, patient's [sic] sleep better, increase daily."

172. Janssen received further warning by way of a September 2, 2004 warning letter. That letter was in relation to Janssen's Duragesic patch. FDA found that a file card used by Janssen in connection with that patch contained false and misleading claims about the abuse potential of Duragesic, as well as unsubstantiated claims of the effectiveness of Duragesic. The FDA noted Janssen's representations could encourage the unsafe use of the drug, potentially resulting in serious or life-threatening hypoventilation, or even death.

173. The FDA requested a letter response (1) describing Janssen's intent to comply with FDA's requests, and (2) listing all promotional materials for Duragesic that were the same as or similar to the offending promotional materials. The FDA also requested that Janssen submit a plan for discontinuing use of the promotional marketing materials in question.

174. Janssen's promotional materials in question included:

(a) "low reported rate of mentions in DAWN data" along with Drug Abuse Warning Network (DAWN) data comparing fentanyl/combination to other listed opioid products, which suggested that Duragesic is less abused than other opioid drugs;

(b) "minimizes the potential for local GI side effects by avoiding GI absorption," which suggested that Duragesic is associated with less constipation, nausea, and vomiting than oral opioids;

(c) "demonstrated effectiveness in chronic back pain with additional patient benefits" which was based on an open-label, single arm trial with no control group which is clearly inadequate to support such a claim;

(d) "86% of patients experienced overall benefit in a clinical study based on: pain control, disability in ADLs, quality of sleep," "all patients who experienced overall benefit from Duragesic would recommend it to others with chronic low back pain," "significantly reduced nighttime awakenings," and "significant improvement in disability scores as measured by the Oswestry Disability Questionnaire and Pain Disability Index," which were again based on an open-label, single arm trial with no control group—a trial inadequate to support such claims;

(e) "Improved patient outcomes: Open-label, crossover comparison study," "Significant improvement in physical functioning summary score," and "Significant improvement in social functioning," which are based on an open label study lacking sufficient support for the cited claims; and

(f) "1,360 loaves . . . and counting," "Work, uninterrupted," "Life, uninterrupted," "Game, uninterrupted," "Chronic pain relief that supports functionality," "Helps patients think less about their pain," and "Improvements in physical and social functioning," which imply that patients will experience improved social or physical functioning, a claim for which Janssen lacks support.

The FDA stated it was not aware of any substantial evidence or clinical experience to support these comparative claims.

175. On September 2, 2004, the FDA determined that Duragesic was misbranded and in violation of Section 502(a) of the Food, Drug, and Cosmetic Act, 21 U.S.C. § 352(a).

176. Janssen thus made misleading safety claims and unsubstantiated effectiveness claims for Duragesic.

177. The FDA would not have approved Duragesic's label had Janssen disclosed misleading safety claims and unsubstantiated effectiveness claims for Duragesic at the time of the FDA approval process.

178. On August 26, 2011, Janssen received a warning letter regarding its opioid drug, Nucynta. The letter informed Janssen that the FDA had become aware of oral statements made by a Janssen representative that promoted an unapproved use for its opioid Nucynta, made unsubstantiated superiority claims about the drug, and minimized the serious risks associated with Nucynta.

179. The statements were made on December 8, 2010, at the 2010 American Society of Health-System Pharmacists ("**ASHP**") Midyear Clinical Meeting and Exhibition in Anaheim, CA.

180. The FDA requested a letter response that (1) described Janssen's intent to comply with the request, (2) listed all promotional materials for Nucynta that contained a violation resulting from the actions within the warning letter or similar to the actions in the warning letter, and (3) Janssen's plan for discontinuing use of such materials.

181. The Janssen representative promoted an unapproved use of Nucynta when the representative indicated that Nucynta is useful in the treatment of Diabetic Peripheral Neuropathic Pain ("**DPNP**"). Nucynta is not approved by the FDA for treatment of DPNP.

182. Janssen also made the following unsubstantiated superiority claims and statements that minimized the risk of Nucynta:

(a) "DPNP patients stay on Nucynta for longer, and Nucynta provides 10 mg of opioid/oxycodone pain control, similar to Tramadol, but with less GI, constipation, nausea, and vomiting," which is misleading and implied that Nucynta is clinically superior compared to oxycodone and Tramadol for DPNP patients; and

(b) When physicians prescribe Nucynta they "won't have to put patients on docusate or senna, patients get out of the hospital a day earlier which saves thousands of dollars because they are going to be able to have a bowel movement," which is misleading and implied that treatment with Nucynta has been shown to reduce the length of a hospital stay in comparison to oxycodone and Tramadol.

183. Following its FDA warnings, Janssen pivoted to promoting Duragesic and Nucynta through patient advocacy organizations or "Front Groups" posing as neutral and credible professional organizations in order to deliberately mislead the medical community and the general public while avoiding FDA violations. Such Front Groups included the APF, APS, and AAPM.

d. *Endo International PLC*

184. On June 8, 2017 the FDA requested that Endo voluntarily remove from the market reformulated Opana ER, an opioid that was purportedly crush-resistant and thus supposedly decreased the risk of addiction. The FDA informed Endo that the benefits of Opana ER may no longer outweigh the risks.

185. Contrary to Endo's statements, reformulated Opana ER hardly reduced the risk of abuse. Instead, abuse of reformulated Opana ER by injection resulted in a serious disease outbreak of HIV and hepatitis C, as well as cases of thrombotic microangiopathy (a serious blood disorder).

186. Endo claimed to have reformulated Opana ER to be resistant to abuse by patients who crush and snort prescription opioid pills. Instead, abuse shifted from insufflation (crushing and snorting) to intravenous injection.

187. The FDA released a statement confirming its decision was the first time that the FDA had taken steps to remove a currently marketed opioid pain medication from sale due to public health concerns of abuse. The request, while voluntary, also stated that the FDA intended to take steps to formally require its removal by withdrawing approval if Endo chose not to discontinue Opana ER.

188. Less than a month later, on July 6, 2017, Endo announced it would voluntarily remove Opana ER from the market after careful consideration and consultation with the FDA.

189. Endo was one of the primary contributors to the APF's numerous published guides and brochures for patients, doctors, and policymakers. The guides minimized the risks of addiction and exaggerated the benefits associated with prescription opioids, including but not limited "Exit Wounds: A Survival Guide to Pain Management for Returning Veterans & Their Families," sponsored by Endo, which falsely claimed that it is unlikely that people who are not predisposed to addiction will become addicted to opioid painkillers, and "Treatment Options: A Guide for People

Living with Pain," which promoted opioids as essential for treating even "moderate" pain.

190. A June 8, 2012 letter submitted by FSMB to the Senate Finance Committee disclosed that Endo paid $50,000 to fund the production of "Responsible Opioid Prescribing," a guide authored by Dr. Scott Fishman, former chairman and president of the now defunct American Pain Foundation in 2007. The guide was ultimately disseminated to 700,000 practicing doctors. Since that time, Endo has paid the FSMB at least $371,620.

e. *Actavis*

191. On February 18, 2010, the FDA issued a warning letter to Actavis, the manufacturer of the opioid Kadian and one of the predecessor companies to Allergan, for distributing a false and misleading co-pay assistance brochure and comparison detailer.

192. The FDA's findings were based on Actavis's omissions and its minimization of serious risks associated with Kadian in its brochure; Actavis's failure to present the limitations to Kadian's approved indication for use and its suggestions that it could be used for broader purposes than indicated; and its unsubstantiated claims of superiority and effectiveness.

193. The brochure presented several effectiveness claims regarding Kadian, but failed to present any contraindications and, additionally, omitted several warnings, precautions, drug interactions, and adverse events.

194. The brochure failed to present risk information with a prominence and readability that is reasonably comparable to the presentation of benefit information. The brochure also minimized the serious and significant risks associated with the use of

Kadian by describing the serious and potentially fatal risks in highly complex, medically technical language not likely to be understood by consumers. The brochure simply included the following language, "Please see accompanying complete Prescribing Information" in an effort to mitigate the misleading omission and/or minimization of risk information.

195. In direct marketing to consumers, Kadian's brochure included the following erroneous claims:

(a) "Allow for less breakthrough pain and more consistent pain relief for patients";

(b) "Better pain control";

(c) "Allow patients to live with less pain";

(d) "Allow individualization and customization of a patient's pain treatment";

(e) "Prescribe KADIAN® - Less pain for your patients. More options for you."; and

(f) "Less pain. More options."

196. The FDA informed Actavis that its brochure and detailer were false and misleading because they omitted and minimized the serious risks associated with Kadian, broadened and failed to present the limitations to the approved indication of Kadian, and presented unsubstantiated claims of superiority and effectiveness.

197. The FDA found Actavis' brochure and detailer for Kadian failed to include important and serious risk information, including contraindications, adverse events, and warnings regarding potentially fatal abuse of opioids.

198. The FDA also found Actavis' brochure and detailer presented broad claims about Kadian's use in treating pain, therefore implying that Kadian was appropriate for use in a broader range of patients than the patients for which FDA approval was granted.

199. Finally, the FDA found Actavis' detailer included efficacy claims and presentations which were unsubstantiated and misleading and implied Kadian was superior to other opioid therapies. The FDA found Actavis' brochure and detailer misbranded the drug in violation of the Food, Drug, and Cosmetic Act, 21 U.S.C. §§ 352(a) & 321(n); *cf.* 21 CFR §§ 202.1(e)(3), (e)(5), (e)(6), and (e)(7) (implementing regulations).

f. *Mallinckrodt*

200. On March 30, 2009, Mallinckrodt received a letter from the FDA stating that Mallinckrodt was found to have been marketing an unapproved new drug, morphine sulfate concentrate oral solution 20 mg/ml, in violation of 21 U.S.C. §§ 331(d) and 355(a).

201. The letter also stated that its unapproved morphine formulation was misbranded under 21 U.S.C. § 352(f)(1) because the conditions it was intended to treat were not amenable to self-diagnosis and treatment. Adequate directions for such use, therefore, could not be written. As a result, introduction or delivery for introduction into interstate commerce of its unapproved morphine formulation violated 21 U.S.C. § 331(a) and (d).

202. Mallinckrodt had been marketing its unapproved morphine formulation since 2005.

203. Mallinckrodt provided considerable funding to FSMB including at least $100,000.

204. Separately and together, Manufacturer Defendants thus engaged in a sustained misinformation campaign regarding both (1) the safety and efficacy of opioids generally; and (2) their products in particular. That misinformation campaign, propagated at times through industry-funded Front Groups, paid tremendous dividends. Across the country, including in the City of Duluth, doctors began prescribing powerful opioids for a wide range of ailments. In turn, patients became addicted, setting into motion the raging opioid epidemic plaguing America today.

C. Defendants' Failures to Maintain Effective Controls Against Diversion and Failures to Report Suspicious Orders

205. The opioid epidemic was further fuelled by all Defendants' failure to follow the specific mandates in the CSA requiring them to help ensure that highly addictive drugs are not diverted to illegal use. The brunt of the opioid epidemic could have been, and should have been, prevented had Defendants fulfilled their duties set by statute and common law. Defendants, who operate at every level of the opioid supply chain, had an obligation and duty to act. They did not—and the country, including the City of Duluth, paid the price.

206. The opioid supply chain begins with manufacturers (including Manufacturer Defendants), who manufacture and package the pill. Manufacturer Defendants then transfer the opioids to wholesale distributors (including Distributor Defendants). Collectively, Distributor Defendants account for over 90% of all drugs

distributed within the United States. Wholesale Distributors then dispense the opioids to hospitals and pharmacies. Those entities then dispense drugs to patients.

207. Recognizing that highly addictive drugs like opioids can be easily abused and diverted to the black market, Congress, in the Controlled Substances Act ("**CSA**") set forth two relevant controls on such drugs:

> (a) *First*, the DEA sets limits on the quantity of schedule II-controlled substances—such as opioids—that may be produced in the United States in any given year. 21 U.S.C. § 826(a); 28 C.F.R. § 0.100. The DEA determines these quotas based on a variety of data including sales, production, inventories, and exports. The DEA can and does lower quotas as a means of addressing abuse and diversion.
>
> (b) *Second*, Congress anticipated that highly addictive prescription drugs like opioids could be abused and diverted to the black market. The CSA thus sought to combat diversion of prescription narcotics by providing for a closed system of drug distribution in which every actor in the opioid supply chain, *i.e.*, manufacturers and wholesale distributors, must register with the DEA. Every registrant, in turn, is charged with being vigilant in deciding whether a customer, be it a pharmacy, wholesaler, or end customer, can be trusted to deliver or use controlled prescription narcotics only for lawful purposes. 21 U.S.C. § 823(e). Specifically, every registrant, including manufacturers and wholesale distributors, is required to "maintain effective control against diversion of particular controlled substances into other than legitimate medical, scientific, and industrial channels." 21 U.S.C. § 823(b)(1)

208. The CSA and its implementing regulations require all registrants to (1) report suspicious orders of prescription opioids to the DEA, and (2) perform required due diligence prior to filling any suspicious orders. See 21 U.S.C. § 823(b)(1); 21 C.F.R. § 1301.74(b). A "suspicious order" is defined as including "orders of unusual size, orders deviating substantially from a normal pattern, and orders of unusual frequency." 21 C.F.R. § 1301.74(b).

209. In addition, the Code of Federal Regulations requires all manufacturers and wholesale distributors to "design and operate a system to disclose to the registrant suspicious orders of controlled substances." 21. C.F.R. § 1301.74(b).

210. So, in addition to reporting suspicious orders, a registrant, whether a manufacturer or wholesaler, must exercise due diligence in confirming the legitimacy of all orders prior to filling.

211. The requirements imposed on Defendants by the CSA-including the requirements to report suspicious orders and create a system to disclose suspicious orders-are crucial. As the United States Supreme Court has explained, the CSA was Congress's attempt "to conquer drug abuse and to control the legitimate and illegitimate traffic in controlled substances." *Gonzales v. Raich*, 545 U.S. 1, 12 (2005).

212. "Congress," the Court has explained, "was particularly concerned with the diversion of drugs from legitimate channels. It was aware that registrants, who have the greatest access to controlled substances and therefore the greatest opportunity for diversion, were responsible for a large part of the illegal drug traffic." *United States v. Moore*, 423 U.S. 122, 135 (1975). Manufacturers and distributors must therefore be vigilant in deciding whether a prospective customer can be trusted to deliver controlled substances only for lawful purposes. This responsibility is critical, as Congress has expressly declared that the illegal distribution of controlled substances has a substantial and detrimental effect on the health and general welfare of the American people.

213. Reflecting the importance of CSA compliance, the DEA has repeatedly provided guidance to registrants emphasizing their obligations under the CSA. A DEA letter dated September 27, 2006, sent to every commercial entity in the United States registered with the DEA, outlined specific circumstances that might be indicative of diversion:

(a) Ordering excessive quantities of a limited variety of controlled substances while ordering few if any other drugs.

(b) Ordering a limited variety of controlled substances in quantities disproportionate to the quantity of non-controlled medications ordered.

(c) Ordering excessive quantities of a limited variety of controlled substances in combination with excessive quantities of lifestyle drugs.

(d) Ordering the same controlled substance from multiple distributors.

214. Additionally, the letter implored Distributor Defendants to know their pharmacy customers, and to follow-up with said pharmacy customers, regarding:

(a) What percentage of the pharmacy's business does dispensing controlled substances constitute?

(b) Is the pharmacy complying with the laws of every state in which it is dispensing controlled substances?

(c) Is the pharmacy soliciting buyers of controlled substances via the internet or is the pharmacy associated with an internet site that solicits orders for controlled substances?

(d) Does the pharmacy, or internet site affiliated with the pharmacy, offer to facilitate the acquisition of a prescription for a controlled substance from a practitioner with whom the buyer has no pre-existing relationship?

(e) Does the pharmacy fill prescriptions issued by practitioners based solely on an on-line questionnaire without a medical examination or bona-fide doctor-patient relationship?

(f) Are the prescribing practitioners licensed to practice medicine in the jurisdictions to which the controlled substances are being shipped, if such a license is required by state law?

(g) Are one or more practitioners writing a disproportionate share of the prescriptions for controlled substances being filled by the pharmacy?

(h) Does the pharmacy offer to sell controlled substances without a prescription?

(i) Does the pharmacy charge reasonable prices for controlled substances?

(j) Does the pharmacy accept insurance payment for purchases of controlled substances made via the internet?

215. In 2007, the DEA sent letters to every registered manufacturer or distributor of controlled substances, including Defendants. As stated in the letter, "the purpose of [the] letter [wa]s to reiterate the responsibilities of controlled substance manufacturers and distributors to inform the DEA of suspicious orders in accordance with 21 C.F.R. § 1301.74(b)."

216. In the letter, the DEA expressly warned that the regulation "requires that the registrant inform the local DEA Division Office of suspicious orders when discovered by the registrant." The DEA also warned that "[r]egistrants 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. Reporting an order as suspicious will not absolve the registrant of responsibility if the registrant knew, or should have known, that the controlled substances were being diverted."

217. In addition, the DEA warned that the "regulation specifically states that suspicious orders include orders of an unusual size, orders deviating substantially from a normal pattern, and orders of an unusual frequency. These criteria are disjunctive and are not all inclusive. For example, if an order deviates substantially from a normal pattern, the size of the order does not matter and the order should be reported as suspicious. Likewise, a registrant need not wait for a 'normal pattern' to develop over time before determining whether an order is suspicious. The size of an order alone, whether or not it deviates from a normal pattern, is enough to trigger the registrant's responsibility to report the order as suspicious. The determination of whether an order is suspicious depends not only on the order patterns of the particular customer, but also on the patterns of the registrant's customer base and the patterns throughout the relevant segment of the regulated industry."

218. Federal law imposes a duty upon Defendants to maintain effective controls against diversion of prescription opiates into other than legitimate medical, scientific, and industrial channels. 21 U.S.C.A. § 823(b)(1).

219. Federal law imposes a duty upon Defendants to comply with applicable State and local law. See 21 U.S.C.A. § 823(b)(2).

220. On information and belief, Defendants knowingly, recklessly, and/or negligently supplied suspicious quantities of prescription opioids to obviously suspicious physicians and pharmacies in and around Duluth, Minnesota, without disclosing suspicious orders as required by regulations and otherwise circumventing their statutory obligations under Federal and Minnesota law.

221. Defendants' refusal to report and investigate suspicious orders had far-reaching effects. As mentioned above, the DEA is required to annually set production quotas for regulated drugs. In the context of opioids, however, DEA has cited the difficulty of determining an appropriate production level to ensure that adequate quantities are available for legitimate medical use. That is because there are no direct measures available to establish legitimate medical need. DEA's difficulty in setting production quotas was compounded by the fact that the Manufacturer and Distributor Defendants failed to report suspicious orders of opioids and failed to maintain effective controls against diversion. Defendants' deliberate failures thus prevented the DEA from realizing the full extent of opioid diversion for years.

222. Defendants could have (and should have) reported and stopped the flow of prescription opioids into the black market. But Defendants intentionally, recklessly, and/or negligently failed to investigate, report, and halt suspicious orders. Accordingly, as a direct result of Defendants' misconduct, substantial and dangerous quantities of prescription opioids were illegally diverted to and overprescribed in Duluth, Minnesota.

i. Failure of the Manufacturer Defendants

223. Manufacturers are the source of the prescription drugs in the pharmaceutical supply chain. The pharmaceutical manufacturing industry is composed of two distinct business models: manufacturers of brand-name drugs and manufacturers of generic drugs.

224. Manufacturers manage the actual distribution of drugs from manufacturing facilities to drug wholesalers, and in some cases, directly to retail pharmacy chains, mail-

order and specialty pharmacies, hospital chains, and some health plans. Manufacturers may also distribute products directly to government purchasers, such as the Veterans Administration.

225. Upon information and belief, the Manufacturer Defendants collected, tracked, and monitored extensive data concerning suspicious physicians and pharmacies through third-party organizations and through Distributor Defendants and pharmacies in exchange for rebates or other consideration to better drive sales.

226. For example, IMS Health furnished Purdue and other Manufacturer Defendants with fine grained information about the prescribing habits of individual doctors and the ordering habits of individual pharmacies.

227. The Manufacturer Defendants could have used these data to identify diversion as required under federal law to satisfy their duty of maintaining "effective control against diversion of particular controlled substances into other than legitimate medical, scientific, and industrial channels." 21 U.S.C. § 823(b)(1).

228. Instead, the Manufacturer Defendants utilized the data to understand which regions, and which doctors, to target through their sales force.

229. With the knowledge that retailers and prescribing doctors were facilitating diversion, the Manufacturer Defendants failed to report each instance of diversion to the DEA while rolling out marketing campaigns to churn prescription opioid sales.

230. Indeed, upon information and belief, the Manufacturer Defendants withheld from the DEA information about suspicious orders and induced the Distributor Defendants to obfuscate the extent of the opioid epidemic. Upon information and belief,

the Manufacturing Defendants knew that if they or the other Defendants disclosed suspicious orders, the DEA would become aware that many opioids were being diverted to illegal channels and would refuse to increase the production quotas for opioids.

231. Upon information and belief, at least Purdue referred to overprescribing doctors or doctors engaged in diversion as "whales."

ii. Failure of the Distributor Defendants

232. The Distributor Defendants purchase prescription opioids from the Manufacturer Defendants to distribute to a variety of customers, hospitals, long-term care, and other medical facilities (*e.g.*, community clinics, physician offices, and diagnostic laboratories).

233. The top three wholesale distributors, McKesson, Cardinal Health, and AmerisourceBergen, account for almost 90 percent of the entire wholesale drug market. This consolidation has forced the industry to change its revenue model, evolving its core distribution business into a low-margin enterprise that makes money by maximizing economies of scale.

234. The Distributor Defendants utilize "just-in-time" delivery methods. In order to keep inventory and liability of pharmaceutical drugs as low as possible, most pharmacies receive drug deliveries from distributors every day of the week. This allows the pharmacy to hold as little inventory of pharmaceutical drugs on site as possible. In making just-in-time deliveries, sometimes multiple times a day to a single pharmacy, distributors know precisely how many opioid prescriptions and individual pills they are delivering to a specific pharmacy.

235. On information and belief, the Distributor Defendants supplied the Manufacturer Defendants with distribution data in exchange for rebates or other consideration so Manufacturer Defendants could better drive sales.

236. The Distributor Defendants report the sale of all prescription opioids to the Automation of Reports and Consolidated Orders System ("**ARCOS**") database. The ARCOS database's purpose is to monitor the flow of DEA-controlled substances from their point of manufacture through commercial distribution channels but does not include prescription or doctor data.

237. The ARCOS database does not alert the DEA to the suspicious nature of a particular order. The DEA investigators regard the database as unwieldy because it encompasses dozens of drugs sold by more than a thousand companies and is frequently six months out of date.

238. Distributors are a crucial link in the closed system envisioned by Congress in enacting the CSA. Industry compliance guidelines established by the Healthcare Distribution Management Association, the trade association of pharmaceutical distributors, explain that distributors, including Distributor Defendants, are "[a]t the center of a sophisticated supply chain" and, therefore, "are uniquely situated to perform due diligence in order to help support the security of the controlled substances they deliver to their customers."

239. The Distributor Defendants have the power to determine that an order is being diverted before filling suspicious orders - thereby preventing diversion before it can even occur.

240. Reporting an order as suspicious will not absolve a distributor, including Distributor Defendants, of responsibility if the registrant and distributor knew, or should have known, that the prescription opioids were being diverted. Indeed, reporting a suspicious order, then filling said order with knowledge it may be suspicious, constitutes a failure to maintain effective controls against diversion under 21 U.S.C. §§ 823 and 824.

241. Once the DEA started to suspend distributors' registrations, the Manufacturer and Distributor Defendants spent million to undermine the DEA's ability to continue doing so.

242. On February 19, 2014, acting at the behest of industry lobbyists, Representative Tom Marino introduced the "Ensuring Patient Access and Effective Drug Enforcement Act" as a supposed effort to define "imminent danger" in the 1970 act. A DEA memo noted that this bill would essentially destroy the agency's power to file an immediate suspension order of any suspicious drug shipments.

243. This bill required that the DEA show the company's actions had shown "substantial likelihood of an immediate threat," whether in death, serious bodily harm, or drug abuse before a suspension order can be sought. It also gave drug companies the ability to submit "corrective action" plans before any penalties could be issued. The law essentially makes it impossible for the DEA to halt any suspicious narcotic shipments before opioids are diverted to the illegal black market.

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

244. Upon information and belief, the Distributor Defendants had a policy of not reporting suspicious orders until the DEA was already aware of wrongdoing. In this

way the Distributor Defendants believed they could protect themselves from liability, while obfuscating the true extent of opioid diversion to keep DEA quota on opioids high.

245. The following fines reflect only a small portion of the hundreds of billions of dollars in revenue the Distributor Defendants receive each year.

(i) McKesson

246. McKesson is a significant distributor of opioids in the United States.

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

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

249. Despite the CSMP, a DEA investigation revealed that between 2008 and 2013, McKesson continued to fail to inform the DEA about a plethora of suspicious

orders of prescription opioids. In that time period, a single warehouse in Aurora, Colorado, filled 1.6 million prescription orders and reported only 16 as suspicious.

250. As recently as December 17, 2017, facts continue to emerge regarding McKesson's misdeeds. According to both the Washington Post and "60 Minutes," McKesson's failures from 2008 to 2013 were so egregious that members of the DEA believed that it warranted a criminal case against the drug distribution company. Apparently, members of the DEA thought prison sentences for McKesson executives would be warranted.

251. The DEA's Denver field division, in conjunction with a local law enforcement investigation into Platte Valley Pharmacy in Brighton, Colo., ascertained that the vast majority of pills prescribed at the Platte Valley Pharmacy originated at McKesson's warehouse in Aurora, CO. According to local law enforcement, a single pharmacist, Jeffrey Clawson, was selling as many as 2,000 opioids a day.

252. None of the 16 suspicious orders that McKesson actually reported from 2008 to 2013 were related to the Platte Valley Pharmacy, or to Jeffrey Clawson.

253. This was in spite of the fact that, from 2008–2011, the percentage increase for oxycodone 30 mg orders supplied by McKesson to Platte Valley Pharmacy was approximately 1,469%. Jeffrey Clawson was eventually indicted and convicted of drug trafficking charges and was given a 15-year prison sentence.

254. McKesson eventually did report Jeffrey Clawson's suspicious orders, but only after he had already been convicted and the Platte Valley Pharmacy closed and was no longer a source of revenue.

255. Subsequently, nine field divisions of the DEA working with 12 U.S. attorney's offices across 11 states began to collect information on McKesson's activity.

256. The investigation discovered that McKesson was acutely aware of the situation at Platte Valley Pharmacy. Worse, McKesson warehouses were supplying pharmacies that sold to criminal drug rings. In all, 12 McKesson distribution centers failed to report suspicious orders involving millions of opioids across the country.

257. The DEA investigative findings revealed that McKesson systematically:

(a) Supplied controlled substances in support of criminal diversion activities;

(b) Ignored blatant diversion;

(c) Would arbitrarily increase the threshold amount of opioids pharmacies could purchase;

(d) Failed to review orders for suspicious activity; and

(e) Ignored its own procedures designed to prevent diversion.

258. David Schiller of the DEA's Denver field division, which first recognized McKesson's bad acts, asserted that "[t]his is the best case we've ever had against a major distributor in the history of the Drug Enforcement Administration." Individuals at the DEA believed that a fine of more than $1 billion would be appropriate, and one unnamed source asserted that "[the DEA] could have fined them out of existence, or indicted the company and put [McKesson] out of business." McKesson is the third-largest corporation in the United States, with revenues in 2016 exceeding $190 billion.

259. On January 17, 2017, McKesson agreed to pay a record $150 million in fines and suspend sales of controlled substances from distribution centers in four states to settle allegations that the company violated federal law. As part of the agreement,

McKesson acknowledged that: "at various times during the Covered Time Period, it did not identify or report to DEA certain orders placed by certain pharmacies, which should have been detected by McKesson as suspicious, in a manner fully consistent with the requirements set forth in the 2008 MOA." The company promised to institute significant changes to its program designed to flag suspicious orders, the same promise it made and broke in 2008. McKesson was fined the equivalent of less than two year's salary of its board chairman and chief executive, John Hammergren.

260. The DEA agents who were involved in the investigation believed that McKesson escaped criminal liability because McKesson had "intimidated" the lawyers of the chief counsel's office in the Division of Diversion Control.

(ii) Cardinal Health

261. Cardinal Health is a significant distributor of opioids in the United States.

262. Cardinal acknowledged that from January 1, 2009, to May 14, 2012, it did fail to comply with regulations that required reports of any suspicious orders from pharmacies. Cardinal Health's chief legal and compliance officer, Craig Morford, also noted that, going forward, it would work "with all participants in addressing the epidemic of prescription drug abuse."

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

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

> (a) "timely identify suspicious orders of controlled substances and inform the DEA of those orders, as required by 21 C.F.R. §1301.74(b)";
>
> (b) "maintain effective controls against diversion of particular controlled substances into other than legitimate medical, scientific, and industrial channels, as required by 21 C.F.R. § 1301.74, including the failure to make records and reports required by the CSA or DEA's regulations for which a penalty may be imposed under 21 U.S.C. § 842(a)(5)"; and
>
> (c) "execute, fill, cancel, correct, file with the DEA, and otherwise handle DEA 'Form 222' order forms and their electronic equivalent for Schedule II controlled substances, as required by 21 U.S.C. § 828 and 21 C.F.R. Part 1305."

265. In the press release announcing the settlement agreement, DEA's Washington Division Special Agent-in-Charge, Karl Colder, clarified that the settlement specifically concerned oxycodone:

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

(iii) <u>AmerisourceBergen</u>

266. AmerisourceBergen is a wholesale distributor of pharmaceuticals, including controlled substances and non-controlled prescription medications. It handles the distribution of approximately 20% of all pharmaceuticals sold and distributed in the U.S. through a network of 26 pharmaceutical distribution centers.

267. AmerisourceBergen is a significant distributor of opioids in the United States.

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

(iv) Mallinckrodt PLC

269. On July 11, 2017, Manufacturer Defendant Mallinckrodt PLC agreed to pay $35 million to the DOJ to settle charges stemming from violations of certain provisions of the Controlled Substances Act, such as (1) 21 C.F.R. § 1301.74(b) for failing to design and operate a system to disclose to the registrant suspicious orders of controlled substances and to inform the DEA Field Division office of such suspicious orders when discovered, and (2) 21 C.F.R. § 1301.71(a) for failing to provide effective controls and procedures to guard against theft and diversion of controlled substance.

270. The July 2017 agreement by Mallinckrodt PLC also settled charges by the DOJ stemming from Mallinckrodt PLC's failure to utilize chargeback data, which Mallinckrodt required distributors to provide to obtain chargeback discounts, to identify suspicious orders of customers further down in the supply chain.

271. Finally, the agreement settled charges stemming from allegations by the DOJ that Mallinckrodt PLC was guilty of record-keeping violations at its manufacturing facility in upstate New York, which created discrepancies between the actual number of oxycodone tablets manufactured in a batch and the number of tablets Mallinckrodt PLC reported on its records.

(v) OmniCare

272. As a result of a multi-jurisdictional investigation by the DOJ, CVS' subsidiary OmniCare, Inc., the nation's leading provider of pharmaceutical care for seniors, was fined $50 million for violations of the Controlled Substances Act.

273. According to the investigation, from 2007 to 2012, OmniCare Inc. filled prescriptions without requiring signed prescriptions by a prescribing doctor. Rather, OmniCare Inc. would dispense prescription narcotics upon oral orders from long term care facility staff. In other words, OmniCare Inc. regularly dispensed opioids without a prescription without knowing to whom they were dispensing opioids.

(vi) Masters Pharmaceutical, Inc.

274. Masters Pharmaceutical, Inc. ("Masters") has a long history of noncompliance with DEA standards. The DEA has, on two separate occasions, issued orders to show cause why Masters' DEA certificate of registration should not be revoked. On October 17, 2008, the DEA issued an order alleging that throughout 2007–2008,

Masters "failed to maintain effective controls against diversion" of hydrocodone. Masters agreed to settle charges brought by the DEA on April 1, 2009.

275. Masters paid $500,000 and agreed to take steps to bring the company into compliance with DEA regulations for detecting suspicious orders and preventing diversion of controlled substances. However, on August 9, 2013, the DEA again issued an order to show cause why Masters' certificate of registration should not be revoked.

276. The 2013 order alleged that Masters ignored and/or failed to implement its controlled substance policies and failed to report suspicious orders.

277. Evidence raised during trial showed that Masters did not report orders held as potentially suspicious, even going so far as to, on numerous occasions, delete orders so they would no longer trigger the hold. Even when customers provided information which confirmed that an order was indeed suspicious, Masters still failed to report the orders to the DEA.

278. On September 8, 2015 Chuck Rosenberg, Acting Administrator of the DEA, ordered Masters' DEA certificate of registration be revoked. On June 30, 2017 the United States Court of Appeals for the District of Columbia Circuit denied Masters' petition for review.

D. The Opioid Epidemic's Devastating Effects

279. As a result of: (1) Manufacturer Defendants' misinformation campaigns, and (2) Defendants' failure to abide by their obligations under the CSA, opioid addiction in the United States has skyrocketed. Defendants' actions created an opioid ecosystem in which prescriptions for highly addictive drugs could be easily obtained and easily filled.

Overprescribing, in turn, drove opioid-related addiction, overdose, and infections, and it sustained nonmedical use of prescription opioids.[10]

280. All Defendants were aware of bad-faith prescribing practices. Yet, far from doing anything to stop the practice of overprescribing, Defendants acted to fuel it. Defendants are thus responsible for the opioid epidemic that, as set forth below, has devastated America and imposed severe burdens on the City of Duluth.

i. Overuse and Overprescription

281. Weighted National Survey on Drug Use and Health ("**NSDUH**") estimates suggested that, in 2016, 91.8 million people—more than one-third the population of civilian, noninstitutionalized U.S. adults—used prescription opioids. For too many of those people, opioid use will prove fatal.

282. Nationwide, from 1997 to 2002, there was a 73%, 226%, and 402% per capita increase in morphine, fentanyl, and oxycodone prescribing, respectively (in grams per 100,000 populations).

283. During that same period, hospital emergency department admissions for morphine, fentanyl, and oxycodone increased 113%, 641%, and 346%, respectively.

ii. Opioid Related Fatalities

284. To date, prescription opioids have accounted for more American deaths than World War I, the Korean War, and the Vietnam War combined.

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[10] L. Manchikanti et al., *Opioid Epidemic in the United States*, 15 PAIN PHYSICIAN ES9–38 (supplemental material) (2012) *available at* http://www.painphysicianjournal.com/ (last accessed October 22, 2018); AM Arria & WM Compton, *Complexities In Understanding and Addressing the Serious Public Health Issues Related to the Nonmedical Use of Prescription Drugs*, 65 ADDICT. BEHAVIORS 215–17 (2017).

285. Mortality rates from opioid overdose have climbed dramatically. In 2002, unintentional overdose deaths from prescription opioids surpassed those from heroin and cocaine nationwide. The CDC reports that every single U.S. state has experienced an increase in per capita opioid overdose fatalities between 2010 and 2016, and fatalities are increasing at a nonlinear pace. For example, synthetic opioids killed twice as many people per capita in 2016 than in 2015.[11] In 2016, the number of all opioid overdose fatalities exceeded 42,000; in 2017, the number rose to over 49,000. In other words, in 2017, 134 Americans died from opioid overdoses every day.[12]

286. In total, since 1999, over two hundred thousand Americans have died because of overdoses from OxyContin and other prescription opioids.

287. Over the next decade, the number of prescription opioid-related deaths is expected to exceed 650,000, outpacing the estimated numbers of deaths caused by breast and prostate cancers combined during the same period. To put this figure in context, that figure exceeds the approximately 620,000 Americans who lost their lives in the line of duty during the entire American Civil War. Viewed another way, opioids could kill nearly as many Americans in a decade as HIV/AIDS has killed since that epidemic began in the early 1980s.

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[11] CTR. FOR DISEASE CONTROL & PREVENTION, *Drug Overdose Deaths in the United States, 1999–2016*, *available at* https://www.cdc.gov/nchs/products/databriefs/db294.htm (last accessed October 22, 2018).

[12] NAT'L INSTITUTE ON DRUG ABUSE, *Overdose Death Rates*, https://www.drugabuse.gov/related-topics/trends-statistics/overdose-death-rates (last accessed October 22, 2018).

iii. Social, Economic, and Health Consequences of Prescription Opioid Abuse

288. The victims of the opioid epidemic, however, are not just those who die from overdoses. Prescription opioid abuse also imposes severe harm on those who live with addiction, their families, and their communities.

289. People suffering from opioid addiction often suffer from a variety of interlocking psychological ailments, including depression, lack of motivation, anxiety, and drug-seeking behavior. Addiction can thus wreak havoc on an individual's ability to complete daily tasks, hold down a job, and care for a family.

290. A recent Brookings Institution study examining the implications of the opioid crisis on the labor force suggests that the increase in opioid prescriptions could account for a significant part of the decline in the labor force participation of "prime age men" (ages 25–54).[13]

291. On any given day, 31% of prime age men not in the labor force report taking prescription pain medication, most likely opioid based. In fact, the true percentage is likely far higher than this self-reported number, due to the stigma and legal risk associated with narcotics.

292. Opioid abuse also devastates families. When a family member is addicted to opioids, each family member is affected differently. The most vulnerable, however, are children.

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[13] Alan B. Krueger, *Where Have All the Workers Gone? An Inquiry into the Decline of the U.S. Labor Force Participation Rate*, BROOKINGS PAPERS ON ECON. ACTIVITY, at 35 (2017), *available at* https://www.brookings.edu/wp-content/uploads/2017/09/1_krueger.pdf (last accessed October 22, 2018).

293. Indeed, a child's vulnerability to opioids begins even before a child is born. Developing fetuses are vulnerable to substance use by the pregnant mother, as drugs such as opioids can easily cross the placenta and enter fetal blood circulation.

294. The number of children experiencing neonatal abstinence syndrome ("NAS"), a group of problems that occur in newborns exposed to opioids in utero, increased 383% during the period 2000-2012 (1.2 cases per 1000 hospital births in 2000 to 5.8 cases per hospital births in 2012).[14]

295. In addition, children whose parents have an opioid addiction may be neglected or require removal to foster care.

296. The adverse effects of the opioid epidemic are not confined to addicted individuals or their families. To the contrary, the costs of the opioid epidemic radiate outward, and are borne by society at large.

297. The monetary costs of prescription opioid overdose, abuse, and dependence are staggering. The White House Council of Economic Advisers reported that, in 2015, "the economic cost of the opioid crisis was $504.0 billion, or 2.8 percent of the GDP that year."[15]

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[14] JY Ko, et al., *Incidence of Neonatal Abstinence Syndrome—28 States, 1999-2013*, 65 MMWR MORB. MORTAL WEEKLY REP. 799, 800 (2016), *available at* https://www.cdc.gov/mmwr/volumes/65/wr/mm6531a2.htm (last accessed October 22, 2018).

[15] COUNCIL OF ECON. ADVISORS, *The Underestimated Cost of the Opioid Crisis*, at 1 (Nov. 2017), *available at* https://www.whitehouse.gov/sites/whitehouse.gov/files/images/The%20Underestimated%20Cost%20of%20the%20Opioid%20Crisis.pdf (last accessed October 22, 2018).

298. The total cost of the opioid crisis is so high, the White House Council of Economic Advisers emphasized, because of the multifaceted harms caused by prescription opioids. Among other things, the opioid epidemic has imposed significant costs on the healthcare system, and on the criminal justice system. It has also significantly reduced worker productivity, both as a result of addiction and incarceration.[16]

299. As staggering as a $504 billion annual cost might be, however, the actual current economic cost of the opioid epidemic is probably even higher. As one commentator noted, the White House's 2015 "estimate is probably low for 2016, given that drug and opioid overdose deaths spiked last year compared to 2015."[17]

iv. The Growing Heroin Epidemic

300. In addition to the costs directly imposed by prescription opioid abuse, the prevalence of prescription opioids in the United States has led to an unprecedented increase in heroin use. According to the Center for Behavioral Health Statistics and Quality, 914,000 people in 2014 reported prior heroin use, a 145% increase from 2007. As a direct result of increased heroin use, heroin-related overdoses are spiking. In 2002, the rate of heroin-related overdose deaths in the United States was 0.7 per 100,000 people. By 2013, that rate had climbed to 2.7 per 100,000 people—a 286% increase.

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[16] *Id.*

[17] German Lopez, *White House: One Year of the Opioid Epidemic Cost the US Economy More Than $500 Billion*, VOX.COM (Nov. 20, 2017), https://www.vox.com/science-and-health/2017/11/20/16679688/white-house-opioid- epidemic-cost (last accessed October 22, 2018).

301. Heroin use in the United States increased dramatically during the period in which the country witnessed a rise in prescription opioid misuse. Data from the 2001–2002 and 2012–2013 National Epidemiologic Survey on Alcohol and Related Conditions I and III ("**NESARC**") showed prevalence of heroin use increased five-fold in the United States during the period between the two surveys.[18]

302. The parallel explosion in rates of prescription opioid abuse and rates of heroin abuse is no coincidence. The pathway from prescription opioids to heroin is well-documented, and well understood. People who are prescribed a prescription opioid, either by a well-meaning physician or through a pill mill, can find that their tolerance and dependence on opioids increases over time. At that point, the allure of heroin, which is substantially chemically similar to prescription opioids, and often cheaper and more readily available, can prompt an individual to begin heroin use.

303. Scientific studies indicate that the prescription opioid epidemic is, far and away, the key driver of new heroin users. People who report previous nonmedical prescription pain-reliever use are 19 times more likely to begin using heroin than the general population.[19] What is more, prescription opioid abuse, not heroin, is now the main pathway into opioid addiction. Fifty years ago, 80% of people who abused opioids

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[18] Silvia S. Martins, Aaron Sarvet, & Julian Santaella-Tenorio, *Changes In Lifetime Heroin Use And Heroin Use Disorder: Prevalence From The 2001–2002 to 2012-2013 National Epidemiologic Survey on Alcohol and Related Conditions.* 74 JAMA PSYCHIATRY 445, 445 (2017), *available at* https://jamanetwork.com/journals/jamapsychiatry/fullarticle/2612444 (last accessed October 22, 2018).

[19] Pradip K. Muhuri, Joseph C. Gfoerer, M. Christine Davies, *Associations of Nonmedical Pain Reliever Use and Initiation of Heroin Use in the United States*, CBHSQ DATA REVIEW (Aug. 2013), *available at* https://www.samhsa.gov/data/sites/default/files/DR006/DR006/nonmedical-pain-reliever-use-2013.htm (last accessed October 22, 2018).

initiated that abuse through heroin. By the 2000s, however, that statistic was inverted: 75% of people who began abusing opioids in the 2000s started through prescription opioids.[20]

304. The heroin epidemic in Minnesota is, like the national heroin epidemic, driven by the prescription opioid epidemic.

V. SPECIFIC FACTUAL ALLEGATIONS

305. From 1999 to 2017, deaths from opioids increased by 681% across the State of Minnesota. Between 2000 and 2016, deaths from prescription opioids increased 631% across the State of Minnesota. In 2016, 395 Minnesotans died from opioid overdoses. Prescription opioids account for the greatest number of overdose deaths in Minnesota. From 1999 to 2014, more people died in Minnesota from prescription painkillers than any other opioid.

306. The City of Duluth has suffered as much as, if not more, than the rest of the State. From 2014 to 2018, the Duluth Police Department responded to 388 incidents of overdoses, 44 of which of were opioid overdose deaths. In December 2018, the Duluth Police Department hired an opioid technician to increase the department's ability to respond to overdose victims, provide chemical dependency referrals, and develop and coordinate outreach and training.

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[20] Theodore J. Cicero, et al., *The Changing Face of Heroin Use in the United States: A Retrospective Analysis of the Past 50 Years*, 71 JAMA PSYCHIATRY 821, 823 (2014), *available at* https://jamanetwork.com/journals/jamapsychiatry/fullarticle/1874575 (last accessed October 22, 2018).

VI. TOLLING THE STATUTES OF LIMITATIONS

A. Tolling of Statute of Limitation for State-Law Actions

307. Minnesota Statute § 541.05 sets a six-year statute of limitations for cases involving liability created by statute, personal injury, and fraud. However, delayed discovery regarding or fraudulent concealment of the facts constituting a cause of action will toll the statute of limitations.

308. In evaluating the allegations below, the economics of Defendants' fraud is an exacerbating factor. During the relevant time period, each Defendant derived record profits as a result of their sale and distribution of prescription opioids. The Defendants had the ability to and did spend enormous amounts of money in furtherance of their purpose to market and promote profitable drugs, notwithstanding the known or reasonably known risks. Aside from the City of Duluth having neither knowledge nor reason to suspect that Defendants were engaged in the wrongdoing alleged herein, the City was without the financial means and requisite expertise to discover Defendants' wrongdoing or independently identify the nature and extent of the devastating health, economic, and other effects of the opioid crisis. As a result of Defendants' concerted effort to conceal their misrepresentations and fraud, Plaintiff relied on Defendants' misrepresentations to its detriment, as demonstrated by the damages suffered described herein.

B. Tolling of Statute of Limitations Against the Manufacturer Defendants

309. The running of any statute of limitation has been tolled because the Manufacturer Defendants fraudulently concealed from Plaintiff the existence of Plaintiff's claims by manipulating and distorting public information, knowledge, and

facts; negligently and recklessly failing to make public or otherwise produce nonpublic information, over which the Manufacturer Defendants had exclusive possession, dominion, and control, that would have revealed the truth; and by deliberately and fraudulently concealing the truth.

310. Specifically, the Manufacturer Defendants concealed from Plaintiff the existence of Plaintiff's claims by manipulating and distorting public information, knowledge, and facts when the Manufacturer Defendants engaged in a public disinformation campaign which knowingly and maliciously misrepresented that opioids, when used correctly, as directed, and for approved indications, were, *inter alia*, non-addictive, abuse proof or deterrent, safe, and effective for daily and/or long-term treatment of pain.

311. The Manufacturer Defendants concealed from Plaintiff the existence of Plaintiff's claims by recklessly and negligently failing to make public or otherwise produce information that would have revealed the truth over which the Manufacturer Defendants had exclusive possession, dominion, and control, such as reports that those treated with opioids in clinical trials exhibited behaviors indicating that the Manufacturer Defendants' opioids were addictive; data suggesting or proving that large amounts of opioids were being diverted from legitimate, legal channels and used for medical treatment; and information that specific doctors and pharmacies were engaged in an illegal pattern of conduct that was designed to provide, in exchange for compensation, opioids to persons who did not suffer from FDA approved indications.

312. Specifically, the Manufacturer Defendants concealed from Plaintiff the existence of Plaintiff's claims when, for example, certain Manufacturer Defendants did not report information about conduct they knew to be illegal by other members of the opioid supply chain; when one Manufacturer Defendant deployed a team of representatives to push prescribers to recommend dosing no more frequently than every 12 hours, despite affirmative knowledge that such prescribing practices were ineffective and increased patients' propensity to become addicted; and when the Manufacturer Defendants sponsored or were otherwise directly involved with organizations that falsely represented themselves as pain patient advocates while simultaneously disseminating the Manufacturer Defendants' desired opioid narrative.

313. Furthermore, each Manufacturer Defendant is equitably estopped from relying on a statute of limitations as a defense to any of Plaintiff's claims because each such Defendant took affirmative action to prevent Plaintiff from discovering the existence of or filing its claims any earlier. Each Manufacturer Defendant was under a duty to disclose the true character, quality, and nature of their opioids, which was nonpublic information over which the Manufacturer Defendants had and continue to have exclusive possession, dominion, and control, but the Manufacturer Defendants breached that duty by failing to disclose such information and by intentionally and fraudulently concealing these facts.

314. The Manufacturer Defendants made material misrepresentations about opioids, such as that they are non-addictive; the Manufacturer Defendants were aware that they were false because they had possession, dominion, and control over information

indicating that opioids were far more addictive that the Manufacturer Defendants misled the public to believe; the Manufacturer Defendants intended that consumers would act upon those misrepresentations as demonstrated by the existence of extensive marketing campaigns that asserted these misrepresentations; and Plaintiff reasonably or justifiably relied on those misrepresentations to its detriment because Plaintiff's reliance on the Manufacturer Defendants was reasonable considering that the Manufacturer Defendants possessed and controlled more information about their opioids than any other party and such reliance was harmful to Plaintiff as set forth in the damages section of this Complaint.

C. Tolling of Statute of Limitations Against the Distributor Defendants

315. The Distributor Defendants fraudulently concealed from Plaintiff the existence of Plaintiff's claims by misrepresenting their compliance with their legal duties under state and federal law and by wrongfully and repeatedly disavowing those duties in an effort to mislead regulators and the public regarding the Distributor Defendants' compliance with their legal duties.

316. Specifically, the Distributor Defendants fraudulently concealed the existence of Plaintiff's claims by affirmatively seeking to convince the public that their legal duties had been satisfied through public assurances that they were working to curb the opioid epidemic.

317. For example, Cardinal Health, through an executive, claimed that it used "advanced analytics" to monitor the supply chain and falsely represented that it was being "as effective and efficient as possible in constantly monitoring, identifying, and eliminating any outside criminal activity."

318. McKesson stated that it has a "best-in-class controlled substance monitoring program to help identify suspicious orders" and claimed that it is "deeply passionate about curbing the opioid epidemic in our country." However, McKesson minimized and misrepresented the extent of its misdeeds, some of which were disclosed in a 60 Minutes episode that aired on December 17, 2017. David Schiller, the Assistant Special Agent in Charge of the Denver Field Division of the Drug Enforcement Agency, spoke in the 60 Minutes episode regarding McKesson's distribution practices to pharmacies that were recklessly distributing opioids, stating:

> The issue with McKesson was, they were providing millions and millions and millions of pills to countless pharmacies throughout the United States, and they did not maintain any sort of due diligence. This wasn't just happening in Denver, Colorado. . . . It was a national problem, and nobody wanted to deal with it.

319. Given each Distributor Defendant's sales volumes and history of violations, these false statements were made intentionally and fraudulently or recklessly without regard to the truth and as a positive assertion.

320. Specifically, the Distributor Defendants fraudulently concealed the existence of Plaintiff's claims through wrongful and repeated disavowal of their duties under state and federal law by individually and collectively through trade groups in the industry pressuring the U.S. Department of Justice to "halt" prosecutions and by lobbying Congress to strip the DEA of its ability to immediately suspend distributor registrations. As a result of their efforts, the Distributor Defendants caused a sharp drop in enforcement actions and secured the passage of legislation raising the legal hurdle the DEA must clear before revoking a registrant's license, an act which was, perhaps not ironically, entitled "Ensuring Patient Access and Effective Drug Enforcement Act."

321. Additionally, the Distributor Defendants are estopped from relying on a statute of limitations as a defense to any of Plaintiff's claims because each such Defendant took affirmative action to prevent Plaintiff from discovering the existence of and filing its claims any earlier.

322. The Distributor Defendants made material misrepresentations about the existence of, and their compliance with, their duties with respect to distributing controlled substances under state and federal law; these statements were false, and the Distributor Defendants were aware of their falsity, because Distributor Defendants were aware of their own history of conduct which included repeated breaches of such duties; Plaintiff did not know such statements were false; the Distributor Defendants intended that members of the public, including Plaintiff, would rely upon such representations, and Plaintiff did rely on such representations to its detriment, as demonstrated by the damages suffered by Plaintiff as set forth herein.

323. Plaintiff had no knowledge that the Manufacturer Defendants or the Distributor Defendants were engaged in any of the wrongdoing alleged herein. Because of the fraudulent acts of concealment of wrongdoing by the Manufacturer and Distributor Defendants, Plaintiff could not have reasonably discovered the wrongdoing at any time prior.

VII. COUNT I
VIOLATIONS OF RICO ACT, 18 U.S.C. § 1961, *ET SEQ.*
Against Manufacturer Defendants and Distributor Defendants

324. The City of Duluth incorporates by reference, as if fully set forth herein, each and every preceding paragraph.

325. The City of Duluth brings this count on behalf of itself against the following Defendants, as defined above: the Manufacturer Defendants and the Distributor Defendants (collectively, for purposes of this Count, the "**RICO Defendants**").

A. Standing

326. Pursuant to 18 U.S.C. § 1961(2) of the RICO Act, the term "person" includes "any individual or entity capable of holding a legal or beneficiary interest in property."

327. Plaintiff, the City of Duluth, is a person under the RICO Act because it is a legal entity capable of holding a legal or beneficial interest in property. Plaintiff is a municipal corporation. Pursuant to its City Charter, Section 72, the City of Duluth is "empowered to acquire, by purchase, gift, devise or condemnation, any property, corporeal, either within or without its corporate boundaries, which may be needed by said city for any public use or purpose . . ."

328. The RICO Defendants' violations of law and their pattern of racketeering activity directly and proximately caused the City of Duluth's injury. Because of the opioid epidemic resulting from the RICO Defendants' violations of the law, the City of Duluth suffered losses and incurred expenses which include, but are not limited to, the losses and expenditures set forth in the paragraphs that follow:

(a) Expenditures to provide health services, mental-health services, and social services to victims of the opioid epidemic and their families, including expenses incurred by Duluth in connection with the provision of services well beyond those anticipated or necessary during the period predating the opioid epidemic;

(b) Expenditures relating to law-enforcement attempts to stem the flow of opioids and heroin into local communities, to arrest and prosecute street-level dealers, to otherwise prevent the current opioid epidemic from spreading and

worsening, and to deal with increased levels of other crimes, such as minor and major violence, burglary, robbery, etc., which has directly resulted from an uptick in the size of the homeless and drug-addicted population;

(c) Expenditures associated with training first responders on how to treat drug overdoses;

(d) Losses caused by decreased productivity of City employees at work who face issues caused by opioid use and abuse;

(e) Losses caused by diminished property values in neighborhoods where the opioid epidemic, and the heroin trade, have taken root, including lost property taxes and assessments;

(f) Expenditures associated with treating infant children who are born addicted to opioids due to drug use by mothers during pregnancy;

(g) Loss of funding for important public services for which the funding was diverted to other public services designed to address the opioid epidemic;

(h) Expenditures associated with providing police officers, firefighters, and emergency responders with Naloxone, an opioid antagonist used to block the deadly effects of opioids in the context of overdose;

(i) Costs incurred by the Duluth Fire Department and its emergency medical services department in connection with emergency responses to opioid overdoses;

(j) expenses incurred in connection with the City's human resources, litigation, and criminal enforcement divisions; and

(k) Expenses incurred by the City of Duluth to address homelessness, blight, and transiency caused by the opioid epidemic.

329. The RICO Defendants' racketeering activities were the factual cause of the City of Duluth's damages because, but for the RICO Defendants' racketeering activities and operation of their enterprise, the City of Duluth would not have incurred the expenditures and losses associated with the opioid epidemic. Nor would the City have incurred any of the other costs associated with the plague of addiction caused by the RICO Defendants' drugs.

330. The City's injuries were directly and proximately caused by the RICO Defendants' violations of law and their pattern of racketeering activity.

331. The City therefore has standing in this civil RICO action.

B. Unlawful Enterprises

332. The City seeks all legal and equitable relief available under the law, in the maximum amount and to the furthest extent permitted by law.

333. The RICO Defendants did and do conduct their business using both legitimate and illegitimate means. Each RICO Defendant belongs to a subgroup of defendants, of which each subgroup forms an association-in-fact enterprise or a legal enterprise (each, a "**Dealing Enterprise**").

334. At all relevant times, the RICO Defendants were "persons" under 18 U.S.C. § 1961(3) because they are entities capable of holding, and do hold, "a legal or beneficial interest in property."

335. Section 1962(c) of RICO makes it unlawful "for any person employed by or associated with any enterprise engaged in, or the activities of which affect, interstate or foreign commerce, to conduct or participate, directly or indirectly, in the conduct of such enterprise's affairs through a pattern of racketeering activity or collection of unlawful debt." 18 U.S.C. § 1962(c); *United States v. Turkette*, 452 U.S. 576, 580 (1981).

336. The term "enterprise" is defined as including "any individual, partnership, corporation, association, or other legal entity, and any union or group of individuals associated in fact although not a legal entity." 18 U.S.C. § 1961(4); *Turkette*, 452 U.S. at 580; *Boyle v. United States*, 556 U.S. 938, 944 (2009). In other words, an enterprise is any company (regardless of form or legal organization), person, or group of persons

(regardless of how the members are associated, regardless of whether any member is aware of his or her membership, regardless of whether they intend to comprise a union or group, and regardless of whether they wish or do not wish to be part of such group or union, provided that, in fact, they are somehow associated).

337. The definition of "enterprise" in Section 1961(4) includes legitimate and illegitimate enterprises within its scope. Specifically, the section "describes two separate categories of associations that come within the purview of an 'enterprise'—the first encompassing organizations such as corporations, partnerships, and other 'legal entities,' and the second covering 'any union or group of individuals associated in fact although not a legal entity.'" *Turkette*, 452 U.S. at 577. The second category is not a more generalized description of the first. *Id.*

i. Diversion Enterprise

338. The Manufacturer Defendants and the Distributor Defendants engaged in a conspiracy to expand the market for opioid drugs—thus inflating their own profits-without regard to legal requirements that Defendants act to prevent the diversion of drugs to illegal channels.

339. These legal associations and/or associations in fact include, at a minimum, a Manufacturer Defendant and a Distributor Defendant. These legal associations and/or associations in fact are, for purposes of the RICO Act, an enterprise (hereinafter, for purpose of this count, an "**Enterprise**," a "**Diversion Enterprise**," or collectively, the "**Enterprises**").

340. Under the present facts, each co-conspirator either (a) agreed to operate or manage the enterprise that did and does feloniously deal in controlled substances, an

offense punishable under the laws of the United States, or (b) if a co-conspirator did not agree to operate or manage the enterprise, each co-conspirator knowingly agreed to facilitate others who did and do operate or manage the enterprise of felonious dealing in controlled substances, an offense punishable under the laws of the United States.

341. The following example embodies the Enterprises. A Manufacturer Defendant manufactures opioids. The Manufacturer Defendant then sells the same opioids to a Distributor Defendant. The Distributor Defendant then distributes, or sells, the same opioids to a retailer. Finally, the retailer sells the same opioids to its customers who have been provided a prescription for the opioids.

342. To the Manufacturer Defendants and Distributor Defendants, it is irrelevant what the customer does with the opioids once the final sale has been made. They may ingest the opioids for legitimate medical purposes, such as to treat severe acute or chronic pain; they may abuse the opioids personally by ingesting them for recreational purposes or to support a drug habit; or they may give or sell them to a third-party abuser who ingests them recreationally or out of habit to support an addiction.

343. Each Diversion Enterprise (which may later include yet unnamed persons implicated by facts uncovered in the future, including doctors who write illegal prescriptions in exchange for cash payments from patients or increase their prescribing practices in exchange for kick-backs from Manufacturer Defendants), and each vertical supply chain therefore constitutes an individual Dealing Enterprise. And any given actor in the Enterprise, whether a Manufacturer Defendant or Distributor Defendant, may belong to one or more Diversion Enterprises.

344. The purpose of the Diversion Enterprises, which are schemes organized to maximize the members' profits at all cost, is to manufacture, encourage excessive prescriptions, distribute, and sell as many highly addictive—and often deadly—pills as legally possible. The Enterprises accomplish this by transferring pills down through the supply chain, entity by entity, from the manufacturer to the end user (who can be anyone with a prescription that at least appears to be legitimate). And they do so without regard for federal law requiring them to take affirmative steps to prevent the diversion of drugs onto the illegal marketplace.

345. For over a decade, the RICO Defendants aggressively sought to bolster their revenue, increase profit, and grow their share of the prescription painkiller market by unlawfully and surreptitiously increasing the volume of opioids they produced and sold. The RICO Defendants, however, are not permitted to engage in a limitless expansion through unlawful sales of regulated painkillers. As "registrants," the RICO Defendants operated and continue to operate within the "closed system" created under the Controlled Substances Act, 21 U.S.C. § 821, et seq. (the "**CSA**"). The CSA restricts the RICO Defendants' ability to manufacture or distribute Schedule II substances like opioids by requiring them to:

(a) Register to manufacture or distribute opioids;

(b) Maintain effective controls against "diversion" of the controlled substances that they manufacturer or distribute (*i.e.*, the transfer of the drug away from the person for whom it was intended);

(c) Design and operate a system to identify suspicious orders of controlled substances, halt such unlawful sales, and report them to the DEA; and

(d) Make sales within a limited quota set by the DEA for the overall production of Schedule II substances like opioids.

346. The closed system created by the CSA, including the establishment of quotas, was specifically intended to reduce or eliminate the diversion of Schedule II substances like opioids from "legitimate channels of trade" to the illicit market.

347. In addition, the CSA imposes strict checks on the size of the market for Schedule II substances such as opioids. The CSA requires the Attorney General to annually establish a "production quota" for Schedule II controlled substances by setting the total quantity of "each basic class of controlled substance" that is legally permitted to be produced in the United States. 21 U.S.C. § 826(a). In turn, each manufacturer of Schedule II drugs must apply for an "individual production quota" allowing that specific manufacturer to produce a certain quantity of drugs. *Id.* § 826(b). When setting the aggregate quota for the United States, the Attorney General must consider, among other things, the estimated legitimate demand for such drugs during the coming year. *Id.* § 826(a). When setting the "individual production quota" for manufacturers, the Attorney General must consider, among other things, the manufacturer's current rate of drug disposal and the "trend of the national disposal rate during the preceding calendar year." *Id.* § 826(c).

348. The Attorney General has delegated the responsibility of setting production quotas to the DEA. 28 C.F.R. § 0.100.

349. Members of the Enterprises systematically violated their statutory duty to maintain effective controls against diversion of their drugs, to design and operate a system to identify suspicious orders of their drugs, to halt unlawful sales of suspicious orders, and to notify the DEA of suspicious orders. Consequently, the RICO Defendants

allowed hundreds of millions of pills to enter the illicit market, which allowed the RICO Defendants to derive and be unjustly enriched by obscene profits.

350. Defendants' illegal scheme was hatched by an association-in-fact enterprise between the Manufacturer Defendants and the Distributor Defendants. Each of the RICO Defendants were associated with, and conducted or participated in, the affairs of the RICO enterprise, whose purpose was to engage in the unlawful sales of opioids and deceive the public and federal and state regulators into believing that the RICO Defendants were faithfully fulfilling their statutory obligations.

351. The RICO Defendants' scheme allowed them to make billions in unlawful sales of opioids and, in turn, increase and/or maintain high production quotas with the purpose of ensuring unlawfully increasing revenues and market share.

352. The RICO Defendants conducted and participated in the conduct of the Diversion Enterprise through a pattern of racketeering activity as defined in 18 U.S.C. § 1961(A) by the felonious dealing in a controlled substance or listed chemical (as defined in § 102 of the Controlled Substance Act), chargeable under state law. The Enterprises are engaged in or affect interstate commerce. The Enterprises are engaged in interstate commerce, or their activities affect interstate commerce, because many of the Enterprise's transactions that occur before opioids arrive in the retail purchaser's possession involve (a) sales between and/or among residents of different states, and/or (b) physical transportation of opioids across state lines.

353. CSA § 102 defines "controlled substance" as a drug or other substance or immediate precursor included in schedule I, II, III, IV, or I of part B of Title II of the Controlled Substances Act.

354. Schedule II controlled substances have a high potential for abuse and have a high potential to lead to physical and/or psychological dependence, despite that such drugs have currently accepted medical uses.

355. Each of the opioids manufactured or sold by the Manufacturer Defendants and Distributor Defendants is a semi-synthetic opiate or a synthetic opiate, including the branded versions of the Manufacturer Defendants' drugs that include morphine, codeine, oxycodone, hydrocodone, oxymorphone, hydromorphone, methadone, buprenorphine, fentanyl, and other similar drugs that are Schedule II controlled substances or listed chemicals as defined in section 102 of part B of Title II of the CSA.

356. The regulations promulgated under the CSA include a requirement that a person licensed to manufacture, distribute, prescribe, or dispense controlled substances design and operate a system to detect and report "suspicious orders" for controlled substances, as that term is defined in the regulation. 21 C.F.R. § 1301.74(b).

357. Each of the RICO Defendants qualifies as registrants under the CSA. Their status as registrants under the CSA requires that they maintain effective controls against diversion of controlled substances in schedule I or II, design and operate a system to disclose to the registrant suspicious orders of controlled substances, and inform the DEA of suspicious orders when discovered by the registrant. 21 U.S.C. § 823; 21 C.F.R. § 1301.74(b). Failure to abide by those requirements is a felony.

358. The multiple acts of racketeering activity that the RICO Defendants committed, or aided and abetted in the commission of, were related to each other, had a similar purpose, involved the same or similar participants and methods of commission, and have similar results affecting similar victims, including the City of Duluth. These acts pose a threat of continued racketeering activity and constitute a "pattern of racketeering activity" within the meaning of 18 U.S.C. § 1961(5).

359. Members of each Enterprise participated in the Enterprise's affairs:

(a) without regard to their obligations under the CSA, such as the obligation to report suspicious orders;

(b) without regard to what effect the Enterprise's operations may have on individuals or the larger community, such as mass overdoses, crime, addiction, and death;

(c) without regard to whether the prescriptions presented by purchasers are for legitimate purposes;

(d) without regard to whether the size of individual doses or collective volume of doses in individual prescriptions is appropriate, or extremely inappropriate, given the conditions for the opioids prescription;

(e) without regard to whether the purchasers did in the past or continue to exhibit drug seeking behavior;

(f) without regard to whether the purchasers have a known history of criminal activity inside the retail store, or on or near their property;

(g) without regard to whether an individual customer presents multiple prescriptions from different doctors, who are unaware of each other, during a single month; and

(h) without regard to whether prescriptions were written by doctors who have a known history of, or presently continue, engaging in suspicious or downright fraudulent over-prescribing.

360. The Predicate Offenses of the Enterprise are related because they:

(a) have the same purpose, results, participants, victims, and/or methods of commission; and/or

(b) are otherwise interrelated by distinguishing characteristics, which include, without limitation, commission in the same manner using the same means, such as: (I) intentionally failing to comply with CSA obligations to flag and report orders of controlled substances as suspicious when they meet certain criteria; (II) using aggressive marketing campaigns that encourage overprescribing medications for unapproved uses; (III) claiming that the drugs were far safer, less addictive, and more effective than alternatives, each of which claim is false and misleading; and (IV) providing such strong incentives for prescribing that such practices would be better described as bribery or coercion, (and which, in fact, in some cases, resulted in criminal convictions for violations of federal anti-kickback laws); and/or

(c) were conducted pursuant to an understanding and agreement, whether explicit or implicit, that each member would participate to facilitate and further the Enterprise's purpose, which was to maximize profits by manufacturing, distributing, and selling as many opioid pills as possible.

361. From at least as early as 1995 and continuing until the time of filing of this Complaint, in Duluth and elsewhere, Defendants and others did knowingly and intentionally devise and intend to devise an illegal scheme and artifice to increase and maintain profits from unlawful sales of opioids.

362. It was further part of said scheme and artifice that, in order to conceal the inundation of opioids in the stream of commerce, Defendants and their co-conspirators:

(a) would and did make representations and statements in national publications;

(b) would and did represent that Defendants would comply with their duty to (I) design and operate a system to disclose to the registrant suspicious orders of controlled substances, and (II) disclose the results of such a program to resolve concerns about over prescription and diversion of opioids; and

(c) would and did suppress and destroy records of suspicious orders to hide evidence of over prescription and diversion.

363. It was further part of said scheme and artifice that Defendants and their co-conspirators would seek to impair, impede, and defeat government authorities' ability to regulate diversion and to impair, impede, and defeat governmental efforts to regulate and control the manufacture and distribution of opioids, and would and did attempt to prevent the public, Congress, courts, and government officials from uncovering those activities.

364. It was further part of said scheme and artifice that Defendants' communications directed toward government officials and courts would be and were designed to preserve and increase the market for prescription opioids while concealing Defendants' role in supporting an illegal market for opioids.

365. Throughout the existence of the Enterprise, the RICO Defendants purposefully failed to comply with all state and federal regulations regarding the identification and reporting of suspicious orders of prescription opioids-all the while espousing to the general public, to Congress, and to federal and state agencies, their commitment to preventing diversion of prescription opioids.

366. The felonious dealings described herein were made in furtherance of RICO Defendants' unified scheme to increase and maintain profits from unlawful sales of opioids while thwarting the ability of federal and state regulators to prevent diversion. This unified scheme was furthered by (1) habitual noncompliance with federal and state law; (2) intensive lobbying of federal and state officials to evade further regulation; and (3) increasing and/or maintaining high production quotas for their prescription opioids from which Defendants could profit for as long as possible.

367. RICO Defendants unlawfully, knowingly, and intentionally combined, conspired, confederated, and agreed together with each other, and with others whose names are both known and unknown, to conduct and participate, directly and indirectly, in the overall objective of their unified scheme, and participated in the common course of conduct to fail to prevent the overprescribing and diversion of prescription opioids.

368. Upon information and belief, each of the Defendants had to agree to implement similar tactics regarding marketing prescription opioids and refusing to report suspicious orders. If any RICO Defendant had disclosed and/or withheld suspicious orders, the conspiracy would be endangered.

369. RICO Defendants engaged in a pattern of related and continuous predicate acts for years. The predicate acts constituted a variety of unlawful activities, each conducted with the common purpose of obtaining significant monies and revenues while benefitting from, encouraging, indirectly creating, contributing to, and maintaining an illegal secondary market for highly addictive and dangerous drugs. The predicate acts involved the same or similar purposes, participants, victims, including criminal acts with the same or similar purposes, results, participants, victims, methods of commission, and are not isolated events.

370. Many of the precise dates of the RICO Defendants' criminal actions are not known and cannot be alleged without access to Defendants' books and records. Indeed, an essential part of the successful operation of the unified scheme alleged herein depended upon secrecy-and, towards that end, RICO Defendants took deliberate steps to conceal their wrongdoing. However, given the massive scope of the illegal scheme,

RICO Defendants likely committed thousands, if not millions, of predicate acts of racketeering activity.

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

372. It was foreseeable to Defendants that refusing to report and halt suspicious orders, as required by the CSA and the Code of Federal Regulations, would harm the City of Duluth by allowing the flow of prescription opioids from appropriate medical channels into the illicit drug market.

373. The following DEA communications reflect the RICO Defendants' pattern and practice of wilfully and intentionally omitting information from their mandatory reports to the DEA as required by 21 C.F.R. § 1301.74:

(a) On April 24, 2007, the DEA issued an Order to Show Cause and Immediate Suspension Order against AmerisourceBergen's distribution center in Orlando, Florida ("**Orlando Facility**"), alleging failure to maintain effective controls against diversion of controlled substances. On June 22, 2007, AmerisourceBergen entered into a settlement that resulted in the suspension of its DEA registration.

(b) On November 28, 2007, the DEA issued an Order to Show Cause and Immediate Suspension Order against Cardinal Health's distribution center in Auburn, Washington ("**Auburn Facility**"), for failure to maintain effective controls against diversion of hydrocodone.

(c) On December 5, 2007, the DEA issued an Order to Show Cause and Immediate Suspension Order against Cardinal Health's distribution center in Lakeland, Florida ("**Lakeland Facility**"), for failure to maintain effective controls against diversion of hydrocodone.

(d) On December 7, 2007, the DEA issued an Order to Show Cause and Immediate Suspension Order against Cardinal Health's distribution center in Swedesboro, New Jersey ("**Swedesboro Facility**"), for failure to maintain effective controls against diversion of hydrocodone.

(e) On January 30, 2008, the DEA issued an Order to Show Cause and Immediate Suspension Order against the Cardinal Health's distribution center in Stafford, Texas ("**Stafford Facility**"), for failure to maintain effective controls against diversion of hydrocodone.

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

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

(h) On February 2, 2012, the DEA issued an Order to Show Cause and Immediate Suspension Order against the Cardinal Health's Lakeland Facility for failure to maintain effective controls against diversion of oxycodone.

(i) On December 23, 2016, Cardinal Health agreed to pay a $44 million fine to the DEA to resolve the civil penalty portion of the administrative action taken against its Lakeland Facility.

(j) On January 5, 2017, McKesson Corporation entered into an Administrative Memorandum Agreement with the DEA wherein it agreed to pay a $150,000,000 civil penalty for violation of the 2008 MOA as well as failure to identify and report suspicious orders at its facilities in Aurora, Colorado; Aurora, Illinois; Delran, New Jersey; LaCrosse, Wisconsin; Lakeland, Florida; Landover, Maryland; La Vista, Nebraska; Livonia, Michigan; Methuen, Massachusetts; Santa Fe Springs, California; Washington Courthouse, Ohio; and West Sacramento, California.

374. These actions against the Distributor Defendants confirm that the Distributors knew they had a duty to maintain effective controls against diversion, design and operate a system to disclose suspicious orders, and report suspicious orders to the DEA. These actions also demonstrate, on information and belief, that the Manufacturer

Defendants were aware of the enforcement against their Distributors and the diversion of the prescription opioids. Manufacturer Defendants had a corresponding duty to report these suspicious orders.

375. Given the continuous nature of these offenses – as demonstrated by the number of co-conspirators convicted, the number of predicate offenses committed by the co-conspirators, and the length of time over which they were committed –the pattern of conduct by the co-conspirators presents a significant risk of continued criminal activity and serious, resulting harm.

ii. Marketing Enterprise

376. In addition to their participation in the Diversion Enterprises, Manufacturer Defendants and their co-conspirators engaged in a coordinated conspiracy to deceive the American public and the medical profession about the efficacy and safety of opioids, including by minimizing perceptions of the addictive qualities of opioids. That conspiracy is referred to as the "**Marketing Enterprise**," or, for purposes of this subsection, the "**Enterprise**."

377. The formation, existence, and actions of the Marketing Enterprise were essential to the success of Manufacturer Defendants' campaign to increase and maintain profits from unlawful sales of opioids. The constituent members of the Marketing Enterprise were aware that, unless they agreed to act and acted as an enterprise, their sales of prescription opioids would substantially decrease, and accordingly, the profits of the Manufacturer Defendants would substantially diminish.

378. At all relevant times, the Marketing Enterprise has existed separate and apart from Defendants' racketeering acts and their conspiracy to commit such acts. The

Marketing Enterprise has an ascertainable structure and purpose beyond the scope and commission of Defendants' predicate acts. It has a consensual decision-making structure that is used to coordinate strategy, manipulate scientific data, suppress the truth about the addictive qualities of opioids, and otherwise further the Manufacturer Defendants' fraudulent unified scheme.

379. The Manufacturer Defendants' conduct, and that of their co-conspirators, has been directed in a uniform manner using the same misleading and deceptive drug labels and promotional practices.

380. The Manufacturer Defendants' deceptive and misleading marketing scheme increased the number of prescriptions of opioids written and filled over the last two decades. Because Defendants withheld material information about the true safety and efficacy of opioids, prescribing physicians did not have the knowledge necessary to make informed decisions regarding opioid prescriptions. Physicians thus wrote prescriptions they would not have otherwise, and the City of Duluth, unaware of Manufacturer Defendants' scheme, was left to pay for the resulting opioid epidemic affecting the City.

381. Effective, safe, and less expensive alternatives to opioids are available. Yet the Manufacturer Defendants were able to dominate the market for pain-relief by funding and carrying out an aggressive misinformation campaign about opioid safety and effectiveness. Because of that campaign, which sparked the opioid epidemic and its widespread devastation, the Manufacturer Defendants raked in billions of dollars in profits. Those are ill-gotten gains to which the Manufacturer Defendants are not entitled.

382. Patients relied on the Manufacturer Defendants' misrepresentations regarding opioid safety and efficacy when making purchases of the drugs. Physicians relied on the Manufacturer Defendants' misrepresentations regarding opioid safety and efficacy when prescribing the drugs for their patients. From both groups, the Manufacturer Defendants withheld material information about the drugs' safety and efficacy that was not otherwise available and undercut the entire rationale for their use.

383. The Marketing Enterprise functioned as an ongoing organization and continuing unit.

384. The Marketing Enterprise was created and/or used as a tool to effectuate a pattern of racketeering activity. Each of the Marketing Enterprise participants, including Defendants, is a "person" distinct from the Marketing Enterprise.

385. Each of the Defendants, in concert with the other Enterprise participants, created and maintained systematic links for a common purpose, *e.g.*, to aid in marketing opioids as effective and safe for use by patients in moderate pain, while suppressing evidence to the contrary. Each of the participants in the Marketing Enterprise received revenue, directly or indirectly, and/or otherwise benefitted from the scheme to promote opioids as safe and non-addictive. Such revenue was exponentially greater than it would have been had opioids been marketed appropriately and the true efficacy and safety risks of prescription opioids disclosed. All participants of the Marketing Enterprise were aware of Defendants' control over the activities of the Enterprise in promoting opioids for use in every situation in which a patient is in pain. Furthermore, each portion of the Enterprise benefited from the existence of the other parts.

386. Defendants established the Marketing Enterprise to accomplish goals that were instrumental to its scheme designed to market and sell opioids in every situation in which a patient is in pain.

387. To further the conspiracy, and as part of an Enterprise that was engaged in a pattern of racketeering activity, Defendants formed multiple front groups or infiltrated existing third-party organizations to avoid regulation from the FDA and other governmental agencies and to spread disinformation to prescribers and the public.

(a) The American Pain Foundation ("**APF**"), founded in 1997, described itself as the nation's largest advocacy group for pain patients. At the heart of its messaging was that the risk of opioid addiction was overblown, and opioids were underused as a treatment for pain. In December 2011, a ProPublica investigation found that in 2010, nearly 90% of APF's funding came from the drug and medical device community, including Manufacturer Defendants. On May 8, 2012, the U.S. Senate Finance Committee sent a letter to APF inquiring about its ties to drug manufactures. That very same day, APF announced it was ceasing operations, effective immediately. APF, upon information and belief, received more than $10 million in funding from opioid manufacturers from 2007 through 2012. The primary opioid manufacturer contributors were Purdue and Endo. Manufacturer Defendants Purdue, Endo, Janssen, and Cephalon all contributed to funding APF;

(b) The American Academy of Pain Management ("**AAPM**") is a medical specialty society which has received funding from Manufacturer Defendants for years. Upon information and belief, Endo, Janssen, and Purdue have contributed funding to AAPM. AAPM issued a statement in 1997 that endorsed opioids and claimed that the risk of opioid addiction in people taking prescription opioids was low. The chairman of AAPM at that time was Dr. David Haddox. Dr. Haddox was, at the time of the statement, a paid speaker for Purdue. He later went on to become Purdue's vice president for health policy and is most known for inventing the pseudoscience of pseudoaddiction (the idea that opioid-seeking patients are not actually addicted to opioids but are "undertreated," requiring higher doses of opioids.);

(c) In 2009, the American Pain Society ("**APS**") and AAPM jointly issued guidelines ("**APS/AAPM Guidelines**") recommending the use of opioids to treat chronic pain. The APS/AAPM guidelines promoted the use of opioids for the treatment of chronic pain and concluded that the risk of opioid addiction was manageable in patients regardless of previous histories of abuse. At least fourteen

of the twenty-one panel members who drafted the APS/AAPM Guidelines received funding from manufacturer defendants Purdue, Endo, Cephalon, or Janssen;

(d) FSMB printed and distributed "Responsible Opioid Prescribing," a guide authored by Dr. Scott Fishman in 2007 on behalf of the Manufacturer Defendants. FSMB received funding from organizations that manufacture opioid-based drugs from 1997 through 2012. Included in the list of payments are Manufacturer Defendants Purdue, Endo, Cephalon, and Mallinckrodt. Total disclosed payments include $822,400.06 from Purdue, $371,620.00 from Endo, $180,000.00 from Cephalon, and $100,000.00 from Mallinckrodt;

(e) The Pain Care Forum ("**PCF**") is a coalition comprised of Manufacturer Defendants, trade groups, and various front groups supported by the pharmaceutical industry. Purdue, Endo, Cephalon, and Janssen are each represented in PCF. Upon information and belief, Distributor Defendants participated directly in PCF as well. PCF projects included making sure that a FDA mandated education project on opioids did not require mandatory participation by prescribers, since Manufacturer Defendants determined this would reduce opioid prescribing habits; and

(f) Healthcare Distribution Alliance ("**HDA**") is an association of pharmaceutical manufacturers and distributors. Upon information and belief, members of the HDA included Manufacturer Defendants Purdue, Endo, Johnson & Johnson (Janssen's parent company), Actavis, and Teva (Cephalon's parent company), and Distributor Defendants McKesson, Cardinal Health, and AmerisourceBergen.

388. The Marketing Enterprise used three principal stratagems to facilitate their goal of misleading doctors and the public about the dangers of opioids.

389. First, using the shadow groups discussed above, the Marketing Enterprise created a marketing structure that appeared independent from the Manufacturer Defendants. In so doing, the Manufacturer Defendants sought to avoid federal regulations concerning off-label promotion.

390. Second, the Manufacturer Defendants generated and published favorable articles that appeared to emanate from independent physicians.

391. Third, to widely disseminate the message that opioids were practically non-addictive, Defendants' marketing enterprise developed misleading labelling. That labelling was widely disseminated across the country to physicians and prescribers.

392. These three stratagems were complementary and mutually reinforcing. The production of favorable publications and the peer-to-peer marketing and promotion allowed aggressive sales pitches to continue with the appearance of legitimacy.

393. There was a common strategy employed by these Enterprise participants whereby the Enterprise participants would recruit and use physicians, both for marketing and publication, to promise the ubiquitous use of opioids. That created the perception that independent physicians were achieving favorable results with opioids with little to no incidence of addiction.

394. The various participants of the Enterprise performed work that the Manufacturer Defendants could not lawfully do, including funnelling payments to physicians, misleading the public into believing the message was coming from a neutral source, covering up Manufacturer Defendants' control over the Enterprises, and actively concealing any negative information.

395. These systematic linkages between physicians, marketing participants, physician participants, Manufacturer Defendants, and all the Enterprise participants were established for a common purpose: to aid in marketing and selling opioids for ubiquitous use to treat all levels of pain. Many of the Enterprise participants received substantial revenue from the scheme to promote opioids. Such revenue was exponentially greater than it would have been if opioids been marketed appropriately.

396. All participants of the Enterprise were fully aware of the Manufacturer Defendants' control over the Enterprise. Furthermore, each portion of the Enterprise benefited from the existence of other parts. For example, medical "experts" and "thought leaders" on the Enterprise's payroll produced literature promoting opioids-which, in turn, provided medical legitimacy to the Enterprise's direct-to-prescriber promotional materials.

397. The Marketing Enterprise are engaged in interstate commerce, or their activities affect interstate commerce, because many of the Enterprise's activities involved (a) promotion of opioid sales between and/or among residents of different states, and/or (b) physical transportation of promotional materials across state lines.

398. The named Manufacturer Defendants exerted control over the Enterprise, and Defendants have participated in the operation or management of the affairs of the Enterprise.

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

> (a) Mail Fraud: The Manufacturer Defendants violated 18 U.S.C. § 1341 by sending and receiving, and by causing to be sent and/or received, materials via U.S. Mail or commercial interstate carriers to execute the unlawful scheme to deceptively market and sell the opioids by means of false pretenses, misrepresentations, promises, and omissions; and
>
> (b) Wire Fraud: The Manufacturer Defendants violated 18 U.S.C. § 1343 by transmitting and/or receiving, and by causing to be transmitted and/or received, materials by wire, to execute the unlawful scheme to defraud and obtain money on false pretenses, misrepresentations, promises, and omissions.

400. The Manufacturer Defendants' use of the mails and wires include, but are not limited to, the transmission, delivery, and shipment of deceptive marketing materials

by the Manufacturer Defendants and other members of the opioid marketing fraud enterprise. These materials would not have been delivered but for the Manufacturer Defendants' illegal scheme, including, but not limited to:

(a) False or misleading communications to the public and regulators;

(b) Sales and marketing materials, including slide decks, presentation materials, purported guidelines, advertising, web sites, product packaging, brochures, labelling and other writings which misrepresented, falsely promoted, and concealed the true nature of opioids;

(c) Numerous guides and brochures for patients, doctors, and policymakers produced by the American Pain Foundation that minimized the risks of addiction and exaggerated the benefits associated with prescription opioids, including but not limited to: the "Policymaker's Guide," sponsored by Purdue, which sought to dispel the "myth" that opioid pain medication leads to addiction; "Exit Wounds: A Survival Guide to Pain Management for Returning Veterans & Their Families," sponsored by Endo, which falsely claimed that it is unlikely that people who are not predisposed to addiction will become addicted to opioid painkillers; and "Treatment Options: A Guide for People Living with Pain," which promoted opioids as essential for treating even "moderate" pain;

(d) Statements by the American Academy of Pain Management that endorsed opioids and claimed that the risk of opioid addiction in people taking prescription opioids was low;

(e) Guidelines issued in 2009 by the American Pain Society ("**APS**") and American Academy of Pain Management ("**AAPM**") recommending the use of opioids to treat chronic pain. The APS/AAPM guidelines promoted the use of opioids for the treatment of chronic pain and concluded that the risk of opioid addiction was manageable in patients regardless of previous histories of abuse; and

(f) Distribution of "Responsible Opioid Prescribing," a guide authored by Dr. Scott Fishman in 2007. The guide was ultimately disseminated to 700,000 practicing doctors, with doctors in Minnesota receiving copies. The "Responsible Opioid Prescribing" guide promoted the use of opioid pain relievers for both acute and chronic pain and severely minimized the risk of addiction—even claiming that opioids could be used safely in patients assessed to have a risk of substance abuse. The guide promoted the widespread use of opioids, stating that "[p]atients should not be denied opioid medications except in light of clear evidence that such medications are harmful to the patient."

401. The conduct of the Enterprise described above constitutes "racketeering activity" within the meaning of 18 U.S.C. § 1961(1). The Manufacturer Defendants' decision for the Enterprise to routinely conduct its transactions in such a manner constitutes a "pattern of racketeering activity" within the meaning of 18 U.S.C. § 1961(5).

402. The above described racketeering activities amounted to a common course of conduct intended to deceive and harm the public and the City of Duluth. The Manufacturer Defendants' racketeering activity was related, had similar purposes, involved similar or the same participants, and methods of commission, and had similar results affecting the same or similar victims, including the City of Duluth. Defendants' racketeering activities were part of their ongoing business and constituted a continuing threat to the property of the City of Duluth.

403. The Manufacturer Defendants' motive in creating and operating the fraudulent scheme and the Enterprises was to obtain additional revenues from the marketing and sale of opioids for treating every conceivable level of patient pain.

404. The City of Duluth has been injured in its property by reason of these violations in that the City has paid and will pay millions of dollars to abate the public nuisance that is the opioid epidemic in Duluth, Minnesota.

405. Defendants' racketeering activity was a substantial factor in bringing about injuries to the City of Duluth. In the absence of the Manufacturer Defendants' unlawful conduct, the American public and the American medical community would not have been misled as to the addictive qualities of opioids.

406. The Enterprise, and the members thereof, acted and participated to further the purpose of the Enterprise wilfully and/or with actual knowledge of the illegal acts of the Enterprise, as evidenced by their aggressive marketing campaigns and even recent activities abroad, which includes companies owned and controlled by Purdue running training seminars where doctors are urged to overcome "opiophobia" and prescribe painkillers.[21]

407. The RICO Defendants did not undertake the practices described herein in isolation, but as part of a common scheme. These actions violate 18 U.S.C. § 1962(c). Various other persons, firms, and corporations, including third-party entities and individuals not named as defendants in this Complaint, may have contributed to and/or participated in the scheme with the RICO Defendants and have performed acts in furtherance of the scheme to increase revenues, increase market share, and/or minimize the losses for the RICO Defendants.

408. The RICO Defendants, with knowledge and intent, agreed to the overall objective of their fraudulent scheme, and participated in the common course of conduct to commit acts of fraud and indecency in manufacturing and distributing prescription opioids.

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[21] Harriet Ryan, Lisa Girion & Scott Glober, *OxyContin goes Global—"We're only just getting started"*, L.A. TIMES (Dec. 18, 2016), *available at* http://www.latimes.com/projects/la-me-oxycontin-part3/ (last accessed Oct. 27, 2018).

409. Indeed, for the Defendants' fraudulent scheme to work, each of the Defendants had to agree to implement similar tactics regarding marketing prescription opioids and refusing to report suspicious orders.

410. As described herein, the RICO Defendants engaged in a pattern of related and continuous predicate acts for years. The predicate acts constituted a variety of unlawful activities, each conducted with the common purpose of obtaining significant monies and revenues from the sale of highly addictive and dangerous drugs. The predicate acts also had the same or similar results, participants, victims, and methods of commission. The predicate acts were related and not isolated events.

411. The predicate acts all had the purpose of generating significant revenue and profits for the RICO Defendants. At the same time, the City of Duluth was forced to shoulder costs related to the damage that the prescription opioid epidemic caused.

412. The pattern of racketeering activity alleged herein, and the Enterprises alleged herein (including both the Diversion Enterprise and the Marketing Enterprise) are separate and distinct from each other. Likewise, Defendants are distinct from the Enterprises.

413. All the RICO Defendants conducted and participated in the conduct of the affairs of the Marketing Enterprise or the Diversion Enterprise through a pattern of racketeering activity as defined in 18 U.S.C. § 1961(1)(D) by the felonious manufacture, importation, receiving, concealment, buying, selling, or otherwise dealing in a controlled substance or listed chemical (as defined in § 102 of the Controlled Substance Act), punishable under any law of the United States.

414. Furthermore, in so doing the acts alleged herein, the members of the Enterprises (the "**Co-Conspirators**") conspired to violate § 1962(c) of the RICO Act, and they thereby violated § 1962(d) of the RICO Act.

415. The Co-Conspirators so conspired because there was a meeting of the minds evidencing the alleged conspiracy of which the intent was to violate § 1962(c).

416. The Diversion Enterprise and Marketing Enterprise did encourage, and indirectly create, contribute to, and maintain an illegal secondary market for opioids.

417. The pattern of racketeering activity alleged herein is continuing as of the date of this Complaint and, upon information and belief, will continue into the future unless enjoined by this Court.

418. But for the conduct of the Enterprises' affairs, the City of Duluth would not have sustained damages.

419. The City of Duluth's damages are neither remote nor are they derivative of harm visited upon third party persons or entities not named in this action.

420. By the foregoing violations of the RICO Act, including 18 U.S.C. § 1962(c), Manufacturer Defendants are liable to the City of Duluth for three times the damages sustained, plus the costs of this suit, including reasonable attorney fees.

VIII. COUNT II
NEGLIGENCE
Against all Defendants

421. The City of Duluth incorporates by reference, as if fully set forth herein, each and every preceding paragraph.

422. Separate and apart from the Defendants' statutory duties, each of the Defendants owed the City of Duluth common-law duties, including the duty to

investigate and report plainly suspicious orders of highly addictive opioids. Each of the Defendants breached these duties by failing to report such suspicious orders to the appropriate regulators, failing to adequately to investigate suspicious orders before filling them, and/or failing to design and operate a system that would disclose the existence of suspicious orders of controlled substances. In so doing, Defendants acted unreasonably, reckless, and with actual malice.

423. Separate and apart from the Manufacturer Defendants' statutory duties, each of the Manufacturer Defendants owed the City of Duluth common-law duties, including the duty to be forthright and honest with the FDA and federal authorities regarding their products; the duty to promote and market opioids truthfully and pursuant to their federally approved indications for use; and the duty to disclose the true risk of addiction associated with the use of opioids. Each of the Manufacturer Defendants breached those duties by, among other things, promoting and marketing opioids for uses not federally approved, circulating false and misleading information concerning their safety and efficacy, and downplaying or failing to disclose the risk of addiction arising from their use. In so doing, Defendants acted unreasonably, reckless, and with actual malice.

424. The City of Duluth suffered both injuries and pecuniary losses proximately caused by Defendants' breaches of their duties set forth in this Count. Among other things, the City's residents are suffering through an unprecedented epidemic of opioid addiction and overdose. This epidemic has forced the City of Duluth to shoulder tremendous costs relating, among other things, to health services, emergency

services, social services, and law enforcement. The City has also suffered a loss of productivity in its municipal workforce, as well as lost tax revenue stemming from the cascading effects of the opioid epidemic.

425. Defendants' breaches of the common-law duties they owed to the City are the proximate cause of this crisis and its resulting harm to the City of Duluth.

426. WHEREFORE, Plaintiff demands judgment against the Defendants for actual and compensatory damages; for restitution; for costs incurred herein; the cost of abating the public nuisance, and such other and further relief as this Court deems just and proper.

427. Further, pursuant to Minn. Stat. § 549.191, Plaintiff reserves the right to seek an amendment to this Complaint to assert a claim for punitive damages under Count II.

IX. COUNT III
NEGLIGENCE PER SE
Against all Defendants

428. The City of Duluth incorporates by reference, as if fully set forth herein, each and every preceding paragraph.

429. Each of the Defendants owed the City of Duluth statutory duties, including the duty to report suspicious orders of opioids (and the appurtenant duty to investigate any such orders before filling them), the duty to abide by any government agreements entered regarding the same, and the duty to comply with the federal CSA, 21 C.F.R. § 1301.74(b), which required the design and operation of a system to detect and disclose suspicious orders of controlled substances.

430. Each of the Defendants breached these duties by failing to report such suspicious orders to the appropriate regulators as required by state and federal law, by failing to adequately investigate suspicious orders before filling them, and/or by failing to design and operate a system that would disclose the existence of suspicious orders of controlled substances. In so doing, Defendants acted unreasonably, reckless, and with actual malice.

431. Each of the Manufacturer Defendants owed the City of Duluth statutory duties, including the duty to be forthright and honest with the FDA and federal authorities regarding their products; the duty to promote and market opioids truthfully and pursuant to their federally approved indications for use; and the duty to disclose the true risk of addiction associated with the use of opioids.

432. Each of the Manufacturer Defendants breached those duties by, among other things, promoting and marketing opioids for uses not federally approved, circulating false and misleading information concerning their safety and efficacy, and downplaying or failing to disclose the risk of addiction arising from their use. In so doing, Defendants acted unreasonably, reckless, and with actual malice.

433. The City of Duluth suffered both injuries and pecuniary losses proximately caused by Defendants' breaches of their duties set forth in this Count. Among other things, the City's residents are suffering through an unprecedented epidemic of opioid addiction and overdose. This epidemic has forced the City of Duluth to shoulder tremendous costs relating, among other things, to health services, emergency services, social services, and law enforcement. The City has also suffered a loss of

productivity in its municipal workforce, as well as lost tax revenue stemming from the cascading effects of the opioid epidemic.

434. Defendants' breaches of the statutory duties they owed to the City are the proximate cause of this crisis and its resulting harm to the City.

435. Plaintiff demands judgment against the Defendants for actual and compensatory damages; for restitution; for costs incurred herein; the cost of abating the public nuisance, and such other and further relief as this Court deems just and proper.

436. Pursuant to Minn. Stat. § 549.191, Plaintiff reserves the right to seek an amendment to this Complaint to assert a claim for punitive damages under Count III.

X. COUNT IV
GROSS NEGLIGENCE
Against All Defendants

437. The City of Duluth incorporates the allegations within all prior paragraphs within this Complaint as if they were fully set forth herein.

438. To establish gross negligence, the City of Duluth must show that Defendants acted with the absence of even slight diligence or scant care, or that they acted with indifference, or were negligent in a very high degree. The City of Duluth has met its burden here.

439. Defendants have a duty to exercise reasonable care in manufacturing, marketing, and selling highly dangerous drug opioids in Duluth.

440. Defendants have a duty to exercise reasonable care under the circumstances, in light of the risks. This includes a duty not to cause foreseeable harm to others. In addition, these Defendants, having engaged in conduct that created an

unreasonable risk of harm to others, had, and still have, a duty to exercise reasonable care to prevent the threatened harm.

441. Defendants also misleadingly portrayed themselves as cooperating with law enforcement and actively working to combat the opioid epidemic when, in reality, Defendants failed to satisfy even their minimum, legally-required obligations to report suspicious prescribers. Defendants voluntarily undertook duties, through their statements to the media, regulators, and the public at large, to take all reasonable precautions to prevent drug diversion.

442. Upon information and belief, each Defendant repeatedly and intentionally breached its duties. These breaches included:

a. Selling prescription opioids in the supply chain when they knew, or should have known, that there was a substantial likelihood the sale was for non-medical purposes and that opioids are an inherently dangerous product when used for non- medical purposes;

b. Using unsafe distribution practices;

c. Inviting criminal activity into the City of Duluth by disregarding precautionary measures built into Minnesota's statutory and regulatory requirements related to controlled substances, to which they agreed to adhere in obtaining licenses or registrations from the Minnesota Board of Pharmacy and the DEA;

d. Failing to comply with the public safety laws described above;

e. Failing to acquire or utilize special knowledge or skills that relate to the dangerous activity of selling opioids in order to prevent or ameliorate such significant dangers;

f. Failing to review prescription orders for red flags;

g. Failing to report suspicious orders or refusing to fill them; and

h. Failing to provide effective controls and procedures to guard against theft and diversion of controlled substances.

443. Each Defendant breached its duty to exercise the degree of care, prudence, watchfulness, and vigilance commensurate with the dangers involved in selling dangerous controlled substances.

444. Defendants acted with actual malice in breaching their duties, *i.e.*, they have acted with a conscious disregard for the rights and safety of other persons and said actions have a great probability of causing substantial harm.

445. In breaching these duties, each Defendant showed the absence of even slight diligence or scant care, or that they acted with indifference, or were negligent in a very high degree.

446. As is described throughout this Complaint, Defendants acted without even slight diligence or scant care, and with indifference, and were negligent in a very high degree, disregarding the rights and safety of other persons, and said actions have a great probability of causing substantial harm.

447. The foreseeable harm from a breach of these duties is the sale, use, abuse, and diversion of prescription opioids..

448. The foreseeable harm from a breach of these duties also includes abuse, addiction, morbidity, and mortality in the City of Duluth's communities, and among its employees and their dependents.

449. Reasonably prudent manufacturers of prescription opioids would have anticipated that the scourge of opioid addiction would wreak havoc on communities

and the significant costs which would be imposed upon the governmental entities serving those communities.

450. Reasonably prudent manufacturers of pharmaceutical products would know that aggressively pushing highly addictive opioids for chronic pain would result in the severe harm of addiction, foreseeably causing patients to seek increasing levels of opioids and to turn to the illegal drug market as a result of a drug addiction that was foreseeable to the Defendants. Reasonably prudent manufacturers would know that failing to report suspicious prescribing, particularly while assuring the public of their commitment to fighting the opioid epidemic, would exacerbate problems of diversion and non-medical use of prescription opioids.

451. The City of Duluth seeks economic losses (direct, incidental, or consequential pecuniary losses) resulting from the gross negligence of Defendants. The City of Duluth does not seek damages which may have been suffered by individual residents of the City of Duluth for wrongful death, physical personal injury, serious emotional distress, or any physical damage to property caused by the actions of Defendants.

452. Defendants' conduct, as described in this Complaint, constitutes an intentional failure to perform a manifest duty in reckless disregard of the consequences as affecting the life or property of another, including the City of Duluth, and also implies an indifferent and thoughtless disregard of the consequences without the exertion of any effort to avoid them. Defendants have acted wantonly and wilfully by inflicting injury intentionally or, alternatively, they have been utterly

indifferent to the rights of others, including the City of Duluth, in that they acted as if such rights did not exist.

453. The City of Duluth is not asserting a cause of action under the CSA or other controlled substance laws cited above. Rather, it seeks to remedy harms caused to it by the breach of duty created by federal and state statutes and under common law.

454. Defendants' conduct as described in this Count demonstrates wanton and wilful disregard and indifference for others, including the City of Duluth.

455. Defendants' breaches of the duties described in this Count directly and proximately resulted in the injuries and damages alleged by the City.

456. The misconduct alleged in this case is ongoing and persistent.

457. The misconduct alleged in this case does not concern a discrete event or discrete emergency of the sort a political subdivision would reasonably expect to occur, and is not part of the normal and expected costs of a local government's existence. The City of Duluth alleges wrongful acts which are neither discrete nor of the sort a local government can reasonably expect.

458. The City of Duluth has incurred expenditures for special programs over and above its ordinary municipal services.

459. WHEREFORE, The City of Duluth seeks all legal and equitable relief as allowed by law, except as expressly disavowed herein, including *inter alia* injunctive relief, compensatory damages, and all damages allowed by law to be paid by

Defendants, attorney fees and costs, and pre and post judgment interest, and such other relief as this Court deems just and equitable.

460. Pursuant to Minn. Stat. § 549.191, Plaintiff reserves the right to seek an amendment to this Complaint to assert a claim for punitive damages under Count IV.

XI. COUNT V.
MINNESOTA FALSE CLAIMS ACT
(Minn. Stat. § 15C.02)
Against Manufacturer Defendants

461. The City of Duluth incorporates the allegations within all prior paragraphs within this Complaint as if they were fully set forth herein.

462. Minnesota Stat. § 15C.02 states that a person may not:

a. Knowingly present, or cause to be presented, a false or fraudulent claim for payment or approval;

b. Knowingly make or use, or cause to be made or used, a false record or statement material to a false or fraudulent claim;

c. Knowingly conspire to commit a violation of clause (1), (2), (4), (5), (6), or (7).

463. Pursuant to Section 15C.04, a "prosecuting attorney may investigate violations of section 15C.0 [and] may bring a civil action under this chapter... to enjoin an act in violation of section 15C.02 and to recover damages and penalties." The definition of "prosecuting attorney" includes "the county attorney, city attorney, or other attorney representing a political subdivision, if the false or fraudulent claim involves money, property, or services provided by the political subdivision."

464. The undersigned attorneys representing Duluth are "prosecuting attorneys" as that term is used in Section 15C.04.

465. Manufacturer Defendants, as described in this Complaint, violated the Minnesota False Claims Act. These Defendants, through their deceptive marketing of opioids for chronic pain knowingly made, or caused to be made, false or fraudulent claims to the City of Duluth and/or its agents; knowingly made or caused to be made or used false statements material to such claims; and conspired to cause such false or fraudulent claims and statements to be made to the City of Duluth and/or its agents.

466. Specifically, Manufacturer Defendants' misrepresentations and false statements material to such false or fraudulent claims include but are not limited to:

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

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

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

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

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

f. Defendants' claims that screening tools effectively prevent addiction;

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

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

i. Purdue's claims OxyContin provides a full 12 hours of pain relief;

j. Purdue's claims that it cooperates with and supports efforts to prevent opioid abuse and diversion;

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

l. Defendants' use of front groups to suggest that the deceptive statements from the sources described in this Complaint came from objective, independent sources; and

m. Manufacturer Defendants' unsubstantiated claims that certain opioids were appropriate for treatment of non-cancer pain and their failure to disclose that those opioid was not approved for such use.

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

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

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

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

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

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

f. Purdue's 12-hour OxyContin fails to last a full twelve hours in many patients;

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

h. Manufacturer Defendants' failure to report suspicious prescribers;

i. Manufacturer Defendants' use of kickback and insurance fraud schemes; and

j. Defendants' fai1ure to disclose their financial ties to and role in connection with Front Groups.

468. Upon information and belief, Manufacturer Defendants knew, deliberately ignored, or recklessly disregarded, at the time of making or disseminating these statements, or causing these statements to be made or disseminated, that such statements were untrue, false, or misleading or contained material omissions and were made for the purpose of inducing the City of Duluth to pay for opioids for long-term treatment of chronic pain. In addition, Manufacturer Defendants knew, deliberately ignored, or recklessly disregarded, that their marketing and promotional efforts created an untrue, false, and misleading impression about the risks, benefits, and superiority of opioids for chronic pain.

469. Manufacturer Defendants knew that the doctors and other health care providers and/or agents of the City of Duluth to whom they deceptively marketed prescription opioids had treated and would continue to treat patients whose prescription costs were paid or reimbursed by the City of Duluth's health plan and City workers' compensation plan.

470. These Defendants' scheme caused doctors to write prescriptions for opioids to treat chronic pain that were submitted to the City of Duluth in an attempt to obtain payment from public funds.

471. Defendants knew, deliberately ignored, or recklessly disregarded that as a natural consequence of their actions, governments such as the City of Duluth would necessarily be paying for long-term prescriptions of opioids to treat chronic pain, which were dispensed as a consequence of Defendants' fraud.

472. These Defendants' misrepresentations and omissions were material because if the City of Duluth had known of the false statements and/or false claims, the City of Duluth would have undertaken efforts to avoid its payment of false claims or to otherwise mitigate its damages.

473. Alternatively, the misrepresentations were material because they would have a natural tendency to influence or be capable of influencing whether the costs of long-term prescriptions of opioids to treat chronic pain were paid by the City of Duluth.

474. Because Defendants' unbranded marketing caused doctors to prescribe and the City of Duluth to pay for long-term opioid treatment using opioids manufactured or distributed by other drug makers, Defendants caused and are responsible for those costs and claims as well.

475. By reason of Defendants' unlawful acts, the City of Duluth has been damaged, and continues to be damaged in a substantial amount to be determined at trial.

476. WHEREFORE, The City of Duluth demands judgment in its favor against the Manufacturer Defendants for civil penalties and treble damages pursuant to Minn. Stat. § l5C.02 together with all the costs of this action, including pre and post judgment interest, costs and expenses, attorney fees, and such other relief as this Court deems just and equitable.

XII. COUNT VI
FALSE STATEMENT IN ADVERTISING
(Minn. Stat. § 325F.67)
Against Manufacturer Defendants

477. The City of Duluth incorporates by reference all other paragraphs of this Complaint as if fully set forth herein.

478. Minn. Stat. § 325F.67 reads in pertinent part.

> Any person, firm, corporation, or association who, with intent to sell ... or with intent to increase the consumption thereof, ... makes, publishes, disseminates, circulates, or places before the public, or causes, directly or indirectly, to be made, published, disseminated, circulated, or placed before the public ... in a newspaper or other publication ... or in any other way, an advertisement of any sort regarding merchandise ... or anything so offered to the public, for use, consumption, purchase, or sale, which advertisement contains any material assertion, representation, or statement of fact which is untrue, deceptive, or misleading, shall, whether or not pecuniary or other specific damage to any person occurs as a direct result thereof, be guilty of a misdemeanor, and any such act is declared to be a public nuisance and may be enjoined as such.

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

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

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

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

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

d. Defendants' overstatement of the risks of NSAIDs when compared to opioids;

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

f. Defendants' claims that screening tools effectively prevent addiction;

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

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

i. Purdue's claims OxyContin provides a full 12 hours of pain relief;

j. Purdue's claims that it cooperates with and support efforts to prevent opioid abuse and diversion;

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

l. Defendants' use of Front Groups, to suggest that the deceptive statements from the sources described in this Complaint came from objective, independent sources;

m. Manufacturer Defendants' unsubstantiated claims that certain opioids were appropriate for treatment of non-cancer pain and their failure to disclose that those opioids was not approved for such use; and

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

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

483. The misconduct alleged in this Complaint does not concern a discrete event or discrete emergency of the sort a political subdivision would reasonably expect to occur, and is not part of the normal and expected costs of a local government's existence. The City of Duluth alleges wrongful acts which are neither discrete nor of the sort a local government can reasonably expect.

484. The City of Duluth has incurred expenditures for special programs over and above its ordinary municipal services.

485. Duluth seeks injunctive relief and actual damages under Minn. Stat. § 325F.67 as well as under Minn. Stat. § 8.31, which creates a private right of action when the action would benefit the public. The present action benefits the public, both

Duluth, as well as all of Minnesota, by reducing the amount of opioid drugs in the State and City, and providing Duluth the necessary resources, both monetary and non-monetary, to redress the opioid epidemic and treat its victims. Slowing the flow of opioids and providing funds to address the epidemic will help to alleviate this problem, save lives, prevent injuries, and make Duluth a safer place to live.

486. WHEREFORE, The City of Duluth demands judgment in its favor against the Manufacturer Defendants for damages and equitable relief pursuant to Minn. Stat. § 325F.67 and Minn. Stat. § 8.31 together with all the costs of this action, including pre and post judgment interest, costs and expenses, attorney fees, and such other relief as this Court deems just and equitable.

XIII. COUNT VII
Minnesota Prevention of Consumer Fraud Act
(Minn. Stat. §§ 325F.68 *et seq.*)
Against Manufacturer Defendants

487. The City of Duluth incorporates the allegations within all prior paragraphs within this Complaint as if they were fully set forth herein.

488. Minnesota Statute §§ 325D.13, 325D.44, and 325F.69 prohibit misrepresenting the quality of goods as well as sales sounding in fraud, misrepresentation, or deceptive practices, providing in pertinent part.

> 325F.69 UNLAWFUL PRACTICES
> Subdivision 1. Fraud, misrepresentation, deceptive practices. The act, use, or employment by any person of any fraud, false pretense, false promise, misrepresentation, misleading statement or deceptive practice, with the intent that others rely thereon in connection with the sale of any merchandise, whether or not any person has in fact been misled, deceived, or damaged thereby, is enjoinable as provided in section 325F.70

489. Manufacturer Defendants committed repeated and wilfully unfair or deceptive acts or practices, in connection with the sale of their opioids.

490. Defendants' fraudulent, deceptive, and unconscionable misrepresentations, concealments, and omissions were reasonably calculated to deceive the State, the public, and the City of Duluth.

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

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

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

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

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

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

d. Defendant's overstatement of the risks of NSAIDs when compared to opioids;

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

f. Defendants' claims that screening tools effectively prevent addiction;

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

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

i. Purdue's claims OxyContin provides a full 12 hours of pain relief;

j. Purdue's claims that it cooperates with and supports efforts to prevent opioid abuse and diversion;

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

l. Defendants' use of Front Groups to suggest that the deceptive statements from the sources described in this Complaint came from objective, independent sources; and

m. Manufacturer Defendants' unsubstantiated claims that certain opioids were appropriate for treatment of non-cancer pain and their failure to disclose that those opioids were not approved for such use.

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

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

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

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

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

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

f. Purdue's 12-hour OxyContin fails to last a full twelve hours in many patients;

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

h. Defendants' failure to report suspicious prescribers;

i. Defendants' use of kickback and insurance fraud schemes; and

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

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

opioid related costs through its employee health plans and workers' compensation program.

496. The misconduct alleged in this Complaint does not concern a discrete event or discrete emergency of the sort a political subdivision would reasonably expect to occur, and is not part of the normal and expected costs of a local government's existence. The City of Duluth alleges wrongful acts which are neither discrete nor of the sort a local government can reasonably expect.

497. The City of Duluth has incurred expenditures for special programs over and above its ordinary municipal services.

498. Duluth seeks injunctive relief and actual damages under Minn. Stat. §§ 325F.68 *et seq.* as well as under Minn. Stat. § 8.31, which creates a private right of action when the action would benefit the public. The present action benefits the public, both in the City of Duluth, as well as all of Minnesota, by reducing the amount of opioid drugs in the City of Duluth, and providing Duluth the necessary resources, both monetary and non-monetary, to redress the opioid epidemic and treat its victims. Slowing the flow of opioids and providing funds to address the epidemic will help to alleviate this problem, save lives, prevent injuries, and make Duluth a safer place to live

499. WHEREFORE, the City of Duluth demands judgment in its favor against the Manufacturer Defendants for damages and equitable relief pursuant to Minn. Stat. §§ 325F.68 et seq. and Minn. Stat. § 8.31, and together with all the costs of this action, including pre and post judgment interest, costs and expenses, attorney fees, and such other relief as this Court deems just and equitable.

XIV. Count VIII
Unlawful Trade Practices Act
(Minn. Stat. §§ 325D.09 *et seq.*)
Against Manufacturer Defendants

500. The City of Duluth incorporates by reference all other paragraphs of this Complaint as if they were fully set forth herein.

501. Minnesota Statute §§ 325D.09, *et seq.*, states, in pertinent part:

> 325D.13 QUALITY, MISREPRESENTED
> No person shall, in connection with the sale of merchandise, knowingly misrepresent, directly or indirectly, the true quality, ingredients or origin of such merchandise

502. Manufacturer Defendants are persons for purposes of this statute.

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

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

505. As alleged herein, each of the Manufacturer Defendants wrongfully represented that the opioid prescription medications they manufactured, marketed, and sold had qualities that they do not have.

506. These Defendants misrepresentations include, but are not limited to:

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

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

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

d. Defendants' overstatement of the risks of NSAIDs when compared to opioids;

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

f. Defendants' claims that screening tools effectively prevent addiction;

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

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

i. Purdue's claims OxyContin provides a full 12 hours of pain relief;

j. Purdue's claims that it cooperates with and support efforts to prevent opioid abuse and diversion;

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

l. Defendants' use of Front Groups, to suggest that the deceptive statements from the sources described in this Complaint came from objective, independent sources; and

m. Defendants' unsubstantiated claims that certain opioids were appropriate for treatment of non-cancer pain and their failure to disclose that Subsys was not approved for such use.

507. By engaging in the acts and practices alleged herein, Manufacturer Defendants omitted material facts, with the intent that others rely on their omissions

or suppression of information, that they had a duty to disclose by virtue of these Defendants' other representations, including, but not limited to, the following:

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

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

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

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

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

f. Purdue’s 12-hour OxyContin fails to last a full twelve hours in many patients;

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

h. Defendants failure to report suspicious prescribers;

i. Defendants’ use of kickback and insurance fraud schemes; and

j. Defendants’ failure to disclose their financial ties to and role m connection with front groups.

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

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

510. The misconduct alleged in this case does not concern a discrete event or discrete emergency of the sort a political subdivision would reasonably expect to occur, and is not part of the normal and expected costs of a local government's existence. The City of Duluth alleges wrongful acts which are neither discrete nor of the sort a local government can reasonably expect.

511. The City of Duluth has incurred expenditures for special programs over and above its ordinary municipal services.

512. Duluth seeks injunctive relief and actual damages under Minn. Stat. § 325D.15 as well as under Minn. Stat. § 8.31, which creates a private right of action when the action would benefit the public. The present action benefits the public, both in Duluth, as well as all of Minnesota, by reducing the amount of opioid drugs in the State and City, and providing Duluth the necessary resources, both monetary and non-monetary, to redress the opioid epidemic and treat its victims. Slowing the flow

of opioids and providing funds to address the epidemic will help to alleviate this problem, save lives, prevent injuries, and make Duluth a safer place to live.

513. WHEREFORE, The City of Duluth demands judgment in its favor against the Manufacturer Defendants for damages and equitable relief pursuant to Minn. Stat. § 325D.15 and Minn. Stat. § 8.31 together with all the costs of this action, including pre and post judgment interest, costs and expenses, attorney fees, and such other relief as this Court deems just and equitable.

XV. COUNT IX
Deceptive Trade Practices Act
(Minn. Stat. §§ 325D.43 *et seq.*)
Against Manufacturer Defendants

514. The City of Duluth incorporates by reference all other paragraphs of this Complaint as if fully set forth herein.

515. Minnesota Statute §§ 325D.43, *et seq.*, states, in pertinent part:

> 325D.44 DECEPTIVE TRADE PRACTICES
> A person engages in a deceptive trade practice when, in the course of business, vocation, or occupation, the person:
>
> (5) represents that goods or services have sponsorship, approval, characteristics, ingredients, uses, benefits, or quantities that they do not have or that a person has a sponsorship, approval, status, affiliation, or connection that the person does not have;
>
> (7) represents that goods or services are of a particular standard, quality, or grade, or those goods are of a particular style or model, if they are of another;
>
> (13) engages in any other conduct which similarly creates likelihood of confusion or of misunderstanding.

516. Manufacturer Defendants' unfair, deceptive, and unconscionable representations, concealments, and omissions were reasonably calculated to create

confusion and misunderstanding as to the nature and efficacy of opioid drugs, and in doing so deceive medical professionals, Duluth, its residents, and its employees and their dependents.

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

518. Because of the dangerously addictive nature of these drugs, the Defendants' manufacturing, marketing, sales, and/or distribution practices unlawfully caused an opioid epidemic in the City of Duluth.

519. As alleged herein, each Manufacturer Defendant wrongfully represented that the opioid prescription medications they manufactured, marketed, and sold had characteristics, uses, or benefits that they do not have.

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

a. Defendants’ claims that the risks of long-term opioid use, especially the risk of addiction were overblown;

b. Defendants’ claims that signs of addiction were "pseudoaddiction" reflecting undertreated pain, and should be responded to with *more* opioids;

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

d. Defendants’ overstatement of the risks of NSAIDs when compared to opioids;

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

f. Defendants' claims that screening tools effectively prevent addiction;

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

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

i. Purdue's claims OxyContin provides a full 12 hours of pain relief;

j. Purdue's claims that it cooperates with and support efforts to prevent opioid abuse and diversion;

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

l. Defendants' use of Front Groups, to suggest that the deceptive statements from the sources described in this Complaint came from objective, independent sources; and

m. Defendants' unsubstantiated claims that certain opioids were appropriate for treatment of non-cancer pain and their failure to disclose that those opioids were not approved for such use.

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

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

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

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

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

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

f. Purdue's 12-hour OxyContin fails to last a full twelve hours in many patients;

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

h. Defendants' failure to report suspicious prescribers;

i. Defendants' use of kickback and insurance fraud schemes; and

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

522. The Defendants' misrepresentations and omissions of material facts created confusion and misunderstanding in Duluth among its residents, its employees and their dependents, and medical professionals.

523. As a result of Manufacturer Defendants' omissions and misrepresentations regarding the use and characteristics of opioids to the City of Duluth, its residents, its employees and their dependents, and medical professionals, Duluth has incurred significant harm including law enforcement costs, medical costs relating to opioid abuse and addiction, and other social and medical costs.

524. The misconduct alleged in this Complaint does not concern a discrete event or discrete emergency of the sort a political subdivision would reasonably expect to occur, and is not part of the normal and expected costs of a local government's existence. The City of Duluth alleges wrongful acts which are neither discrete nor of the sort a local government can reasonably expect.

525. The City of Duluth has incurred expenditures for special programs over and above its ordinary municipal services.

526. The City of Duluth seeks injunctive relief as well as costs and fees incurred in pursuing this claim, pursuant to Minn. Stat. § 325D.45.

527. WHEREFORE, The City of Duluth demands judgment in its favor against the Manufacturer Defendants for equitable relief pursuant to Minn. Stat. § 325D.45 together with all the costs of this action, including pre and post-judgment interest, costs and expenses, attorney fees, and such other relief as this Court deems just and equitable.

XVI. COUNT X
Fraudulent and Intentional Misrepresentation
Against All Defendants

528. The City of Duluth repeats, reiterates, and realleges each and every allegation contained in the paragraphs above as if fully set forth herein.

529. Defendants' business practices as described in this Complaint are deceptive, unconscionable, and violate Minnesota law (i.e. Minn. Stat. § 325.43 *et seq*) because the practices deceived doctors, insurers, and consumers in Minnesota, fraudulently misrepresenting the need for and efficacy of their product, which led to the sale of opioids that should not have been sold, and thereby harmed the City of Duluth.

530. Each Defendant, acting individually and in concert, has created or assisted in the creation of the opioid epidemic and the harm to the City of Duluth through their fraudulent misrepresentations. Specifically, as further described in this Complaint, the Defendants' misrepresentations included the following:

a. Representing that opioids pose a low risk of addiction;

b. Representing that many individuals who exhibit signs of opioid addiction are experiencing "pseudoaddiction" which should be treated by increasing opioid use;

c. Representing the nature of the signs of addiction and the ease of preventing addiction;

d. Claiming that opioid dependence can be easily addressing by tapering opioids and that opioid withdrawal is not a problem or concern for patients and doctors;

e. Claiming that doctors and patients could increase opioid dosages indefinitely without added risk;

f. Claiming that abuse-deterrent properties of some opioids can prevent and curb opioid addiction and abuse;

g. Overstating the positive long-term outcomes of opioid use to treat chronic pain; and

h. Improperly presenting the relative risks associated with non-opioid pain-relief and pain-treatment strategies.

531. In addition, the Distributor Defendants were in the position to implement effective business practices to guard against diversion of the highly-addictive opioid products they sell and distribute. They repeatedly purported to have done so. But those representations were untrue. Instead, they profited off the opioid epidemic by flouting anti-diversion laws, while burdening Minnesota consumers by their conduct and profiting from the sale of prescription opioids in quantities that far exceeded the number of

prescriptions that could reasonably have been used for legitimate medical purposes, despite having notice or actual knowledge of widespread opioid diversion from prescribing records, pharmacy orders, field reports, and sales representatives.

532. The Defendants knew and should have known at the time of making or disseminating these statements, or causing these statements to be made or disseminated, that such statements were false or asserted without knowing whether these statements were true or false. Their omissions, which are deceptive and misleading in their own right, render even seemingly truthful statements about opioids false and misleading. All of this conduct, separately and collectively, was likely to deceive Minnesota doctors who prescribed opioids based on the Manufacturer Defendants' deception, which has had a devastating impact on the lives of the City of Duluth residents.

533. These statements and representations regarding the efficacy of opioid usage were material to the prescription of opioids by doctors and their use by patients in the City of Duluth.

534. The Defendants made the statements or representations or caused the statements or representations to be made with the intent to induce doctors and patients to act, i.e., increase the prescription of opioids by doctors, increase their purchase, and increase their use by patients. All Defendants' actions have increased the costs associated with opioids, and the City of Duluth has been injured.

535. WHEREFORE, The City of Duluth demands judgment in its favor against the Defendants for damages and equitable relief as its residents were injured due to their reliance on the statements and representation of the Defendants.

XVII. COUNT XI
Negligent Misrepresentation
Against All Defendants

536. The City of Duluth repeats, reiterates, and realleges each and every allegation contained in the paragraphs above as if fully set forth herein.

537. Through the course of Defendants' business practices, Defendants deceived doctors and consumers in Minnesota, negligently misrepresenting the need for and efficacy of their product, which led to the sale of opioids that should not have been sold, and thereby caused the City of Duluth to be injured.

538. Each Defendant, acting individually and in concert, has created or assisted in the creation of the opioid epidemic and the harm to the City of Duluth through their negligent misrepresentations. Specifically, as further described in this Complaint, during the course of Defendants' manufacturing and distribution of opioids, Defendants made statements and misrepresentations, including the following:

a. Representing that opioids pose a low risk of addiction;

b. Representing that many individuals who exhibit signs of opioid addiction are experiencing "pseudoaddiction" which should be treated by increasing opioid use;

c. Representing the nature of the signs of addiction and the ease of preventing addiction;

d. Claiming that opioid dependence can be easily addressing by tapering opioids and that opioid withdrawal is not a problem or concern for patients and doctors;

e. Claiming that doctors and patients could increase opioid dosages indefinitely without added risk;

f. Claiming that abuse-deterrent properties of some opioids can prevent and curb opioid addiction and abuse;

g. Overstating the positive long-term outcomes of opioid use to treat chronic pain; and

h. Improperly presenting the relative risks associated with non-opioid pain relief and pain treatment strategies.

539. In addition, the Distributor Defendants were in the position to implement effective business practices to guard against diversion of the highly-addictive opioid products they sell and distribute. They repeatedly purported to have done so. But those representations were untrue. Instead, they profited off the opioid epidemic by flouting anti-diversion laws, while burdening Minnesota consumers by their conduct and profiting from the sale of prescription opioids in quantities that far exceeded the number of prescriptions that could reasonably have been used for legitimate medical purposes, despite having notice or actual knowledge of widespread opioid diversion from prescribing records, pharmacy orders, field reports, and sales representatives.

540. The Defendants knew and should have known at the time of making or disseminating these statements, or causing these statements to be made or disseminated, that such statements were false or asserted without knowing whether these statements were true or false. Their omissions, which are deceptive and misleading in their own right, render even seemingly truthful statements about opioids false and misleading. This supply of false information, separately and collectively, was provided in order to guide Minnesota doctors, who prescribed opioids based on the Manufacturer Defendants' representations, and insurers who purchased, or covered the costs for the purchase of, opioids for chronic pain, and consumers and patients who purchased and use(d) opioids for chronic pain.

541. Defendants failed to exercise reasonable care or competence in communicating statements and representations concerning opioids to Minnesota doctors, insurers, and patients.

542. These statements and representations regarding the efficacy of opioid usage were material to the prescription of opioids by doctors, their use by patients, and their purchase and coverage by insurers, and the doctors, patients, and the insurers relied on these representations and statements made by Defendants.

543. The Defendants made the statements or representations or caused the statements or representations to be made with the intent to induce doctors, patients, and insurers to act, i.e., increase the prescription of opioids by doctors, increase their purchase and coverage by insurers, and increase their use by patients.

544. Minnesota doctors, insurers, consumers, and patients reasonably relied on information disseminated by Defendants regarding opioids. Reasonably prudent manufacturers of prescription opioids would have anticipated that the scourge of opioid addiction would wreak havoc on communities and the significant costs would be imposed upon the governmental entities associated with these communities as a proximate result of Defendants' representations.

545. The City of Duluth seeks economic losses (direct, incidental, or consequential pecuniary losses) resulting from the negligent misrepresentation of Defendants.

546. WHEREFORE, The City of Duluth demands judgment in its favor against the Defendants for damages and equitable relief as its residents were injured due to their reliance on the statements and representation of the Defendants.

XVIII. COUNT XII
Unjust Enrichment
Against All Defendants

547. The City of Duluth repeats, reiterates, and realleges each and every allegation contained in the paragraphs above as if fully set forth herein.

548. To the detriment of the City of Duluth, all Defendants have been, and continue to be, unjustly enriched as a result of the unlawful and/or wrongful conduct alleged herein.

549. All Defendants have voluntarily accepted and retained the inflated prices paid for their opioid products with full knowledge that they were not lawfully entitled to them.

550. All Defendants have voluntarily accepted and retained the inflated prices based on unlawful and fraudulent conduct in the marketing, sale, and distribution of the opioid products.

551. The City of Duluth bears the costs of the benefits conveyed to all Defendants in the form of increased insurance premiums.

552. Between Defendants and the City of Duluth, it would be unjust and morally wrong for Defendants to retain the benefits attained by their wrongful actions.

553. WHEREFORE, All Defendants have been unjustly enriched, in the form of inflated prices, at the expense of the City of Duluth who are entitled in equity to disgorgement and restitution of Defendants' wrongful profits, revenue, and benefits, to

the extent, and in the amount deemed appropriate by the Court, and any other relief the Court deems just and proper to remedy Defendants' unjust enrichment.

XIX. COUNT XIII PUBLIC NUISANCE
Against All Defendants

554. The City of Duluth incorporates by reference, as if fully forth herein, each and every preceding paragraph.

555. The common law prohibits the creation and maintenance of a public nuisance. A public nuisance is generally understood to apply to whomever by an act or failure to perform a legal duty maintains or permits a condition which unreasonably annoys, injures, or endangers the safety, health, morals, comfort, or repose of any considerable number of members of the public. This common law principle has been incorporated into Minnesota state law.

556. Defendants' conduct as described herein, has created a public nuisance within the City of Duluth by unreasonably interfering with and unreasonably annoying, injuring, and endangering the health, safety, morals, peace, comfort, repose, and convenience of the general public in the City of Duluth.

557. Defendants, individually and acting through their employees and agents, have unreasonably interfered with a right common to the general public of the City of Duluth, including by: (a) interfering significantly with the public health, safety, peace, comfort and convenience of the general community; (b) engaging in conduct proscribed by statute, ordinance, or administrative regulation; and (c) engaging in conduct of a continuing nature that Defendants knew or should have known produced and continues to

produce permanent and long-lasting significant effect of these rights common to the general public.

558. The Manufacturer Defendants, individually and acting through their employees and agents, through fraudulent and deceptive marketing practices and schemes created a market for opioids and the resulting and foreseeable epidemic that has damaged the City of Duluth and its citizens. The Manufacturer Defendants knew and should have known that their promotion of opioids was false and misleading and that their deceptive marketing scheme and other unlawful, unfair, and fraudulent actions would create or assist in the creation of the public nuisance, i.e., the opioid epidemic. The Manufacturer Defendants' actions were, at the very least, a substantial factor in opioids becoming widely available and widely used. Their actions were, at the very least, a substantial factor in deceiving doctors and patients about the risks and benefits of opioids for the treatment of chronic pain. Their actions were, at the very least, a substantial factor in an increase in opioid prescriptions for medical conditions for which they were not approved, and an increase in opioid prescriptions overall. Their actions were, at the very least, a substantial factor in the increase of opioid addiction and resulting overdose and deaths.

559. Each of the Defendants unreasonably interfered with rights common to the general public of the City of Duluth, including by interfering with the public health, safety, peace, and comfort by failing to design and operate a system that would disclose the existence of suspicious orders of controlled substances and/or by failing to report suspicious orders of opioids as required by the CSA, 21 C.F.R. § 1301.74(b). In so doing, Defendants acted unreasonably, recklessly, and intentionally.

560. Defendants' conduct is pervasive, persistent, and continuous, and has created substantial ongoing harm. It has caused deaths, serious injuries, and severe disruption of public peace, health, order, and safety. It has impacted the economic vitality of the residents of the City of Duluth and, as a result, the City. Defendants' conduct contributing to the opioid epidemic has impinged the rights of the public to use the streets, public ways, and public facilities without fear, apprehension, and injury. The public nuisance created by Defendants has significantly harmed the City of Duluth and diverted resources for public health and safety to respond to the harms and impacts of the epidemic on the individual residents of Duluth. Defendants' conduct is producing permanent and long-lasting damage.

561. Considering Defendants' failures to disclose suspicious orders of opioids, and in light of Manufacturer Defendants' aggressive misinformation campaign regarding opioids, the City of Duluth was unaware of, and could not reasonably have known or have learned through reasonable diligence, that it had been exposed to the risks alleged herein. Information pertaining to the suspicious orders of opioids Defendants were required to disclose—but did not—was nonpublic information over which the Defendants had and continue to have exclusive control, and which Defendants knew was unavailable to the City of Duluth. Defendants knew of the public health hazard that flooding the market with opioids, given their addictive properties and other risks, would create across the country, including in the City of Duluth.

562. The City of Duluth had neither knowledge nor reason to suspect that the Defendants were engaged in the wrongdoing alleged herein. Because of the fraudulent

acts of concealment by the Defendants, the City of Duluth could not have reasonably discovered the wrongdoing in time to stem the effects of the opioid epidemic within the City of Duluth that the City is now required to address through public health and safety initiatives and will continue to address for the foreseeable future. Defendants' conduct and the opioid epidemic they created are likely to continue to cause significant harm to the City and its residents.

563. At all times relevant to this Complaint, Defendants were in complete control over the instrumentalities constituting the public nuisance. Defendants have complete control over and can take actions to abate the pubic nuisance within the City of Duluth and across the country.

564. As detailed herein, Defendants' conduct has interfered and continues to interfere with rights common to the general public of the City of Duluth, and has caused the City of Duluth to sustain damages, special and particular in kind, including the substantial costs from investigating, monitoring, mitigating, policing, and remediating the opioid epidemic, which specifically may include, without limitation, increased law enforcement and overtime pay for police officer patrols, judicial expenditures, increased jail and public works expenditures, increased substance abuse treatment and diversion plan expenditures, increased emergency and medical care services, increased medical examiner expenditures, increased traffic incident investigation costs, and lost economic opportunity.

565. WHEREFORE, Plaintiff demands judgment against the Defendants for injunctive relief, abatement of the public nuisance, and for actual and compensatory

damages; for restitution; for costs incurred herein; the cost of abating the public nuisance, attorney fees, and such other and further relief as this Court deems just and proper.

XX. COUNT XIV CIVIL CONSPIRACY
Against All Defendants

566. The City of Duluth repeats, reiterates, and realleges each and every allegation contained in the paragraphs above as if fully set forth herein.

567. The Manufacturer Defendants have engaged and continue to engage in a massive marketing campaign to misstate and conceal the risks of treating chronic pain with opioids. Their aggressive marketing campaign enabled Manufacturer Defendants to overcome the longstanding medical consensus that opioids were unsafe for the treatment of chronic pain and resulted in a significant increase in the number of opioids prescribed nationwide.

568. In response to and in conjunction with this increased demand, the Distributor Defendants continuously supplied prescription opioids. These transactions occurred despite the Distributor Defendants having actual or constructive knowledge that they were habitually breaching their common law and statutory duties.

569. None of the Defendants would have succeeded in profiting so significantly from the opioid epidemic without the concerted conduct of the other parties.

570. As a result of the concerted action between the Manufacturer Defendants and the Distributor Defendants, Minnesota law was continually violated by the provision of opioids through the supply chain.

571. Defendants formed an agreement to commit the aforementioned unlawful acts.

572. Defendants commissioned the aforementioned unlawful acts.

573. WHEREFORE, The City of Duluth incurred damages—related to the opioid epidemic—as a result of Defendants' aforementioned conspiracy.

XXI. DEMAND FOR JURY TRIAL

Pursuant to Fed. R. Civ. P. 38, Plaintiff City of Duluth demands a trial by jury on all issues so triable.

XXII. PRAYER FOR RELIEF

WHEREFORE, Plaintiff City of Duluth, acting on behalf of itself and its inhabitants, prays that the Court grant the following relief:

A. Enjoin Defendants from failing to report suspicious orders as required by the Federal Controlled Substances Act and the Minnesota Uniform Controlled Substances Act;

B. Award Plaintiff, City of Duluth, damages caused by the opioid epidemic, including the increased costs of providing governmental services attributable to the crisis;

C. Order that Defendants compensate Plaintiff for past and future costs to abate the ongoing public nuisance caused by the opioid epidemic;

D. Order Defendants to fund an "abatement fund" for the purposes of implementing programs necessary to abate the opioid nuisance;

E. Award actual damages, treble damages, injunctive and equitable relief, forfeiture as deemed proper by the Court, and attorney fees, and all costs and expenses of suit pursuant to Plaintiff's racketeering claims;

F. Award the costs of investigation, reasonable attorney fees, and all costs and expenses;

G. Award pre-judgment and post-judgment interest; and

H. Grant any such further relief as this Court deems appropriate.

Respectfully submitted,

CITY OF DULUTH

Dated: April 19, 2019

By: /s/ *Jared D. Shepherd*
One of Plaintiff's Attorneys

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**Pro Hac Vice* admission to be sought

Counsel for Plaintiff