

**UNITED STATES DISTRICT COURT
WESTERN DISTRICT OF LOUISIANA
LAKE CHARLES DIVISION**

**FOUR WINDS TRIBE LOUISIANA
CHEROKEE**

*** CIVIL ACTION**

VERSUS

NO. 2019-cv-

**PURDUE PHARMA, L.P.; PURDUE
PHARMA, INC.; THE PURDUE
FREDERICK COMPANY, INC.; TEVA
PHARMACEUTICAL INDUSTRIES,
LTD.; TEVA PHARMACEUTICALS
USA, INC.; CEPHALON, INC.;
JOHNSON & JOHNSON; JANSSEN
PHARMACEUTICALS, INC.; ORTHO-
MCNEIL-JANSSEN**

*** JUDGE**

*** DIVISION**

*** MAGISTRATE JUDGE**

*** SECTION**

**PHARMACEUTICALS, INC. N/K/A
JANSSEN PHARMACEUTICALS, INC.;
JANSSEN PHARMACEUTICA, INC.
N/K/A JANSSEN**

*** JURY TRIAL DEMANDED**

**PHARMACEUTICALS, INC.;
NORAMCO, INC.; ENDO HEALTH
SOLUTIONS, INC.; ENDO**

**PHARMACEUTICALS, INC.;
ALLERGAN PLC F/K/A ACTAVIS PLC;
ALLERGAN FINANCE, LLC F/K/A**

**ACTAVIS, INC. F/K/A WATSON
PHARMACEUTICALS, INC.; WATSON
LABORATORIES, INC.; ACTAVIS,
LLC; ACTAVIS PHARMA, INC. F/K/A
WATSON PHARMA, INC.;**

**MALLINCKRODT PLC;
MALLINCKRODT LLC; SPECGX,
LLC; MCKESSON CORPORATION;
CARDINAL HEALTH, INC.;
AMERISOURCEBERGEN DRUG
CORPORATION; AND MORRIS &
DICKSON CO., LLC**

COMPLAINT

The Four Winds Tribe Louisiana Cherokee, (“Plaintiff”), a Louisiana non-profit corporation, brings this Complaint against the following Defendants:

- (1) Purdue Pharma, L.P.;
- (2) Purdue Pharma, Inc.;
- (3) The Purdue Frederick Company, Inc.;
- (4) Teva Pharmaceutical Industries, LTD.;
- (5) Teva Pharmaceuticals USA, Inc.;
- (6) Cephalon, Inc.;
- (7) Johnson & Johnson;
- (8) Janssen Pharmaceuticals, Inc.;
- (9) Ortho-McNeil-Janssen Pharmaceuticals, Inc. n/k/a Janssen Pharmaceuticals, Inc.;
- (10) Janssen Pharmaceutica, Inc. n/k/a Janssen Pharmaceuticals, Inc.;
- (11) Noramco, Inc.;
- (12) Endo Health Solutions, Inc.;
- (13) Endo Pharmaceuticals, Inc.;
- (14) Allergan PLC f/k/a Actavis PLC;
- (15) Allergan Finance, LLC f/k/a Actavis, Inc. f/k/a Watson Pharmaceuticals, Inc.;
- (16) Watson Laboratories, Inc.;
- (17) Actavis, LLC;
- (18) Actavis Pharma, Inc. f/k/a Watson Pharma, Inc.;
- (19) Mallinckrodt PLC;
- (20) Mallinckrodt LLC;
- (21) SpecGx, LLC

- (22) McKesson Corporation;
- (23) Cardinal Health, Inc.;
- (24) AmerisourceBergen Drug Corporation;
- (25) Morris & Dickson Co., LLC

(collectively “Defendants”) and alleges as follows:

TABLE OF CONTENTS

	PAGE
I. PARTIES	6
A. Plaintiff.....	6
B. Defendants.....	8
Pharmaceutical Defendants	8
Distributor Defendants	13
II. JURISDICTION AND VENUE	15
III. FACTUAL BACKGROUND	17
A. The Opioid Epidemic	17
1. The National Opioid Epidemic	17
2. The Louisiana Opioid Epidemic	20
3. The Opioid Epidemic Disproportionately Affects American Indians	25
4. The Opioid Epidemic in Plaintiff’s Community	26
B. The Pharmaceutical Defendants’ false, deceptive, and unfair marketing of opioids	28
1. The Pharmaceutical Defendants’ Marketing Scheme	29
2. The Pharmaceutical Defendants’ unlawful failure to prevent diversion and monitor, report, and prevent suspicious orders	50
3. The Pharmaceutical Defendants made and/or disseminated deceptive statements regarding material facts and further concealed material facts, in the course of manufacturing, marketing, and selling prescription opioids ..	55
C. Distributor Defendants’ Wrongful Conduct	61
1. The Distributor Defendants’ conduct fostered and/or Promoted Opioid Diversion	61
2. The Distributor Defendants breached their duties	80
3. The Distributor Defendants have sought to avoid and have misrepresented their purported compliance with their legal duties.....	82

D. Defendants’ unlawful conduct and breaches of legal duties caused the harm alleged herein and substantial damages	88
E. Statutes of Limitations are tolled and defendants are estopped from asserting statutes of limitations as defenses	91
1. Continuing conduct	91
2. Equitable estoppel and Fraudulent Concealment.....	92
IV. LEGAL CAUSES OF ACTION	95
Count I - Public Nuisance	95
Count II - Louisiana Products Liability Act.....	105
Count III - Louisiana Unfair Trade Practices and Consumer Protection Law ...	111
Count IV - Negligence and Negligent Misrepresentation	116
Count V - Fraud and Fraudulent Misrepresentation.....	120
Count VI - False Advertising	123
Count VII - Misbranding Drugs or Devices	126
Count VIII - Unjust Enrichment.....	129
Count IX - Racketeer Influenced and Corrupt Organizations Act	131
A. The RICO Enterprise	132
B. Conduct of the RICO Enterprise	141
C. Pattern of Racketeering Activity	143
D. Damages.....	147
Count X - Louisiana Racketeering Act	148
Count XI - Lanham Act.....	152
JURY DEMAND	153
RELIEF	153

I.
PARTIES

A. PLAINTIFF

1. Plaintiff, Four Winds Tribe Louisiana Cherokee, a Louisiana non-profit corporation domiciled in Allen Parish (hereinafter “Plaintiff” or “The Tribe”), is authorized to bring this action on behalf of itself and its members.

2. The descendants of the original American inhabitants of western Louisiana incorporated and formed the Tribe in 1995. The Tribe has been recognized by the State of Louisiana. As such, it appoints a member of “The Native American Commission,” which is a body created within the Louisiana Governor’s Office of Indian Affairs. La. R. S. 46:2305 (7). The Tribe has members in a number of Louisiana Parishes, including Allen, Beauregard, Calcasieu, Evangeline, Grant, Jefferson Davis, Lafayette, Natchitoches, Rapides, Sabine, and Vernon. The geographic area which the members of the Tribe inhabit is sometimes referred to hereafter as “The Plaintiff’s Community.” The purpose for which the corporation and Tribe were formed were to advance the preservation of its culture, to protect and assist the youth, elderly and handicapped, particularly those of The Tribe, and to provide for educational needs of its members and their families, and to pass down to its members, their families, the Plaintiff’s Community and all, the rich heritage of the American Indians of this portion of Louisiana.

3. Plaintiff has standing to recover damages incurred as a result of Defendants’ actions and omissions, and to request injunctive and other relief, for the following reasons: (1) Its members would otherwise be able to bring suit in their own right; (2) the interests the Plaintiff seeks to protect are pertinent to its purpose; and (3) neither the claims asserted nor the relief sought requires the participation of its individual members. ***Ramsey River Road Property Owners Association, Inc. v. Reeves, et al*, 396 So. 2d 873 (La. 1981).** It is also averred that the Opiod Epidemic caused

by the actions of the Defendants as set forth herein, has directly harmed the Tribe, and, if not abated, will continue to injure the Tribe and undermine its mission, and, further threatens the future of the Tribe and its mission.

4. Plaintiff brings this civil action for injunctive relief, compensatory damages, statutory damages, and any other relief allowed by law against the Defendant opioid drug distributors and manufacturers that, by their actions and omissions, knowingly or negligently have distributed and dispensed prescription opioid drugs in a manner that foreseeably injured, and continues to injure Plaintiff, its members and their families.

5. Plaintiff also seeks the means to abate the epidemic created by Defendants' wrongful and/or unlawful conduct, including future treatment and monitoring pursuant to Article 2315(B) of the Louisiana Civil Code and the hiring of social workers and other professionals to assist the Tribe and directly monitor opioid use and treatment within the Tribe.

6. The distribution and diversion of opioids into Louisiana ("the State"), and into the Tribe, its members, and their families created the foreseeable opioid crisis and opioid public nuisance for which Plaintiff here seeks relief.

7. Opioid abuse, addiction, morbidity and mortality has created a serious public health and safety crisis, and is a public nuisance, and that the diversion of legally produced controlled substances into the illicit market causes or contributes to this public nuisance.

8. Plaintiff directly and foreseeably sustained all economic damages alleged herein. These damages have been suffered, and continue to be suffered, directly by the Plaintiff. Defendants' misconduct, which is ongoing and persistent, has caused certain members of the Tribe to become addicted to prescription opioid drugs, which has foreseeably caused damages to Plaintiff, its members, and their families, such as severe injury or death, in addition to un-recouped

and un-reimbursable costs, including but not limited to (a) rehabilitation and medical treatment for substance abuse, (b) additional care and needs for children born addicted to prescription opioids and other controlled substances, (c) treatment necessary to cope with short and long-term emotional and physical damage, (d) long-term opioid abuse treatment, and (e) foster care and/or adoption.

Defendants' ongoing actions and years of misconduct has foreseeably caused damage and has negatively affected the next generation of Tribe members, especially through the deleterious effects of opioids upon the health of Tribe children. As such, the cumulative impact of Defendants' misconduct is so severe that it threatens the continuation of Tribe culture, identity, and continuity.

B. DEFENDANTS

PHARMACEUTICAL DEFENDANTS

9. The Pharmaceutical Defendants are defined below. At all relevant times, the Pharmaceutical Defendants have packaged, distributed, supplied, sold, placed into the stream of commerce, labeled, described, marketed, advertised, promoted and purported to warn or purported to inform prescribers and users regarding the benefits and risks associated with the use of the prescription opioid drugs. The Pharmaceutical Defendants, at all times, have manufactured and sold prescription opioids without fulfilling their legal duties under federal and state law to prevent diversion and report suspicious orders.

10. **PURDUE PHARMA L.P.** is a limited partnership organized under the laws of Delaware. **PURDUE PHARMA INC.** is a New York corporation with its principal place of business in Stamford, Connecticut, and **THE PURDUE FREDERICK COMPANY, INC.** is a Delaware corporation with its principal place of business in Stamford, Connecticut (collectively, "Purdue").

11. Purdue manufactures, promotes, sells, and distributes opioids such as OxyContin, MS Contin, Dilaudid/Dilaudid HP, Butrans, Hysingla ER, and Targiniq ER in the United States, including Louisiana and Plaintiff's Community. OxyContin is Purdue's best-selling opioid. Upon information and belief, since 2009, Purdue's annual nationwide 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 (painkillers).

12. **CEPHALON, INC.** ("Cephalon") is a Delaware corporation with its principal place of business in Frazer, Pennsylvania. Cephalon manufactures, promotes, sells, and distributes opioids such as Actiq and Fentora in the United States, including Louisiana and Plaintiff's Community. Actiq and Fentora have been approved by the 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."¹ In 2008, Cephalon pled guilty to a criminal violation of the Federal Food, Drug and Cosmetic Act for its misleading promotion of Actiq and two other drugs and agreed to pay \$425 million.²

13. **TEVA PHARMACEUTICAL INDUSTRIES, LTD.** ("Teva Ltd.") is an Israeli corporation with its principal place of business in Petah Tikva, Israel. Teva Pharmaceuticals USA, Inc. ("Teva USA") is a wholly-owned subsidiary of Teva Ltd. and is a Delaware corporation with its principal place of business in Pennsylvania. Teva USA acquired Cephalon in October 2011.

14. Teva Ltd., Teva USA, and Cephalon collaborate to market and sell Cephalon products in the U.S. Teva Ltd. conducts all sales and marketing activities for Cephalon in the U.S.

¹ Highlights of Prescribing information, ACTIQ® (fentanyl citrate) oral transmucosal lozenge, CII (2009), https://www.accessdata.fda.gov/drugsatfda_docs/label/2009/020747s0301bl.pdf. Highlights of Prescribing Information, FENTORA® (fentanyl citrate) buccal tablet, CII (2011), https://www.accessdata.fda.gov/drugsatfda_docs/label/2011/021947s0131bl.pdf

² Press Release, U.S. Dep't of Justice, Biopharmaceutical Company, Cephalon, to Pay \$425 Million & Enter Plea to Resolve Allegations of Off-Label Marketing (Sept. 29, 2008), <https://www.justice.gov/archive/opa/pr/2008/September/08-civ-860.html>.

through Teva USA. Teva Ltd. and Teva USA publicize Actiq and Fentora as Teva products. Teva USA sells all former Cephalon branded products through its “specialty medicines” division. The FDA³-approved prescribing information and medication guide, which is distributed with Cephalon opioids marketed and sold in Louisiana and in Plaintiff’s Community discloses that the guide was submitted by Teva USA, and directs physicians to contact Teva USA to report adverse events. Teva Ltd. has directed Cephalon to disclose that it is a wholly-owned subsidiary of Teva Ltd. on prescription savings cards distributed in Louisiana, indicating Teva Ltd. would be responsible for covering certain co-pay costs. Cephalon’s promotional websites, including those for Actiq and Fentora, prominently displayed Teva Ltd.’s logo. Teva Ltd.’s financial reports listed Cephalon’s and Teva USA’s sales as its own. Through interrelated operations like these, Teva Ltd. operated in Louisiana (including in Plaintiff’s Community) and the rest of the U.S. through its subsidiaries Cephalon and Teva USA. Upon information and belief, the U.S. is the largest of Teva Ltd.’s global markets, representing 53% of its global revenue in 2015, and, were it not for the existence of Teva USA and Cephalon, Inc., Teva Ltd. would conduct those companies’ business in the United States itself. Upon information and belief, Teva Ltd. directs the business practices of Cephalon and Teva USA, and their profits inure to the benefit of Teva Ltd. as controlling shareholder. (Teva Ltd., Teva USA, and Cephalon, Inc. are hereinafter collectively referred to as “Cephalon”).

15. **JANSSEN PHARMACEUTICALS, INC.** is a Pennsylvania corporation with its principal place of business in Titusville, New Jersey, and is a wholly owned subsidiary of **JOHNSON & JOHNSON (J&J)**, a New Jersey corporation with its principal place of business in New Brunswick, New Jersey. **NORAMCO, INC.** (“Noramco”) is a Delaware company headquartered in Wilmington, Delaware and was a wholly owned subsidiary of J&J until July

³ U.S. Food and Drug Administration.

2016. **ORTHO-MCNEIL-JANSSEN PHARMACEUTICALS, INC.**, now known as **JANSSEN PHARMACEUTICALS, INC.**, is a Pennsylvania corporation with its principal place of business in Titusville, New Jersey. **JANSSEN PHARMACEUTICA INC.**, now known as **JANSSEN PHARMACEUTICALS, INC.**, is a Pennsylvania corporation with its principal place of business in Titusville, New Jersey. J&J is the only company that owns more than 10% of Janssen Pharmaceuticals' stock, and corresponds with the FDA regarding Janssen's products. Upon information and belief, J&J controls the sale and development of Janssen Pharmaceuticals' drugs and Janssen's profits inure to J&J's benefit. Janssen Pharmaceuticals, Inc., Ortho-McNeil- Janssen Pharmaceuticals, Inc., Janssen Pharmaceutical, Inc., Noramco, and J&J are referred to as "Janssen."

16. Janssen manufactures, promotes, sells, and distributes drugs in the United States, including Louisiana and Plaintiff's Community, including the opioid Duragesic (fentanyl). Before 2009, Duragesic accounted for at least \$1 billion in annual sales. Until January 2015, Janssen developed, marketed, and sold the opioids Nucynta (tapentadol) and Nucynta ER. Together, Nucynta and Nucynta ER accounted for \$172 million in sales in 2014.

17. **ENDO HEALTH SOLUTIONS INC.** is a Delaware corporation with its principal place of business in Malvern, Pennsylvania. **ENDO PHARMACEUTICALS INC.** is a wholly owned subsidiary of Endo Health Solutions Inc. and is a Delaware corporation with its principal place of business in Malvern, Pennsylvania. Endo Health Solutions Inc. and Endo Pharmaceuticals Inc. are referred to as "Endo."

18. Endo develops, markets, and sells prescription drugs, including the opioids Opana/Opana ER, Percodan, Percocet, and Zydane, in the United, including Louisiana and Plaintiff's Community. Opioids made up roughly \$403 million of Endo's overall revenues of \$3

billion in 2012. Opana ER yielded \$1.15 billion in revenue from 2010 and 2013, and it accounted for 10% of Endo's total revenue in 2012. Endo also manufactures and sells generic opioids such as oxycodone, oxymorphone, hydromorphone, and hydrocodone products in the United States, including Louisiana and Plaintiff's Community by itself and through its subsidiary, Qualitest Pharmaceuticals, Inc.

19. **ALLERGAN PLC** is a public limited company incorporated in Ireland with its principal place of business in Dublin, Ireland. **ACTAVIS PLC** acquired **ALLERGAN PLC** in March 2015, and the combined company changed its name to **ALLERGAN PLC**. Before that, **WATSON PHARMACEUTICALS, INC.** acquired **ACTAVIS, INC.** in October 2012, and the combined company changed its name to Actavis, Inc. as of January 2013 and then **ACTAVIS PLC** in October 2013. **WATSON LABORATORIES, INC.** is a Nevada corporation with its principal place of business in Corona, California, and is a wholly-owned subsidiary of **ALLERGAN PLC** (Allergan Finance, LLC, f/k/a Actavis, Inc., f/k/a Watson Pharmaceuticals, Inc.). **ACTAVIS PHARMA, INC.** (f/k/a Actavis, Inc.) is a Delaware corporation with its principal place of business in New Jersey and was formerly known as **WATSON PHARMA, INC.** **ACTAVIS LLC** is a Delaware limited liability company with its principal place of business in Parsippany, New Jersey. Each of these defendants is owned by **ALLERGAN PLC**, which uses them to market and sell its drugs in the United States, including Louisiana and Plaintiff's Community. Upon information and belief, **ALLERGAN PLC** exercises control over these marketing and sales efforts and profits from the sale of Allergan/Actavis products ultimately inure to its benefit. **ALLERGAN PLC, ACTAVIS PLC, ACTAVIS, INC., Actavis LLC, Actavis Pharma, Inc., Watson Pharmaceuticals, Inc., Watson Pharma, Inc., and Watson Laboratories, Inc.** are referred to as "Actavis."

20. Actavis manufactures, promotes, sells, and distributes opioids, including the branded drugs Kadian and Norco, a generic version of Kadian, and generic versions of Duragesic and Opana, in the United States, including Louisiana and Plaintiff's Community. Actavis acquired the rights to Kadian from King Pharmaceuticals, Inc. on December 30, 2008, and began marketing Kadian in 2009.

21. **MALLINCKRODT, PLC** is an Irish public limited company headquartered in Staines-upon-Thames, United Kingdom, with its U.S. Headquarters in St. Louis, Missouri.

22. **MALLINCKRODT, LLC** is a limited liability company organized and existing under the laws of the State of Delaware. Mallinckrodt, LLC is a wholly owned subsidiary of Mallinckrodt, PLC.

23. **SPECGX, LLC** ("SpecGx") is a Delaware limited liability company with its headquarters in Clayton, Missouri and is a wholly-owned subsidiary of Mallinckrodt, Plc.

24. Mallinckrodt Plc, Mallinckrodt LLC, and SpecGx (collectively referred to now as "Mallinckrodt") and their DEA registrant subsidiaries and affiliates manufacture, market, sell and distribute pharmaceutical drugs, (including generic oxycodone, of which it is one of the largest manufacturers) throughout the United States and in Plaintiff's Community. Mallinckrodt is the largest U.S. supplier of opioid pain medications and among the top ten generic pharmaceutical manufacturers in the United States, based on prescriptions. Mallinckrodt's misconduct, which is ongoing and persistent, is in violation of its legal duties under federal and state law to prevent diversion and report suspicious orders.

DISTRIBUTOR DEFENDANTS

25. The Distributor Defendants are defined below. At all relevant times, the Distributor Defendants have distributed, supplied, sold, and placed into the stream of commerce the

prescription opioids, without fulfilling the fundamental the legal duties under federal and state law of wholesale drug distributors; that is, to detect, warn of, and prevent diversion of dangerous drugs for non-medical purposes, and to report suspicious orders. The Distributor Defendants are engaged in “wholesale distribution,” as defined under state and federal law. Plaintiff alleges the unlawful conduct by the Distributors is responsible for the volume of prescription opioids plaguing Plaintiff’s Community.

26. **McKESSON CORPORATION** (“McKesson”) at all relevant times, operated as a licensed distributor in Louisiana, licensed by both the Louisiana Board of Drug and Device Distributors and the Louisiana Board of Pharmacy. McKesson is a Delaware corporation. McKesson has its principal place of business located in San Francisco, California. During all relevant times, McKesson has distributed substantial amounts of prescription opioids to providers and retailers in the state of Louisiana, including in Plaintiff’s Community.

27. **CARDINAL HEALTH, INC.** (“Cardinal”) at all relevant times, operated as a licensed distributor wholesaler in Louisiana, licensed by both the Louisiana Board of Drug and Device Distributors and the Louisiana Board of Pharmacy. Cardinal’s principal office is located in Dublin, Ohio. During all relevant times, Cardinal has distributed substantial amounts of prescription opioids to providers and retailers in the state of Louisiana, including in Plaintiff’s Community.

28. **AMERISOURCEBERGEN DRUG CORPORATION** (“AmerisourceBergen”) at all relevant times, operated as a licensed distributor wholesaler in Louisiana, licensed by the Louisiana Board of Pharmacy. AmerisourceBergen is a Delaware corporation and its principal place of business is located in Chesterbrook, Pennsylvania. During all relevant times, AmerisourceBergen has distributed substantial amounts of prescription opioids to providers and

retailers in the state of Louisiana, including in Plaintiff's Community.

29. **MORRIS & DICKSON CO., L.L.C.** and **MORRIS & DICKSON CO., L.L.C.** d/b/a/ Spark Drug ("M&D") is a Limited Liability Company organized under the laws of Louisiana with its principal place of business and domicile in Shreveport, Louisiana. By its own admission, M&D is "the largest independently owned and privately held drug wholesale distributor in the nation."⁴ Its distribution center is located in Shreveport and it has a regional transportation hub in Jefferson Parish, Louisiana.⁵ M&D is licensed with the Louisiana Board of Drug and Device Distributors for both its Shreveport and Jefferson Parish facilities. M&D services 30-40% of the hospital drug market in Louisiana.⁶ On May 24, 2019, it was reported that Morris & Dickson Company, LLC reached an agreement to pay the United States \$22 million in civil penalties to resolve claims that it violated the Controlled Substances Act by failing to report suspicious orders of hydrocodone and oxycodone.⁷

At all relevant times, M&D has distributed opioids into the Plaintiff's Community, in violation of its duties under federal and state laws to detect, warn of, and prevent diversion of dangerous drugs for non-medical purposes, and to report suspicious orders. M&D's conduct is ongoing and persistent.

II.

JURISDICTION AND VENUE

30. This Court 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.

⁴ Pl. Compl. Inj. Relief, p 4, *Morris & Dickson Co., LLC v. Jefferson B. Sessions, III, et al.*, No. 5:18-cv-00605-EEF-MLH (May 3, 2018 W.D. La.).

⁵ *Id.*, at p. 10.

⁶ *Id.*

⁷ DEA Press Release; May 24, 2019 (<https://www.dea.gov/press-releases/2019/05/24/dea-and-us-attorney-western-district-louisiana-announce-settlement-drug-0>)(last accessed 5/28/2019)

§ 1961, *et seq.* (“RICO”) and under the Lanham Act, 15 U.S.C. § 1125(a)(1)(B). This Court has supplemental jurisdiction over Plaintiff’s state law claims pursuant to 28 U.S.C. § 1367 because those claims are so related to Plaintiff’s federal claims that they form part of the same case or controversy.

31. This Court has personal jurisdiction over Defendants because (1) they conduct business in the State, including in Plaintiff’s Community; (2) they purposefully direct or directed their actions toward the State, including Plaintiff’s Community; (3) some or all consented to be sued in the State by registering an agent for service of process; (4) they consensually submitted to the jurisdiction of the State of Louisiana when obtaining a manufacturer or distributor license; and (5) they have the requisite minimum contacts with the State of Louisiana necessary to constitutionally permit the Court to exercise jurisdiction.

32. This Court also has personal jurisdiction over all of the defendants under 18 U.S.C. § 1965(b). This Court may exercise nation-wide jurisdiction over the named Defendants where the “ends of justice” require national service and Plaintiff demonstrates national contacts. Here, the interests of justice require that Plaintiff be allowed to bring all members of the nationwide RICO enterprise before the court in a single trial. *See, e.g., Iron Workers Local Union No. 17 Insurance Fund v. Philip Morris Inc.*, 23 F. Supp. 2d 796, 803 (N.D. Ohio 1998) (citing *LaSalle National Bank v. Arroyo Office Plaza, Ltd.*, 1988 WL 23824, *2 (N.D. Ill. Mar 10, 1988); *Butcher’s Union Local No. 498 v. SDC Invest., Inc.*, 788 F.2d 535, 539 (9th Cir. 1986)).

33. Venue is proper in this District pursuant to 28 U.S.C. § 1391 and 18 U.S.C. §1965 because a substantial part of the events or omissions giving rise to the claim occurred in this District and each Defendant transacted affairs and conducted activity that gave rise to the claim of relief in this District. 28 U.S.C. § 1391(b); 18 U.S.C. §1965(a).

III. FACTUAL BACKGROUND

A. THE OPIOID EPIDEMIC

1. The National Opioid Epidemic

34. The United States is in the midst of an opioid epidemic caused by Defendants' unlawful marketing, sales, and distribution of prescription opioids that has resulted in addiction, criminal activity, serious health issues, and loss of life.

35. Opioid or Opiate means is "Any of various sedative narcotics containing opium or one or more of its natural or synthetic derivatives."⁸ The Controlled Substances Act ("CSA") defines "opiate" or "opioid" as "any drug or other substance having an addiction-forming or addiction-sustaining ability similar to morphine or being capable of conversion into a drug having such addiction-forming or addiction-sustaining ability."⁹

36. The FDA's website describes this class of drugs as follows: "Prescription opioids are powerful pain-reducing medications that include prescription oxycodone, hydrocodone, and morphine, among others, and have both benefits as well as potentially serious risks. These medications can help manage pain when prescribed for the right condition and when used properly. But when misused or abused, they can cause serious harm, including addiction, overdose, and death."¹⁰

37. Prescription opioids with the highest potential for addiction are categorized under Schedule II of the CSA. They include non-synthetic derivatives of the opium poppy (such as codeine and morphine, which are also called "opiates"), partially synthetic derivatives (such as

⁸ The American Heritage Dictionary of English Language, Third Edition.

⁹ 21 U.S.C.S. § 802 (18). Titles II and III of the Comprehensive Drug Abuse Prevention and Control Act of 1970, as amended, 21 U.S.C. §§ 801-971, were collectively referred to as the "Controlled Substances Act."

¹⁰ U.S. Food and Drug Administration, Information by Drug Class – Opioid Medications. Available at <https://www.fda.gov/Drugs/DrugSafety/InformationbyDrugClass/ucm337066.htm>. Accessed January 2, 2019.

hydrocodone and oxycodone), or fully synthetic derivatives (such as fentanyl and methadone).

38. Opioid analgesics are widely diverted and improperly used, and the widespread abuse of opioids has resulted in a national, epidemic of opioid overdose deaths and addictions.¹¹ The number of annual opioid prescriptions written in the United States is now roughly equal to the number of adults in the population.¹² The National Institute on Drug Abuse identifies misuse and addiction to opioids as “a serious national crisis that affects public health as well as social and economic welfare.”¹³ The economic burden of prescription opioid misuse alone is \$78.5 billion a year, including the costs of healthcare, lost productivity, addiction treatment, and criminal justice expenditures.¹⁴ The opioid problem has become a scourge upon our nation that has caused municipalities, including the Tribe to incur extraordinary economic damages and a substantial loss, use and diminution of resources, all as set forth hereinafter.

39. The opioid epidemic is “directly related to the increasingly widespread misuse of powerful opioid pain medications.” The opioid epidemic has exacted a “staggering” human and financial cost in the United States over the past 20 years.¹⁵ A minority staff report issued in September 2017 by the U.S. Senate Homeland Security & Governmental Affairs Committee (“Committee”) stated that “[a]pproximately 183,000 Americans died from prescription opioid overdoses between 1999 and 2015 alone.”¹⁶ According to a second report by the Committee entitled “Fueling an Epidemic Report Two: Exposing the Financial Ties Between Opioid

¹¹ See Nora D. Volkow & A. Thomas McLellan, *Opioid Abuse in Chronic Pain—Misconceptions and Mitigation Strategies*, 374 N. Eng. J. Med. 1253 (2016).

¹² See Robert M. Califf *et al.*, *A Proactive Response to Prescription Opioid Abuse*, 374 N. Eng. J. Med. 1480 (2016).

¹³ Opioid Crisis, NIH.

¹⁴ *Id.* (citing at note 2 Florence CS, Zhou C, Luo F, Xu L, *The Economic Burden of Prescription Opioid Overdose, Abuse, and Dependence in the United States, 2013*, *MED CARE* 2016;54(10):901-906, doi:10.1097/MLR.0000000000000625).

¹⁵ *Fueling an Epidemic*, McCaskill, HSGAC Minority Staff Rpt, (2017).
<https://www.hsdl.org/?abstract&did=803959>

¹⁶ *Id.*

Manufacturers and Third party Advocacy Groups,” more than 42,000 American died from opioid overdoses in 2016.¹⁷

40. Prescription opioids are deadlier than heroin. According to the National Institutes of Health, prescription opioids kill almost twice as many people in the United States as heroin. Prescription opioids and related drug overdose deaths surpass car accident deaths in the U.S.

41. This epidemic and its consequences could have been, and should have been, prevented by the Defendants, who control the U.S. drug distribution industry and the Defendants who manufacture the prescription opioids. These Defendants have profited greatly by allowing the geographic area that Plaintiff serves to become flooded with prescription opioids.

42. The Pharmaceutical Defendants aggressively marketed highly addictive and dangerous opioids, falsely representing to doctors that patients would only rarely succumb to drug addiction. These Pharmaceutical Defendants aggressively advertised to and persuaded doctors to prescribe highly addictive, dangerous opioids, turning patients into drug addicts for their own corporate profit. Such actions were intentional and/or unlawful.

43. The drug distribution industry is supposed to serve as a "check" in the drug delivery system, by securing and monitoring opioids at every step of the stream of commerce, protecting them from theft and misuse, and refusing to fulfill suspicious or unusual orders by downstream pharmacies, doctors, clinics, or patients. The Distributor Defendants woefully failed in this duty, instead consciously ignoring known or knowable problems and data in their supply chains.

44. Defendants thus intentionally and negligently created conditions in which vast amounts of opioids have flowed freely from drug manufacturers to innocent patients who became addicted, to opioid abusers, and even to illicit drug dealers - with distributors regularly fulfilling

¹⁷ *Id.*

suspicious orders from pharmacies and clinics, who were economically incentivized to ignore "red flags" at the point of sale and before dispensing the pills.

45. Defendants' wrongful conduct has allowed millions of opioid pills to be diverted from legitimate channels of distribution into the illicit black market in quantities that have fueled the opioid epidemic in the United States, the State of Louisiana, and in Plaintiff's Community. This is characterized as "opioid diversion." Acting against their legal and statutory duties, Defendants have created an environment in which opioid diversion is rampant. As a result, patients and unauthorized opioid users have ready access to illicit sources of diverted opioids.

46. For years, Defendants and their agents have had the ability to substantially reduce the death toll and adverse economic consequences of opioid diversion, including the deaths and health ruination of hundreds of thousands of citizens. Substantial expenditures by Plaintiff in dealing with the problem have gone un-recouped and unreimbursed. All the Defendants in this action share responsibility for perpetuating the epidemic.

47. Many Americans are now addicted to prescription opioids, and the number of deaths due to prescription opioid overdose is unacceptable. In 2016, drug overdoses killed roughly 64,000 people in the United States, an increase of 21% percent over the previous year.¹⁸

48. Moreover, the Centers for Disease Control and Prevention ("CDC") has identified addiction to prescription pain medication as the strongest risk factor for heroin addiction. People who are addicted to prescription opioid painkillers are forty times more likely to be addicted to heroin.¹⁹

49. Heroin is pharmacologically similar to prescription opioids. The majority of current

¹⁸ See Ctrs. for Disease Control and Prevention, U.S. Dep't of Health and Human Servs., Drug Overdose Deaths in the United States <https://www.cdc.gov/nchs/products/databriefs/db294.htm>.

¹⁹ See Ctrs. for Disease Control and Prevention, U.S. Dep't of Health and Human Servs., *Today's Heroin Epidemic*, <https://www.cdc.gov/vitalsigns/heroin/index.html> (last updated July 7, 2015).

heroin users report having used prescription opioids non-medically before they initiated heroin use. Available data indicates that the nonmedical use of prescription opioids is a strong risk factor for heroin use.²⁰

50. The CDC reports that drug overdose deaths involving heroin continued to climb sharply, with heroin overdoses more than tripling in 4 years. This increase mirrors large increases in heroin use across the country and has been shown to be closely tied to opioid pain reliever misuse and dependence. ***Past misuse of prescription opioids is the strongest risk factor for heroin initiation and use***, specifically among persons who report past-year dependence or abuse. The increased availability of heroin, combined with its relatively low price (compared with diverted prescription opioids) and high purity appear to be major drivers of the upward trend in heroin use and overdose.²¹

51. Across the nation, local governments, including Plaintiff, are struggling with an ever-expanding epidemic of opioid addiction and abuse. Every day, more than 90 Americans lose their lives after overdosing on opioids.²² Opioid-related death tolls are rising at such a rapid pace that cities and parishes, such as Plaintiff and Plaintiff's Community, are being overburdened by increased law-enforcement, EMS, fire, foster care and other associated costs.

52. The U.S. opioid epidemic is continuing, and drug overdose deaths nearly tripled during 1999–2014. Among 47,055 drug overdose deaths that occurred in 2014 in the United States,

²⁰ See Wilson M. Compton, *Relationship Between Nonmedical Prescription-Opioid Use and Heroin*, 374 N. Eng. J. Med. 154 (2016).

²¹ See Rose A. Rudd et al., *Increases in Drug and Opioid Overdose Deaths- United States, 2000-2014*, 64 Morbidity & Mortality Wkly. Rep 1378 (2016).

²² Opioid Crisis, NIH, National Institute on Drug Abuse (available at <https://www.drugabuse.gov/drugs-abuse/opioids/opioid-crisis>, last visited Sept. 19, 2017) (“Opioid Crisis, NIH”) (citing at note 1 Rudd RA, Seth P, David F, Scholl L, Increases in Drug and Opioid-Involved Overdose Deaths — United States, 2010–2015, *MMWR MORB MORTAL WKLY REP.* 2016;65, doi:10.15585/mmwr.mm655051e1).

28,647 (60.9%) involved an opioid.²³

53. The rate of death from opioid overdose has quadrupled during the past 15 years in the United States. Nonfatal opioid overdoses that require medical care in a hospital or emergency department have increased by a factor of six in the past 15 years.²⁴

54. Every day brings a new revelation regarding the depth of the opioid plague: just to name one example, the New York Times reported in September 2017 that the epidemic, which now claims 60,000 lives a year, is now killing babies and toddlers because ubiquitous, deadly opioids are “everywhere” and mistaken as candy.²⁵

55. In 2016, the President of the United States declared an opioid and heroin epidemic.²⁶

56. The epidemic of prescription pain medication and heroin deaths is devastating families and communities across the country.²⁷ Meanwhile, the manufacturers and distributors of prescription opioids extract billions of dollars of revenue from the addicted American public while public entities experience hundreds of millions of dollars of injury – if not more – caused by the reasonably foreseeable consequences of the prescription opioid addiction epidemic.

57. The prescription opioid manufacturers and distributors, including the Defendants, have continued their wrongful, intentional, and unlawful conduct, despite their knowledge that such conduct is causing and/or contributing to the national, state, and local opioid epidemic.

²³ See Rose A. Rudd et al., *Increases in Drug and Opioid-Involved Overdose Deaths—United States, 2010–2015*, 65 *Morbidity & Mortality Wkly. Rep.* 1445 (2016).

²⁴ See Nora D. Volkow & A. Thomas McLellan, *Opioid Abuse in Chronic Pain—Misconceptions and Mitigation Strategies*, 374 *N. Eng. J. Med.* 1253 (2016).

²⁵ Julie Turkewitz, *‘The Pills are Everywhere’: How the Opioid Crisis Claims Its Youngest Victims*, N.Y. Times, Sept. 20, 2017 (“‘It’s a cancer,’ said [grandmother of dead one-year old], of the nation’s opioid problem, ‘with tendrils that are going everywhere.’”).

²⁶ See Proclamation No. 9499, 81 Fed. Reg. 65,173 (Sept. 16, 2016) (proclaiming “Prescription Opioid and Heroin Epidemic Awareness Week”).

²⁷ See Presidential Memorandum – Addressing Prescription Drug Abuse and Heroin Use, 2015 Daily Comp. Pres. Doc. 743 (Oct. 21, 2015), <https://www.gpo.gov/fdsys/pkg/DCPD-201500743/pdf/DCPD-201500743.pdf>.

2. The Louisiana Opioid Epidemic

58. Louisiana has been especially ravaged by the national opioid crisis.

59. Louisiana was among the states to see a statistically significant increase in the drug overdose death rate from 2014 to 2015, according to data from the Centers for Disease Control and Prevention (CDC).²⁸ More recently, the death rate rose by 12.4 percent from 2016-2017²⁹ and from 2015 to 2016, the death rate rose by 14.7 percent.³⁰ In fact, the age adjusted rate of drug overdose deaths in Louisiana has increased each year since 2014; from 16.9% that year, to 19% in 2015, to 21.8% in 2016, reaching 24.5% in 2017.³¹

60. In 2017, 1,108 people died from drug overdoses in the State of Louisiana, up from 996 in 2016.³² Earlier, in 2015, 861 people died from drug overdoses in the State of Louisiana,³³ up from 777 in 2014.³⁴ Another 809 lost their lives to drug overdoses in 2013.³⁵ Many of these deaths are due to opioids. The Louisiana Department of Health's Bureau of Vital Records tracked a rise in deaths due to opioid overdoses from 155 in 2012 to 305 in 2016, numbers the state government believes are under-reported.³⁶

61. This high rate of overdoses is due at least in part to the extremely high rates at

²⁸ Centers for Disease Control and Prevention, *Drug Overdose Death Data, 2014-2015 Death Increases*, available at <https://www.cdc.gov/drugoverdose/data/statedeaths.html> (as listed on Feb. 6, 2019).

²⁹ <https://www.cdc.gov/drugoverdose/data/statedeaths.html> (last visited June 11, 2019).

³⁰ *Id.*

³¹ *Id.*

³² *Id.*

³³ Centers for Disease Control and Prevention, *Drug Overdose Death Data, Number and age-adjusted rates of drug over dose deaths by state, US 2015*, available at <https://www.cdc.gov/drugoverdose/data/statedeaths.html> (last visited Feb. 6, 2019).

³⁴ Centers for Disease Control and Prevention, *Drug Overdose Death Data, Number and age-adjusted rates of drug over dose deaths by state, US 2014*, available at <https://www.cdc.gov/drugoverdose/data/statedeaths.html> (last visited Feb. 6, 2019).

³⁵ Centers for Disease Control and Prevention, *Drug Overdose Death Data, Number and age-adjusted rates of drug over dose deaths by state, US 2013*, available at <https://www.cdc.gov/drugoverdose/data/statedeaths.html> (last visited Dec. 19, 2017).

³⁶ Office of the Governor, *Louisiana Department of Health continues efforts to reduce opioid abuse*, Sept. 18, 2017, available at <http://gov.louisiana.gov/index.cfm/newsroom/detail/1029>.

which opioids have been prescribed in Louisiana. According to the CDC, in 2016 Louisiana had an opioid prescription rate of 98.1 per 100 persons, which ranked fifth in the country.³⁷ Louisiana's rate of opioid prescriptions has consistently been among the highest in the country and the equivalent to more than one prescription for each resident. For example, that rate was 100.4 prescriptions per 100 people in 2015³⁸ and 108.9 in 2014.³⁹ It was even higher in earlier years at 112.4 prescriptions per 100 persons in 2013,⁴⁰ 113 in 2012,⁴¹ 111.7 in 2011,⁴² 112.6 prescriptions per 100 people in 2010,⁴³ 113 in 2009⁴⁴ and 113.7 in 2008.⁴⁵

62. The Louisiana Commission on Preventing Opioid Abuse estimates that 108 to 122 opioid prescriptions are written per 100 persons in Louisiana per year, among the highest in the country.⁴⁶ The rate of 122 prescriptions per 100 people over the last six years is 39 percent higher than the national average.⁴⁷

63. This high rate of prescriptions translates into efforts to get people off of opioids. From 2013-2015 there were 6,252 opioid-related substance abuse treatment admissions in

³⁷ Centers for Disease Control and Prevention, *U.S. State Prescribing Rates, 2016*, available at <https://www.cdc.gov/drugoverdose/maps/rxstate2016.html>.

³⁸ Centers for Disease Control and Prevention, *U.S. State Prescribing Rates, 2015*, available at <https://www.cdc.gov/drugoverdose/maps/rxstate2015.html>.

³⁹ Centers for Disease Control and Prevention, *U.S. State Prescribing Rates, 2014*, available at <https://www.cdc.gov/drugoverdose/maps/rxstate2014.html>.

⁴⁰ Centers for Disease Control and Prevention, *U.S. State Prescribing Rates, 2013*, available at <https://www.cdc.gov/drugoverdose/maps/rxstate2013.html>.

⁴¹ Centers for Disease Control and Prevention, *U.S. State Prescribing Rates, 2012*, available at <https://www.cdc.gov/drugoverdose/maps/rxstate2012.html>.

⁴² Centers for Disease Control and Prevention, *U.S. State Prescribing Rates, 2011*, available at <https://www.cdc.gov/drugoverdose/maps/rxstate2011.html>.

⁴³ Centers for Disease Control and Prevention, *U.S. State Prescribing Rates, 2010*, available at <https://www.cdc.gov/drugoverdose/maps/rxstate2010.html>.

⁴⁴ Centers for Disease Control and Prevention, *U.S. State Prescribing Rates, 2009*, available at <https://www.cdc.gov/drugoverdose/maps/rxstate2009.html>.

⁴⁵ Centers for Disease Control and Prevention, *U.S. State Prescribing Rates, 2008*, available at <https://www.cdc.gov/drugoverdose/maps/rxstate2008.html>.

⁴⁶ Louisiana Commission on Preventing Opioid Abuse, *The Opioid Epidemic: Evidence Based Strategies Legislative Report*, April 2017, at 20 (citations omitted), available at <http://dhh.louisiana.gov/assets/docs/BehavioralHealth/Opioids/LCPOAFinalReportPkg20170331.pdf>.

⁴⁷ *Id.* at 21.

Louisiana.⁴⁸

64. The costs related to the opioid crisis are steep. The Louisiana Commission on Preventing Opioid Abuse has estimated that opioid abuse costs Louisiana \$296 million a year in health care expenditures alone.⁴⁹

3. The Opioid Epidemic Disproportionately Affects American Indian and Alaska Native Population

65. The American Indian and Alaska Native population has been significantly and disproportionately impacted by the opioid epidemic.

66. The Substance Abuse and Mental Health Services Administration reports that the rates of opioid abuse are consistently the highest among Caucasian and Native peoples.⁵⁰

67. This ongoing epidemic is further complicated among tribal communities given their lack of access to medical care, short-age of law enforcement and insufficient data on substance abuse.⁵¹

68. As of 2016, four percent of the American Indian and Alaska Native population (of those 12 and older) reported prescription opioid misuse.⁵²

69. The overdose death rate among American Indian and Alaska Natives of 13.9 deaths per 100 people was the second highest overdose death rate in the United States in 2016 and represents a **400 percent increase** among its population since 2000.⁵³

70. From 1999 to 2015, American Indians and Alaska Natives have had the highest

⁴⁸ Louisiana Department of Health, *Opioid Abuse, Prevention, Treatment and Policy, Quick Facts* (January 2017), available at http://ldh.la.gov/assets/opioid/OpioidAbsePrvntn_2017.pdf.

⁴⁹ Louisiana Commission on Preventing Opioid Abuse, *supra* note 44, at 17, citing Matrix Global Advisors, LLC (2014) Health Care Costs from Opioid Abuse: A State by State Analysis.

⁵⁰ Hearing, Committee on Indian Affairs United States Senate: *Opioids in Indian Country: Beyond the Crisis to Healing the Community*; S. Hrg. 115-383, March 14, 2018 (p. 1)

⁵¹ *Id.*

⁵² *Id.*

⁵³ *Id.* at p. 10. (Testimony of Capt. Christopher Jones, Pharm.D., M.P.H., Director of National Mental Health and Substance Abuse Policy Laboratory, Substance Abuse and Mental Health Services Administration, U.S. DHH)

drug overdose death rates and the largest percentage increase in number of deaths compared to other racial and ethnic groups, seeing deaths among their population rise by **more than 500 percent** during that time frame.⁵⁴

71. Yet, the opioid epidemic among American Indians is likely more severe and widespread than described hereinabove. According to the CDC, that the actual drug overdose death count among American Indians, as of 2017, could have been underestimated by as much as 35 percent due to racial misclassification on death certificates.⁵⁵

4. The Opioid Epidemic in Plaintiff's Community

72. Defendants created a virtually limitless opioid market through false and deceptive advertising and other unlawful and unfair conduct, which significantly harmed Plaintiff and the members of Plaintiff's Tribe and their families. Defendants' success in extending the market for opioids to new patients and chronic pain conditions created an abundance of drugs available for non-medical and criminal use and fueled a new wave of addiction and injury.

73. Tribe Members of the Four Winds Louisiana Cherokee live within the Louisiana Parishes of Allen, Beauregard, Calcasieu, Evangeline, Grant, Jefferson Davis, Lafayette, Natchitoches, Rapides, Sabine, and Vernon. These parishes represent some of the hardest hit by the opioid epidemic in a State that has already incurred significant impact from the crisis.

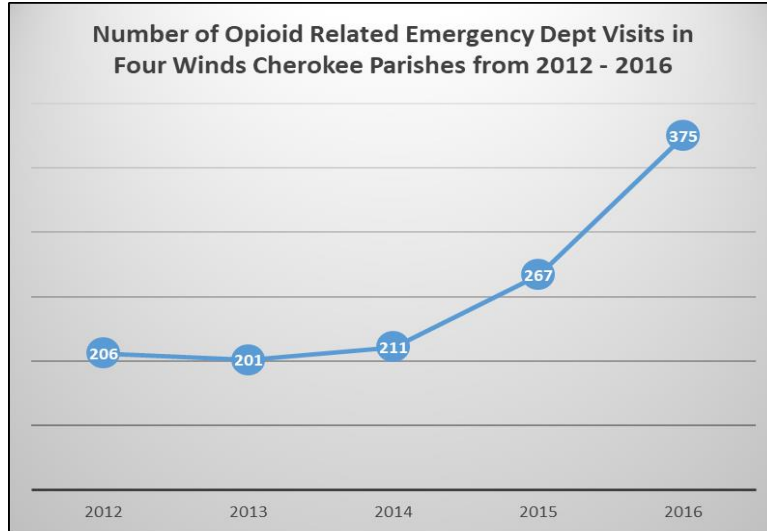
74. From 2012 through 2016, the number of opioid related emergency department visits across the Tribe's eleven parish rose sharply from 206 and 201 visits in 2012 and 2013, respectively, to 375 in 2016.⁵⁶ (See below illustration which has been prepared using the

⁵⁴ *Id.*, at p. 15. (Testimony of Rear Admiral Michael Toedt, M.D., Chief Medical Officer, Indian Health Service, US DHH)

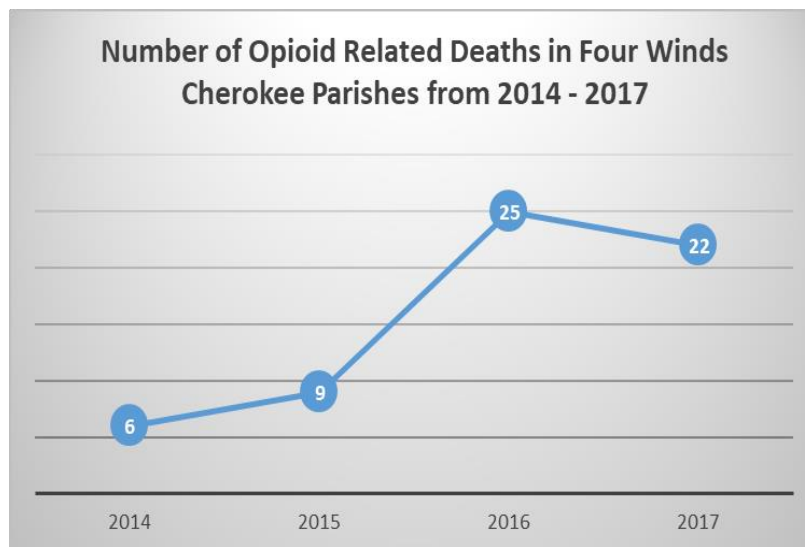
⁵⁵ *Id.*, at 50 (Excerpt from prepared statement of Samuel Moose).

⁵⁶ <https://lodss.lhdh.la.gov/> - Louisiana Department of Health Louisiana Opioid Data and Surveillance System (lasted accessed 6/14/2019).

referenced data from the Louisiana Department of Health).



75. Additionally, the eleven parishes of Plaintiff's Community saw a drastic increase in Opioid related deaths from 2014 through 2017. As of 2014, at least⁵⁷ six opioid related deaths were reported in the eleven parishes, but by 2016 that number had risen to 25, decreasing slightly in 2017 (22 deaths).⁵⁸



⁵⁷ LDH suppresses the actual number of deaths for Parishes with less than five, but more than zero deaths in a year.

⁵⁸ <https://lodss.ldh.la.gov/> - Louisiana Department of Health Louisiana Opioid Data and Surveillance System (lasted accessed 6/14/2019).

76. Rapides Parish represents one of the hardest hit areas within Plaintiff's Community. As illustrated below (following page), in each year since 2014 the opioid prescription rate per 100 individuals in Rapides Parish has virtually doubled that of the State of Louisiana's, which, at 105 opioid prescriptions per 100 individuals⁵⁹, was nearly double the national average of 58.7 in 2017.⁶⁰ The opioid prescription rate in within Rapides Parish has not dropped below 210 per 100 individual since 2014, and was nearly four times the national average in 2017.⁶¹

77. Upon information and belief, as a direct and foreseeable result of the intentional and/or unlawful acts of the Defendants, as set forth herein, Plaintiff's Community has been completely oversaturated with opioids, including those illegally distributed, all of which has caused and will continue to cause addiction, death, and injury to Plaintiff and its members. As set forth hereinafter, Plaintiff and its members have suffered economic damages as a direct result of the intentional and/or unlawful conduct of the Defendants.

B. THE PHARMACEUTICAL DEFENDANTS' FALSE, DECEPTIVE, AND UNFAIR MARKETING OF OPIOIDS.

78. Over the course of a given year, approximately 100 million people in the United States suffer from pain. Some 9 million to 12 million of them have chronic or persistent pain.⁶²

79. Before the 1990s, the generally accepted standard of medical practice was that opioids should only be used short-term for acute pain, pain relating to recovery from surgery, or for cancer or palliative (end-of-life) care. Due to the lack of evidence that opioids improved patients' ability to overcome pain and function, coupled with evidence of greater pain complaints as patients developed tolerance to opioids over time and the serious risk of addiction and other

⁵⁹ *Id.*

⁶⁰ <https://www.cdc.gov/drugoverdose/maps/rxrate-maps.html> (last accessed 6/14/19).

⁶¹ <https://lodss.ldh.la.gov/> - Louisiana Department of Health Louisiana Opioid Data and Surveillance System (lasted accessed 6/14/2019).

⁶² See Robert M. Califf *et al.*, *A Proactive Response to Prescription Opioid Abuse*, 374 N. Eng. J. Med. 1480 (2016).

side effects, the use of opioids for chronic pain was discouraged or prohibited. As a result, doctors generally did not prescribe opioids for chronic pain.

1. The Pharmaceutical Defendants' Marketing Scheme

80. To establish and exploit the lucrative market of chronic pain patients, each Pharmaceutical Defendant developed a well-funded, sophisticated, and deceptive marketing and/or distribution scheme targeted at consumers and physicians. The marketing/distribution scheme was multi-faceted. These Defendants used a variety of methods to promote their scheme including (1) direct marketing; (2) so-called “unbranded” marketing, for example, using websites; (3) payment to doctors to serve on “speakers’ bureaus” and to attend programs to incentivize doctors to prescribe opioids; (4) use of doctors who have become known as “Key Opinion Leaders” (KOLs); (5) detailing to doctors; and (6) “veiled” advertising by seemingly independent third parties (“Advocacy Groups”), all with the purpose of spreading false and deceptive statements about the risks and benefits of long-term opioid use – statements that created the “new” market for prescription opioids, upended the standard medical practice, and benefited other Defendants and opioid manufacturers. These statements were unsupported by and contrary to the scientific evidence. These statements were also contrary to pronouncements by and guidance from the FDA and CDC. The marketing practices by these defendants targeted the Plaintiff’s Community, *inter alia*, susceptible prescribers, such as general practitioners, and vulnerable patient populations.

81. To convince doctors and patients in Louisiana and in Plaintiff’s Community that opioids can and should be used to treat chronic pain, these Defendants had to persuade them that long-term opioid use was both safe and helpful. Knowing that they could do so only by deceiving those doctors and patients about the risks and benefits of long-term opioid use, these Defendants made claims that were not supported by or were contrary to the scientific evidence and which were

contradicted by data.

82. To convince doctors and patients in Louisiana and in Plaintiff's Community that opioids were safe, the Pharmaceutical Defendants deceptively trivialized and failed to disclose the risks of long-term opioid use, particularly the risk of addiction, through a series of misrepresentations that have been conclusively debunked by the FDA and CDC. These misrepresentations – some of which are illustrated below – reinforced each other and created the dangerously misleading impression that: (a) starting patients on opioids was low-risk because most patients would not become addicted, and because those who were at greatest risk of addiction could be readily identified and managed; (b) patients who displayed signs of addiction probably were not addicted and, in any event, could easily be weaned from the drugs; (c) the use of higher opioid doses, which many patients need to sustain pain relief as they develop tolerance to the drugs, do not pose special risks; and (d) abuse-deterrent opioids both prevent abuse and overdose and are inherently less addictive. These Defendants have not only failed to correct these misrepresentations; they continue to make them today.

83. The Pharmaceutical Defendants spread their false and deceptive statements by directing their marketing strategies directly to doctors and patients throughout the State of Louisiana and Plaintiff's Community. Upon information and belief, the following non-exclusive examples illustrate their false, misleading, and deceptive marketing practices:

- (a) Endo distributed and made available on its website opana.com a pamphlet promoting Opana ER with photographs depicting patients with physically demanding jobs, misleadingly implying that the drug would provide long-term pain-relief and functional improvement.⁶³

⁶³ *In the Matter of Endo Health Solutions Inc. and Endo Pharmaceuticals Inc.*, Assurance No.: 15-228, Attorney General of the State of New York, p. 8, ¶ 26.

- (b) Purdue ran a series of ads, called “Pain Vignettes,” for OxyContin that featured chronic pain patients and recommended OxyContin for each. One ad described a “54-year-old writer with osteoarthritis of the hands” and implied that OxyContin would help the writer work more effectively.
- (c) Endo sponsored a website, Painknowledge.com, which falsely claimed that “[p]eople who take opioids as prescribed usually do not become addicted”;
- (d) Janssen distributed a patient education guide entitled *Finding Relief: Pain Management for Older Adults* (2009), which described as “myth” the claim that opioids are addictive, and asserted as fact that “[m]any studies show that opioids are rarely addictive when used properly for the management of chronic pain.”
- (e) A Janssen website, Prescriberesponsibly.com (last updated July 2, 2015), which claims that “While these concerns [addiction] are not without some merit, it would appear that they are *often overestimated*. According to clinical opinion polls, true *addiction occurs only in a small percentage of patients with chronic pain* who receive chronic opioid analgesics analgesic therapy.”
- (f) Purdue sponsored American Pain Foundation’s (“APF”) *A Policymaker’s Guide to Understanding Pain & Its Management* – that falsely claims that pain is undertreated due to “misconceptions about opioid addiction.”
- (g) An Actavis patient brochure stated - “Over time, your body may become tolerant of your current dose. You may require a dose adjustment to get the right amount of pain relief. This is not addiction”;
- (h) Cephalon and Purdue sponsored APF’s *Treatment Options: A Guide for People Living with Pain* (2007), which suggested that addiction is rare and limited to extreme cases

- of unauthorized dose escalations, obtaining duplicative opioid prescriptions from multiple sources, or theft. This publication is still available online.⁶⁴ The same publication asserts that some patients need larger doses of opioids, with “no ceiling dose” for appropriate treatment of severe, chronic pain;
- (i) An Endo website, painknowledge.com, claimed that opioid dosages may be increased until “you are on the right dose of medication for your pain”;
 - (j) Endo distributed a pamphlet edited by a KOL entitled *Understanding Your Pain: Taking Oral Opioid Analgesics* (2004 Endo Pharmaceuticals PM-0120). In Q&A format, it asked “If I take the opioid now, will it work later when I really need it?” The response is, “The dose can be increased. ... You won’t ‘run out’ of pain relief.”⁶⁵
 - (k) A Janssen patient education guide *Finding Relief: Pain Management for Older Adults* listed dosage limitations as “disadvantages” of other pain medicines yet omitted any discussion of the risks of increased opioid dosages;
 - (l) Purdue’s *A Policymaker’s Guide to Understanding Pain & Its Management* stated that dosage escalations are “sometimes necessary,” even unlimited ones, but did not disclose the risks from high opioid dosages;
 - (m) A Purdue CME entitled *Overview of Management Options* taught that nonsteroidal anti-inflammatory drugs (“NSAIDs”) and other drugs, but not opioids, were unsafe at high dosages;
 - (n) An Actavis advertisement claimed that the use of Kadian to treat chronic pain would allow patients to return to work, relieve “stress on your body and your mental health,”

⁶⁴ Am. Pain Found., *Treatment Options: A Guide for People Living in Pain* (2007) [hereinafter APF, *Treatment Options*], <https://assets.documentcloud.org/documents/277605/apf-treatmentoptions.pdf>.

⁶⁵ Margo McCaffery & Chris Pasero, Endo Pharm., *Understanding Your Pain: Taking Oral Opioid Analgesics* (Russell K Portenoy, M.D., ed., 2004).

- and help patients enjoy their lives;
- (o) A Janssen patient education guide *Finding Relief: Pain Management for Older Adults* stated as “a fact” that “opioids may make it easier for people to live normally” such as sleeping peacefully, working, recreation, sex, walking, and climbing stairs;
 - (p) Purdue advertisements of OxyContin entitled “Pain vignettes” implied that OxyContin improves patients’ function;
 - (q) *Responsible Opioid Prescribing*, by Cephalon, Endo and Purdue, taught that relief of pain by opioids, by itself, improved patients’ function;
 - (r) Cephalon and Purdue sponsored APF’s *Treatment Options: A Guide for People Living with Pain* (2007), which counseled patients that opioids “give [pain patients] a quality of life we deserve.”⁶⁶ This publication is still available online.
 - (s) Endo’s NIPC website *painknowledge.com* claimed that with opioids, “your level of function should improve; you may find you are now able to participate in activities of daily living, such as work and hobbies, that you were not able to enjoy when your pain was worse”;
 - (t) Endo CMEs titled *Persistent Pain in the Older Patient* claimed that chronic opioid therapy had been “shown to reduce pain and improve depressive symptoms and cognitive functioning”;
 - (u) Janssen sponsored, funded, and edited a website, *Let’s Talk Pain*, in 2009, which featured an interview edited by Janssen claiming that opioids allowed a patient to “continue to function”;
 - (v) Purdue’s *A Policymaker’s Guide to Understanding Pain & Its Management*, originally

⁶⁶ Am. Pain Found., *Treatment Options: A Guide for People Living in Pain* (2007) [hereinafter APF, *Treatment Options*], <https://assets.documentcloud.org/documents/277605/apf-treatmentoptions.pdf>.

- published in 2011, claimed that “multiple clinical studies” had shown opioids as effective in improving daily function, psychological health, and health-related quality of life for chronic pain patients;⁶⁷
- (w) Purdue’s, Cephalon’s, Endo’s, and Janssen’s sales representatives have conveyed and continue to convey the message that opioids will improve patient function.
- (x) Actavis’s predecessor caused a patient education brochure, *Managing Chronic Back Pain*, to be distributed beginning in 2003 that admitted that opioid addiction is possible, but falsely claimed that it is “less likely if you have never had an addiction problem.” Based on Actavis’s acquisition of its predecessor’s marketing materials along with the rights to Kadian, it appears that Actavis continued to use this brochure in 2009 and beyond.
- (y) Consistent with the Pharmaceutical Defendants’ published marketing materials, upon information and belief, detailers for Purdue, Endo, Janssen, and Cephalon in the State and Plaintiff’s Community minimized or omitted any discussion with doctors of the risk of addiction; misrepresented the potential for abuse of opioids with purportedly abuse-deterrent formulations; and routinely did not correct the misrepresentations noted above.
- (z) Purdue sponsored APF’s *A Policymaker’s Guide to Understanding Pain & Its Management*, which claims that less than 1% of children prescribed opioids will become addicted and that pain is undertreated due to “[m]isconceptions about opioid addiction.”⁶⁸

⁶⁷ Am. Pain Found., *A Policymaker’s Guide to Understanding Pain and Its Management* 6 (2011) [hereinafter APF, *Policymaker’s Guide*], <http://s3.documentcloud.org/documents/277603/apf-policymakers-guide.pdf>, at 32.

⁶⁸ Am. Pain Found., *A Policymaker’s Guide to Understanding Pain and Its Management* 6 (2011) [hereinafter APF, *Policymaker’s Guide*], <http://s3.documentcloud.org/documents/277603/apf-policymakers-guide.pdf>.

- (aa) An investigation of Endo by the New York Attorney General resulted in this finding: "...Endo disseminated to New York [Healthcare Providers] and stated on its website www.opana.com that '[m]ost healthcare providers who treat patients with pain agree that patients treated with prolonged opioid medicines usually do not become addicted.'" The New York Attorney General further determined that Endo "has not conducted nor does it possess a survey that shows that most healthcare providers who had patients with pain agree that patients treated with prolonged opioid medicines usually do not become addicted."⁶⁹
- (bb) Janssen promoted Ultracet for everyday chronic pain and distributed posters, for display in doctors' offices, of presumed patients in active professions; the caption read, "Pain doesn't fit into their schedules."
- (cc) Endo was the sole sponsor, through NIPC, of a series of CMEs entitled "Persistent Pain in the Older Patient."⁷⁰ Upon information and belief, a CME disseminated via webcast claimed that chronic opioid therapy has been "shown to reduce pain and improve depressive symptoms and cognitive functioning."
- (dd) Purdue sponsored the development and distribution of APF's *A Policymaker's Guide to Understanding Pain & Its Management*, which claimed that "[m]ultiple clinical studies" have shown that opioids are effective in improving "[d]aily function," "[p]sychological health," and "[o]verall health-related quality of life for chronic pain."⁷¹ The Policymaker's Guide was originally published in 2011.

⁶⁹ *In the Matter of Endo Health Solutions Inc. and Endo Pharmaceuticals Inc.*, Assurance No.: 15-228, Attorney General of the State of New York, p. 6, ¶ 20.

⁷⁰ E.g., NIPC, *Persistent Pain and the Older Patient* (2007), https://www.painedu.org/Downloads/NIPC/Activities/B173_Providence_RI_%20Invite.pdf.

⁷¹ Am. Pain Found., *A Policymaker's Guide to Understanding Pain and Its Management* 6 (2011) [hereinafter APF, *Policymaker's Guide*], <http://s3.documentcloud.org/documents/277603/apf-policymakers-guide.pdf>, at 29.

84. The Pharmaceutical Defendants also promoted the use of opioids for chronic pain through “detailers” – sophisticated and specially trained sales representatives who visited individual doctors and medical staff. Upon information and belief, in 2014, for instance, these Defendants spent almost \$200 million on “detailing” branded opioids to doctors. The Pharmaceutical Defendants’ “detailing” to doctors was highly effective in the national proliferation of prescription opioids. Defendants used sophisticated data mining and intelligence to track and understand the rates of initial prescribing and renewal by individual doctors, allowing specific and individual targeting, customizing, and monitoring of their marketing.

85. The FDA has cited at least one of these Defendants for deceptive promotions by its detailers and direct-to-physician marketing. In 2010 the FDA issued a “WARNING LETTER”⁷² to Actavis US which stated in pertinent part as follows:

The Division of Drug Marketing, Advertising, and Communications (DDMAC) of the U.S. Food and Drug Administration (FDA) has reviewed a Co-Pay Assistance Program brochure (KAD200901) for Kadian® (morphine extended-release) Capsules, CII (Kadian), submitted by Actavis Elizabeth LLC (Actavis) ... DDMAC has also reviewed a PK to PK Comparison Detailer (Comparison Detailer) (KADI8D0231) for Kadian that was originally submitted by Alpharma... The Co-Pay Assistance Program brochure and Comparison Detailer are false or misleading because they omit and minimize the serious risks associated with the drug, broaden and fail to present the limitations to the approved indication of the drug, and present unsubstantiated superiority and effectiveness claims. Therefore, the Co-Pay Assistance Program brochure and Comparison Detailer misbrand the drug in violation of the Federal Food, Drug, and Cosmetic Act (the Act), 21 U.S.C. 352(a) & 321(n). Cf. 21 CFR 202.1(e)(3)(i); (e)(5); (e)(6)(i), (ii) & (xviii); (e)(7)(i) & (viii). These violations are a concern from a public health perspective because they suggest that the product is safer and more effective than has been demonstrated.

The letter concluded as follows:

For the reasons discussed above, the Comparison Detailer and Co-Pay Assistance Program brochure misbrand Kadian in violation of the Act, 21 U.S.C. 352(a) & 321(n). Cf. 21 CFR 202.1(e)(3)(i); (e)(5); (e)(6)(i), (ii) & (xviii); (e)(7)(i) & (viii).

⁷² <https://www.fdanews.com/ext/resources/files/archives/a/ActavisElizabethLLC.pdf>

DDMAC requests that Actavis immediately cease the dissemination of violative promotional materials for Kadian such as those described above. (**Emphasis added**)

86. Another marketing strategy involved the employment of doctors to speak at seminars and other events. The Pharmaceutical Defendants invited doctors to participate, for payment and other remuneration, on and in speakers' bureaus and programs paid for by these Defendants. These speaker programs were designed to provide incentives for doctors to prescribe opioids, including recognition and compensation for being selected as speakers. These speakers gave the false impression that they were providing unbiased and medically accurate presentations when they were, in fact, presenting a script prepared by these Defendants.

87. Another marketing strategy involved the use of Key Opinion Leaders (KOLs). Pharmaceutical Defendants also employed small circle of physicians who held themselves out as experts in the pain management field. In order to spread their fraudulent and deceptive science to bolster their marketing schemes, the Pharmaceutical Defendants enlisted the help of so-called KOLs to espouse pro-opioid misinformation to practicing doctors, and most importantly, general practitioners. Upon information and belief, these presentations by KOLs conveyed misleading information, omitted material information, and failed to correct the Pharmaceutical Defendants' prior misrepresentations about the risks and benefits of opioids. The KOLs were a small circle of doctors who were vetted, selected, funded, and promoted by these Defendants because their public positions supported the use of prescription opioids to treat chronic pain. These Defendants paid KOLs to serve in a number of doctor-facing and public-facing capacities, all designed to promote a pro-opioid message and to promote the opioid industry pipeline, from manufacture to distribution to retail.

88. The Pharmaceutical Defendants have had unified marketing plans and strategies from state to state, including Louisiana and the Plaintiff's Community. This unified approach

ensures that Defendants' messages were and are consistent and effective across all their marketing efforts.

89. The Pharmaceutical Defendants deceptively marketed opioids in Louisiana and in the Plaintiff's Community through "unbranded" advertising that promoted opioid use generally, but silent as to a specific opioid. This advertising was ostensibly created and disseminated by independent third parties, but funded, directed, coordinated, edited, and distributed, in part or whole, by these Defendants and their public relations firms and agents.

90. The Pharmaceutical Defendants used putative third-party, "unbranded" advertising to avoid regulatory scrutiny as such advertising is not submitted to or reviewed by the FDA. These Defendants used this "unbranded" advertising to create the false appearance that the deceptive messages came from an independent and objective source. Upon information and belief, the Pharmaceutical Defendants' deceptive unbranded marketing also contradicted their branded materials reviewed by the FDA.

91. In order to effect this type of third-party marketing, the Pharmaceutical Defendants entered into and/or benefitted from arrangements with seemingly unbiased and independent organizations or groups that generated treatment guidelines, unbranded materials, and programs promoting chronic opioid therapy. These relationships were chronicled in the recent minority staff report of the U.S. Senate Homeland Security & Governmental Affairs Committee issued in February 2018 entitled "Fueling an Epidemic: Exposing the Financial Ties Between Opioid Manufactures and Third Party Advocacy Groups."⁷³ The facts set forth in the Committee Report are made a part herein as if copied herein *in extenso*.

92. The Pharmaceutical Defendants collaborated, through the aforementioned

⁷³ <https://www.hsgac.senate.gov/.../hsgac-minority-staff-report-fueling-an-epidemic>.

organizations and groups, to spread deceptive messages about the risks and benefits of long-term opioid therapy.

93. In their marketing efforts described above, the Pharmaceutical Defendants falsely claimed that the risk of opioid addiction was low and that addiction was unlikely to develop when opioids are prescribed, as opposed to obtained illicitly; and failed to disclose the greater risk of addiction with prolonged use of opioids. These claims are contrary to longstanding scientific evidence, as the FDA and CDC have conclusively declared. As noted in the 2016 CDC Guideline endorsed by the FDA, there is “extensive evidence” of the “possible harms of opioids (including opioid use disorder [an alternative term for opioid addiction]).” The Guideline points out that “[o]pioid pain medication use presents serious risks, including ... opioid use disorder” and that “continuing opioid therapy for three (3) months substantially increases risk for opioid use disorder.”⁷⁴

94. The FDA further exposed the falsity of the Pharmaceutical Defendants’ claims about the low risk of addiction when it announced changes to the labels for certain opioids in 2013⁷⁵ and for other opioids in 2016.⁷⁶ In its September 10, 2013 announcement, the FDA stated that extended-release and long-acting (ER/LA) opioid pain relievers were no longer indicated for merely moderate pain. Previously, the labels for ER/LA opioid analgesics stated that they were indicated for “moderate to severe pain in patients requiring continuous, around-the-clock opioid treatment for an extended period of time.” The September 10, 2013 announcement further stated that in the future labels would state that the drugs are indicated “for the management of pain severe enough to require daily, around-the-clock opioid treatment and for which alternative treatments

⁷⁴ <https://www.cdc.gov/mmwr/volumes/65/rr/rr6501e1.htm>

⁷⁵ <https://www.medscape.com/viewarticle/810732>

⁷⁶ <https://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm518697.htm>

are inadequate.”⁷⁷

95. The State of New York, in a 2016 settlement agreement with Endo, found that opioid “use disorders appear to be highly prevalent in chronic pain patients treated with opioids, with up to 40% of chronic pain patients treated in specialty and primary care outpatient centers meeting the clinical criteria for an opioid use disorder.”⁷⁸ Endo had claimed on its www.opana.com website that “[m]ost healthcare providers who treat patients with pain agree that patients treated with prolonged opioid medicines usually do not become addicted,” but the State of New York found no evidence for that statement. Consistent with this, Endo agreed not to “make statements that ... opioids generally are non-addictive”⁷⁹ or “that most patients who take opioids do not become addicted”⁸⁰ in New York. This agreement, however, did not extend to Louisiana.

96. The Pharmaceutical Defendants falsely instructed doctors and patients that the signs of addiction are actually signs of undertreated pain and should be treated by prescribing more opioids. Defendants called this phenomenon “pseudo-addiction.” Defendants falsely claimed that pseudo-addiction was substantiated by scientific evidence. Some examples of these deceptive claims are: (a) Cephalon and Purdue sponsored *Responsible Opioid Prescribing*, which taught that behaviors such as “requesting drugs by name,” “demanding or manipulative behavior,” seeing more than one doctor to obtain opioids, and hoarding, are all signs of pseudo-addiction, rather than true addiction; (b) Janssen sponsored, funded, and edited the *Let’s Talk Pain* website, which in 2009 stated: “pseudo-addiction ... refers to patient behaviors that may occur when pain is undertreated”; (c) Endo sponsored a National Initiative on Pain Control (NIPC) Continuing Medical

⁷⁷ <https://www.forbes.com/sites/robertglatter/2013/09/15/fda-announces-new-labeling-guidelines-for-longer-acting-painkillers/#2c1f442f5f8d>

⁷⁸ In the Matter of Endo Health Solutions Inc. and Endo Pharmaceuticals Inc., Assurance No.: 15-228, Attorney General of the State of New York, p. 13.

⁷⁹ *Id.*, at 15.

⁸⁰ *Id.*

Education (“CME”) program in 2009 titled *Chronic Opioid Therapy: Understanding Risk While Maximizing Analgesia*, which promoted pseudo-addiction by teaching that a patient’s aberrant behavior was the result of untreated pain; (d) Purdue sponsored a deceptive CME program entitled *Path of the Patient, Managing Chronic Pain in Younger Adults at Risk for Abuse* in which a narrator notes that because of pseudo-addiction, a doctor should not assume the patient is addicted.

97. The 2016 CDC Guideline rejects the concept of pseudo-addiction, explaining that “[p]atients who do not experience clinically meaningful pain relief early in treatment ... are unlikely to experience pain relief with longer- term use,” and that “reassessment of pain and function within 1 month of initiating opioids provides an opportunity to minimize risks of long-term opioid use by discontinuing opioids among patients not receiving a clear benefit from these medications.”⁸¹ The New York Attorney General has observed that “The ‘pseudoaddiction’ concept has never been empirically validated and in fact has been abandoned by some of its proponents.” In connection with its investigation of Endo, the New York Attorney General further reported that “Endo’s Vice President for Pharmacovigilance and Risk Management testified to OAG that he was not aware of any research validating the ‘pseudoaddiction’ concept...”

98. The Pharmaceutical Defendants falsely instructed doctors and patients that addiction risk screening tools, patient agreements, urine drug screens, and similar strategies were very effective to identify and safely prescribe opioids to even those patients predisposed to addiction. These misrepresentations were reckless because Pharmaceutical Defendants directed them to general practitioners and family doctors who lack the time and expertise to closely manage higher-risk patients on opioids. Pharmaceutical Defendants’ misrepresentations were intended to make doctors more comfortable in prescribing opioids. Some examples of these deceptive claims

⁸¹ <https://www.cdc.gov/mmwr/volumes/65/rr/rr6501e1.htm>.

are: (a) an Endo supplement in the *Journal of Family Practice* emphasized the effectiveness of screening tools to avoid addictions; (b) Purdue's webinar, *Managing Patient's Opioid Use: Balancing the Need and Risk*, claimed that screening tools, urine tests, and patient agreements prevent "overuse of prescriptions" and "overdose deaths"; (c) Purdue represented in scientific conferences that "bad apple" patients – and not opioids – were the source of the addiction crisis.

99. The 2016 CDC Guideline exposes the falsity of these misrepresentations, noting that there are no studies "...evaluat[ing] the effectiveness of risk mitigation strategies (use of risk assessment instruments, opioid management plans, patient education, urine drug testing, use of PDMP data, use of monitoring instruments, more frequent monitoring intervals, pill counts, or use of abuse-deterrent formulations) for improving outcomes related to overdose, addiction, abuse, or misuse." The Guideline emphasizes that available risk screening tools "show insufficient accuracy for classification of patients as at low or high risk for [opioid] abuse or misuse" and counsels that doctors "should not overestimate the ability of these tools to rule out risks from long-term opioid therapy."⁸²

100. To underplay the risk and impact of addiction and make doctors feel more comfortable starting patients on opioids, Pharmaceutical Defendants falsely claimed that opioid dependence can easily be solved by tapering, that opioid withdrawal was not difficult, and that there were no problems in stopping opioids after long-term use.

101. A CME sponsored by Endo, entitled *Persistent Pain in the Older Adult*, claimed that withdrawal symptoms could be avoided by tapering a patient's opioid dose by up to 20% for a few days. Purdue sponsored APF's *A Policymaker's Guide to Understanding Pain & Its Management*, that claimed "[s]ymptoms of physical dependence can often be ameliorated by

⁸² <https://www.cdc.gov/mmwr/volumes/65/rr/rr6501e1.htm>.

gradually decreasing the dose of medication during discontinuation,” without mentioning any known or foreseeable issues.⁸³

102. Pharmaceutical Defendants deceptively minimized the significant symptoms of opioid withdrawal – which, as explained in the 2016 CDC Guideline, include drug cravings, anxiety, insomnia, abdominal pain, vomiting, diarrhea, sweating, tremor, tachycardia (rapid heartbeat), spontaneous abortion and premature labor in pregnant women, and the unmasking of anxiety, depression, and addiction.⁸⁴ The Pharmaceutical Defendants grossly understated the difficulty of tapering, particularly after long-term opioid use. The 2016 CDC Guideline recognizes:

Because physical dependence on opioids is an expected physiologic response in patients exposed to opioids for more than a few days ..., limiting days of opioids prescribed also should minimize the need to taper opioids to prevent distressing or unpleasant withdrawal symptoms. Experts noted that more than a few days of exposure to opioids significantly increases hazards, that each day of unnecessary opioid use increases likelihood of physical dependence without adding benefit, and that prescriptions with fewer days’ supply will minimize the number of pills available for unintentional or intentional diversion.⁸⁵

The Guideline further states that “tapering opioids can be especially challenging after years on high dosages because of physical and psychological dependence.”⁸⁶

103. The CDC 2016 Guideline further states that, the “[b]enefits of high-dose opioids for chronic pain are not established” while the “risks for serious harms related to opioid therapy increase at higher opioid dosage.” More specifically, the CDC explains that “there is now an established body of scientific evidence showing that overdose risk is increased at higher opioid dosages.” The CDC states that “there is an increased risk for opioid use disorder, respiratory

⁸³ Am. Pain Found., *A Policymaker’s Guide to Understanding Pain and Its Management* 6 (2011) [hereinafter APF, *Policymaker’s Guide*], <http://s3.documentcloud.org/documents/277603/apf-policymakers-guide.pdf>.

⁸⁴ <https://www.cdc.gov/mmwr/volumes/65/rr/rr6501e1.htm>.

⁸⁵ *Id.*

⁸⁶ *Id.*

depression, and death at higher dosages.”⁸⁷

104. The 2016 CDC Guideline reinforces earlier findings announced by the FDA. In 2013, the FDA acknowledged “that the available data to suggest a relationship between increasing opioid dose and risk of certain adverse events.” For example, the FDA noted that studies “appear to credibly suggest a positive association between high-dose opioid use and the risk of overdose and/or overdose mortality.”⁸⁸

105. The numerous, longstanding misrepresentations by the Pharmaceutical Defendants minimizing the risks of long-term opioid use persuaded doctors and patients to discount or ignore the true risks. Pharmaceutical Defendants sought to persuade them that there was a significant upside to long-term opioid use. But as the 2016 CDC Guideline states: “The clinical evidence review found insufficient evidence to determine the long-term benefits of opioid therapy for chronic pain and found an increased risk for serious harms related to long-term opioid therapy that appears to be dose-dependent.” In fact, the CDC found that “[n]o evidence shows a long-term benefit of opioids in pain and function versus no opioids for chronic pain with outcomes examined at least 1 year later (with most placebo-controlled randomized trials \leq 6 weeks in duration).” The CDC further reported that “Extensive evidence suggests some benefits of nonpharmacologic and nonopioid pharmacologic treatments compared with long-term opioid therapy, with less harm.”⁸⁹ The FDA, too, has recognized the lack of evidence to support long-term opioid use. In 2013, the FDA stated that it was “not aware of adequate and well-controlled studies of opioids use longer

⁸⁷ *Id.*

⁸⁸ Food and Drug Administration, *Response to Physicians for Responsible Opioid Prescribing Partial Petition Approval and Denial*; September 10, 2013. http://paindr.com/wp-content/uploads/2013/09/FDA_CDOR_Response_to_Physicians_for_Responsible_Opioid_Prescribing_Partial_Petition_Approval_and_Denial.pdf

⁸⁹ <https://www.cdc.gov/mmwr/volumes/65/rr/rr6501e1.htm>.

than 12 weeks.”⁹⁰ Despite this, Defendants falsely and misleadingly touted the benefits of long-term opioid use and falsely and misleadingly suggested that these benefits were supported by scientific evidence. Not only have Defendants failed to correct these false and deceptive claims, they continue to make them today.

106. The CDC also noted that “opioid use disorder is a problematic pattern of opioid use leading to clinically significant impairment or distress. This disorder is manifested by specific criteria such as unsuccessful efforts to cut down or control use and use resulting in social problems and a failure to fulfill major role obligations at work, school, or home.”⁹¹

107. The 2016 CDC Guideline was not the first time a federal agency repudiated the Pharmaceutical Defendants’ claim that opioids improved function and quality of life. In 2010, the FDA warned Actavis that “[w]e are not aware of substantial evidence or substantial clinical experience demonstrating that the magnitude of the effect of the drug [Kadian] has in alleviating pain, taken together with any drug-related side effects patients may experience ... results in any overall positive impact on a patient’s work, physical and mental functioning, daily activities, or enjoyment of life.”⁹² In 2008, the FDA sent a warning letter to an opioid manufacturer, making it clear “that [the claim that] patients who are treated with the drug experience an improvement in their overall function, social function, and ability to perform daily activities ... has not been demonstrated by substantial evidence or substantial clinical experience.”^{93 94}

⁹⁰ Food and Drug Administration, *Response to Physicians for Responsible Opioid Prescribing Partial Petition Approval and Denial*; September 10, 2013. http://paindr.com/wp-content/uploads/2013/09/FDA_CDOR_Response_to_Physicians_for_Responsible_Opioid_Prescribing_Partial_Petition_Approval_and_Denial.pdf

⁹¹ <https://www.cdc.gov/mmwr/volumes/65/rr/rr6501e1.htm>

⁹² Letter from Thomas Abrams, Dir., Div. of Drug Mktg., Advert., & Commc’ns, U.S. Food & Drug Admin., to Doug Boothe, CEO, Actavis Elizabeth LLC (Feb. 18, 2010), <http://www.fdanews.com/ext/resources/files/archives/a/ActavisElizabethLLC.pdf>

⁹³ 21 C.F.R. § 202.1(e)(6)(ii).

⁹⁴ Letter from Thomas Abrams, Dir., FDA Div. of Mktg., Adver., & Commc’ns, to Brian A. Markison, Chairman, President and Chief Executive Officer, King Pharmaceuticals, Inc. (March 24, 2008).

108. The Pharmaceutical Defendants also falsely and misleadingly emphasized or exaggerated the risks of competing products like NSAIDs, so that doctors and patients would look to opioids first for the treatment of chronic pain. Once again, these misrepresentations by Defendants contravene pronouncements by and guidance from the FDA and CDC based on the scientific evidence. Indeed, the FDA changed the labels for ER/LA opioids in 2013 and IR opioids in 2016 to state that opioids should only be used as a last resort “in patients for which alternative treatment options” like non-opioid drugs “are inadequate.” The 2016 CDC Guideline states that NSAIDs, not opioids, should be the first-line treatment for chronic pain, particularly arthritis and lower back pain.⁹⁵

109. Purdue misleadingly promoted OxyContin as being unique among opioids in providing 12 continuous hours of pain relief with one dose. In fact, OxyContin does not last for 12 hours – a fact that Purdue has known at all relevant times. According to Purdue’s own research, OxyContin wears off in under six hours in one quarter of patients and in under 10 hours in more than half. This is because OxyContin tablets release approximately 40% of their active medicine immediately, after which release tapers. This triggers a powerful initial response, but provides little or no pain relief at the end of the dosing period, when less medicine is released. This phenomenon is known as “end of dose” failure, and the FDA found in 2008 that a “substantial number” of chronic pain patients taking OxyContin experience it. This not only renders Purdue’s promise of 12 hours of relief false and deceptive, it also makes OxyContin more dangerous because the declining pain relief patients experience toward the end of each dosing period drives them to take more OxyContin before the next dosing period begins, quickly increasing the amount of drug they are taking and spurring growing dependence.

⁹⁵ <https://www.cdc.gov/mmwr/volumes/65/rr/rr6501e1.htm>.

110. Purdue's competitors were aware of this problem. For example, Endo ran advertisements for Opana ER referring to "real" 12-hour dosing. In connection with an investigation of Endo by the New York Attorney General, an Endo sales representative testified to OAG that "she was trained to distinguish Opana ER from OxyContin by informing New York [Health Care Providers] that patients who take Opana ER only need to take it twice a day, whereas those who take OxyContin need to take it three times per day." The Attorney General's Assurance concludes: "This statement was not supported by any clinical evidence or study."⁹⁶ Nevertheless, Purdue falsely promoted OxyContin as if it were effective for a full 12 hours. Indeed, Purdue's sales representatives continued to tell doctors that OxyContin lasts a full 12 hours.

111. Cephalon deceptively marketed its opioids Actiq and Fentora for chronic pain even though the FDA has expressly limited their use to the treatment of cancer pain in opioid-tolerant individuals. Both Actiq and Fentora are extremely powerful fentanyl-based IR opioids. Neither is approved for or has been shown to be safe or effective for chronic pain. Indeed, the FDA expressly prohibited Cephalon from marketing Actiq for anything but cancer pain, and refused to approve Fentora for the treatment of chronic pain because of the potential harm, including the high risk of "serious and life-threatening adverse events" and abuse – which are greatest in non-cancer patients. The FDA also issued a Public Health Advisory in 2007 emphasizing that Fentora should only be used for cancer patients who are opioid-tolerant and should not be used for any other conditions, such as migraines, post-operative pain, or pain due to injury.⁹⁷ Actiq and Fentora have been approved by the 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

⁹⁶ *In the Matter of Endo Health Solutions Inc. and Endo Pharmaceuticals Inc.*, Assurance No.: 15-228, Attorney General of the State of New York, p. 9, ¶ 18.

⁹⁷ See U.S. Food & Drug Admin., *Public Health Advisory: Important Information for the Safe Use of Fentora (fentanyl buccal tablets)* (Sept. 26, 2007)

underlying persistent cancer pain.”⁹⁸ In September 2008, Cephalon pled guilty to a criminal violation of the Federal Food, Drug and Cosmetic Act for its misleading promotion of Actiq and two other drugs and agreed to pay criminal fines and monetary civil settlements totaling \$425 million.⁹⁹ The Press Release issued by the U.S. Department of Justice made the following comments:

Defendant Cephalon undertook its off-label promotional practices using a variety of techniques. It trained its sales force to disregard the restrictions of the FDA-approved label, and: to promote the drugs for off-label uses. For example, the Actiq label stated that the drug was for "opioid tolerant cancer patients with breakthrough cancer pain, to be prescribed by oncologist or pain specialists familiar with opioids." Using the mantra "pain is pain," Cephalon instructed the Actiq sales representatives to focus on physicians other than oncologists, including general practitioners, and to promote the drug for many uses other than breakthrough cancer pain. In the case of Gabitril, which had been approved for use for epilepsy, Cephalon told the sales force to visit not just neurologists, but also psychiatrists, and to promote the drug for anxiety and other psychiatric indications. Cephalon also structured its sales quota and bonuses in such a way that sales representatives could reach their sales goals only if they promoted and sold the drugs for off-label uses.

"These are potentially harmful drugs that *were being peddled as if they were, in the case of Actiq, actual lollipops* instead of a potent pain medication intended for a specific class of patients," said Magid. "This company subverted the very process put in place to protect the public from harm, and put patients' health at risk for nothing more than boosting its bottom line. People have an absolute right to their doctors' best medical judgement. They need to know the recommendations a doctor makes are not influenced by sales tactics designed to convince the doctor that the drug being prescribed is safe for uses beyond what the FDA has approved." (*emphasis supplied*)

112. Despite this, Cephalon conducted a well-funded campaign to promote Actiq and Fentora for chronic pain and other non-cancer conditions for which it was not approved, appropriate, or safe. As part of this campaign, Cephalon used CMEs, speaker programs, KOLs, journal supplements, and detailing by its sales representatives to give doctors the false impression

⁹⁸ US. Department of Justice Press Release dated September 29, 2008.

⁹⁹ *Id.*

that Actiq and Fentora are safe and effective for treating non-cancer pain. For example: (a) Cephalon paid to have a CME it sponsored, *Opioid-Based Management of Persistent and Breakthrough Pain*, published in a supplement of *Pain Medicine News* in 2009. The CME instructed doctors that “clinically, broad classification of pain syndromes as either cancer- or noncancer-related has limited utility” and recommended Actiq and Fentora for patients with chronic pain; (b) Cephalon’s sales representatives set up hundreds of speaker programs for doctors, including many non-oncologists, which promoted Actiq and Fentora for the treatment of non-cancer pain; and (c) in December 2011, Cephalon widely disseminated a journal supplement entitled “*Special Report: An Integrated Risk Evaluation and Mitigation Strategy for Fentanyl Buccal Tablet (FENTORA) and Oral Transmucosal Fentanyl Citrate (ACTIQ)*” to *Anesthesiology News*, *Clinical Oncology News*, and *Pain Medicine News* – three publications that are sent to thousands of anesthesiologists and other medical professionals. The Special Report openly promotes Fentora for “multiple causes of pain” – and not just cancer pain.

113. Cephalon’s deceptive marketing gave doctors and patients the false impression that Actiq and Fentora were not only safe and effective for treating chronic pain, but were also approved by the FDA for such uses.

114. Pharmaceutical Defendants’ deceptive marketing of the so-called abuse-deterrent properties of some of their opioids created false impressions that these opioids can curb addiction and abuse. Indeed, in a 2014 survey of 1,000 primary care physicians, nearly half reported that they believed abuse-deterrent formulations are inherently less addictive.

115. Pharmaceutical Defendants have made misleading claims about the ability of their so-called abuse-deterrent opioid formulations to deter abuse. For example, Endo’s advertisements for the 2012 reformulation of Opana ER falsely claimed that it was designed to be crush resistant,

in a way that suggested it was more difficult to abuse. The FDA warned in a 2013 letter that there was no evidence Endo's design "would provide a reduction in oral, intranasal or intravenous abuse." Moreover, Endo's own studies, which it failed to disclose, showed that Opana ER could still be ground and chewed.¹⁰⁰ Further, the FDA declared that Endo's "true interest in expedited FDA consideration stems from business concerns rather than protection of the public health".¹⁰¹

116. In a 2016 settlement with the State of New York, Endo agreed not to make statements in New York that Opana ER was "designed to be, or is crush resistant."¹⁰² The State found those statements false and deceptive because there was no difference in the ability to extract the narcotic from Opana ER. Similarly, the 2016 CDC Guideline states that "[n]o studies" support the notion that "abuse-deterrent technologies [are] a risk mitigation strategy for deterring or preventing abuse," noting that the technologies – even when they work – "do not prevent opioid abuse through oral intake, the most common route of opioid abuse, and can still be abused by non-oral routes."¹⁰³

2. The Pharmaceutical Defendants' Unlawful Failure to Prevent Diversion and Monitor, Report, and Prevent Suspicious Orders

117. The same legal duties to prevent diversion, and to monitor, report, and prevent suspicious orders of prescription opioids that were incumbent upon the Distributor Defendants were also legally required of the Pharmaceutical Defendants under federal and Louisiana law.

118. Under Louisiana and federal law, the Pharmaceutical Defendants were required to comply with the same licensing requirements as the Distributor Defendants and the same rules

¹⁰⁰ <https://www.npr.org/sections/health-shots/2016/04/01/472538272/how-a-painkiller-designed-to-deter-abuse-helped-spark-an-hiv-outbreak>

¹⁰¹ United States District Court for the District of Columbia; *Defendants' Response to the Court's November 30, 2012 Order*, Civil Action 12-1936 (RBW); Filed 12/03/12.

¹⁰² https://ag.ny.gov/pdfs/Endo_AOD_030116-Fully_Executed.pdf

¹⁰³ <https://www.cdc.gov/mmwr/volumes/65/rr/rr6501e1.htm>

regarding prevention of diversion and reporting suspicious orders, as set out above. See La. Rev. Stat. Ann. §§ 40:973(A); 40:974(A)(1) & (A)(4); 40:975; 40:967(A).

119. Like the Distributor Defendants, the Pharmaceutical Defendants were required to register with the DEA to manufacture schedule II controlled substances, such as prescription opioids. *See* 21 U.S.C. § 823(a). A requirement of such registration is the:

maintenance of effective controls against diversion of particular controlled substances and any controlled substance in schedule I or II compounded therefrom into other than legitimate medical, scientific, research, or industrial channels, by limiting the importation and bulk manufacture of such controlled substances to a number of establishments which can produce an adequate and uninterrupted supply of these substances under adequately competitive conditions for legitimate medical, scientific, research, and industrial purposes....

21 U.S.C. § 823(a)(1) (emphasis added).

120. Additionally, as “registrants” under Section 823, the Pharmaceutical Defendants were also required to monitor, report, and prevent suspicious orders of controlled substances, and to:

...design and operate a system to disclose to the registrant suspicious orders of controlled substances. The registrant shall inform the Field Division Office of the Administration in his area of suspicious orders when discovered by the registrant. Suspicious orders include orders of unusual size, orders deviating substantially from a normal pattern, and orders of unusual frequency.

21 C.F.R. § 1301.74. *See also* 21 C.F.R. § 1301.02 (“Any term used in this part shall have the definition set forth in section 102 of the Act (21 U.S.C. 802) or part 1300 of this chapter.”); 21 C.F.R. § 1300.01 (“Registrant means any person who is registered pursuant to either section 303 or section 1008 of the Act (21 U.S.C. 823 or 958).” Like the Distributor Defendants, the Pharmaceutical Defendants breached these duties.

121. The Pharmaceutical Defendants had access to and possession of the information necessary to monitor, report, and prevent suspicious orders and to prevent diversion. The Pharmaceutical Defendants engaged in the practice of paying “chargebacks” to opioid distributors.

A “chargeback” is a payment made by a manufacturer to a distributor after the distributor sells the manufacturer’s product at a price below a specified rate. After a distributor sells a manufacturer’s product to a pharmacy, for example, the distributor requests a chargeback from the manufacturer and, in exchange for the payment, the distributor identifies to the manufacturer the product, volume and the pharmacy to which it sold the product. Thus, the Pharmaceutical Defendants knew – just as the Distributor Defendants knew – the volume, frequency, and pattern of opioid orders being placed and filled. The Pharmaceutical Defendants built receipt of this information into the payment structure for the opioids provided to the opioid distributors.

122. Federal statutes and regulations – and Louisiana law incorporating those requirements – are clear: just like opioid distributors, opioid manufacturers are required to “design and operate a system to disclose ... suspicious orders of controlled substances” and to maintain “effective controls against diversion.” 21 C.F.R. § 1301.74; 21 U.S.C. § 823(a)(1). Some examples of the violation by the Pharmaceutical Defendants of this obligation are as follows:

123. Purdue unlawfully and unfairly failed to report or address illicit and unlawful prescribing of its drugs, despite knowing about it for years. Purdue’s sales representatives have maintained a database since 2002 of doctors suspected of inappropriately prescribing its drugs. Rather than report these doctors to state medical boards or law enforcement authorities (as Purdue is legally obligated to do) or cease marketing to them, Purdue used the list to demonstrate the high rate of diversion of OxyContin – the same OxyContin that Purdue had promoted as less addictive – in order to persuade the FDA to bar the manufacture and sale of generic copies of the drug because the drug was too likely to be abused. In an interview with the *Los Angeles Times*, Purdue’s senior compliance officer acknowledged that in five years of investigating suspicious pharmacies, Purdue failed to take action – even where Purdue employees personally witnessed the diversion of

its drugs. Despite its knowledge of illegal prescribing, Purdue did not report until years after law enforcement shut down a Los Angeles clinic that prescribed more than 1.1 million OxyContin tablets and that Purdue's district manager described internally as "an organized drug ring." In doing so, Purdue protected its own profits at the expense of public health and safety.¹⁰⁴

124. The State of New York's settlement with Purdue specifically cited the company for failing to "comply with New York's Internet System for Tracking Over-Prescribing/Prescription Monitoring Program (I-STOP/PMP)."¹⁰⁵ Yet, on information and belief, Purdue continues to profit from the prescriptions of such prolific prescribers.

125. Like Purdue, Endo has been cited for its failure to set up an effective system for identifying and reporting suspicious prescribing. Upon information and belief, in its settlement agreement with Endo, the State of New York found that Endo failed to require sales representatives to report signs of abuse, diversion, and inappropriate prescribing; paid bonuses to sales representatives for detailing prescribers who were subsequently arrested or convicted for illegal prescribing; and failed to prevent sales representatives from visiting prescribers whose suspicious conduct had caused them to be placed on a no-call list.¹⁰⁶

126. Mallinckrodt, one of the largest manufacturers of the generic opioid oxycodone, recently agreed to pay a \$35 million penalty to settle allegations by the U.S. Department of Justice that it failed to report suspicious drug orders. This is a record settlement of claims that a pharmaceutical drug manufacturer failed to meet its obligations to detect and notify the U.S. Drug Enforcement Administration of suspicious orders for controlled substances such as oxycodone.

¹⁰⁴ Harriet Ryan et al., *More Than 1 Million Oxycontin Pills Ended Up in the Hands of Criminals and Addicts. What the Drugmaker Knew*, L.A. Times, July 10, 2016, <http://www.latimes.com/projects/la-me-oxycontin-part2/>.

¹⁰⁵ In the Matter of Purdue Pharma L.P., Assurance No.: 15-151, Attorney General of the State of New York, p. 13.

¹⁰⁶ In the Matter of Endo Health Solutions Inc. and Endo Pharmaceuticals Inc., Assurance No.: 15-228, Attorney General of the State of New York, p 9.

U.S. Attorney General Jeff Sessions said that “Mallinckrodt’s actions and omissions formed a link in the chain of supply that resulted in millions of oxycodone pills being sold on the street.” According to the Justice Department, from 2008 to 2011, Mallinckrodt supplied distributors, and the distributors then supplied various U.S. pharmacies and pain clinics an increasingly excessive quantity of oxycodone pills without notifying the DEA of the suspicious orders.

127. In the Administrative Memorandum of Agreement between Mallinckrodt and the Department of Justice, Mallinckrodt acknowledged that “[a]s part of their business model Mallinckrodt collects transaction information, referred to as chargeback data, from their direct customers (distributors). The transaction information contains data relating to the direct customer sales of controlled substances to ‘downstream’ registrants.” Mallinckrodt agreed that, from this data, it would “report to the DEA when Mallinckrodt concludes that the chargeback data or other information indicates that a downstream registrant poses a risk of diversion.”¹⁰⁷

128. The same duties imposed by federal law on Mallinckrodt were imposed upon all Pharmaceutical Defendants.

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

130. Through, *inter alia*, the charge back data, the Pharmaceutical Defendants could monitor suspicious orders of opioids.

131. The Pharmaceutical Defendants failed to monitor, report, and halt suspicious orders of opioids as required by federal and state law.

¹⁰⁷ <https://www.justice.gov/usao-edmi/press-release/file/986026/download>

132. The Pharmaceutical Defendants' failures to monitor, report, and halt suspicious orders of opioids were intentional and unlawful.

133. The Pharmaceutical Defendants have misrepresented their compliance with federal and state law.

134. The Pharmaceutical Defendants enabled the supply of prescription opioids to obviously suspicious physicians and pharmacies, enabled the illegal diversion of opioids, aided criminal activity, and disseminated massive quantities of prescription opioids into the black market.

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

136. The Pharmaceutical Defendants' actions and omissions in failing to effectively prevent diversion and failing to monitor, report, and prevent suspicious orders have enabled the unlawful diversion of opioids into Plaintiff's Community.

3. The Pharmaceutical Defendants made and/or disseminated deceptive statements regarding material facts and further concealed material facts, in the course of manufacturing, marketing, and selling prescription opioids.

137. Moreover, at all times relevant to this Complaint, the Pharmaceutical Defendants took steps to avoid detection of and to conceal their deceptive marketing and unlawful, unfair, and fraudulent conduct. For example, the Pharmaceutical Defendants disguised their own role in the deceptive marketing of chronic opioid therapy by funding and working through putative independent third parties like Advocacy Groups and KOLs. These Defendants purposefully hid behind the assumed credibility of these individuals and organizations and relied on them to vouch

for the accuracy and integrity of Defendants' false and deceptive statements about the risks and benefits of long-term opioid use for chronic pain.

138. The Pharmaceutical Defendants also never disclosed their role in shaping, editing, and approving the content of information and materials disseminated by these third parties. These Defendants exerted considerable influence on these promotional and "educational" materials in emails, correspondence, and meetings with KOLs, putative independent groups, and public relations companies that were not, and have not yet fully become, public. For example, painknowledge.org, which is run by the NIPC, did not disclose Endo's involvement. Other Pharmaceutical Defendants, such as Purdue and Janssen, ran similar websites that masked their own direct role.

139. Finally, the Pharmaceutical Defendants manipulated their promotional materials and the scientific literature to make it appear that these items were accurate, truthful, and supported by objective evidence when they were not. These Defendants distorted the meaning or import of studies they cited and offered them as evidence for propositions the studies did not support. The lack of support for these Defendants' deceptive messages was not apparent to medical professionals who relied upon them in making treatment decisions.

140. Thus, the Pharmaceutical Defendants successfully concealed from the medical community, patients, and health care payors facts sufficient to arouse suspicion of the claims that Plaintiff now asserts. Plaintiff did not know of the existence or scope of Defendants' industry-wide fraud and could not have acquired such knowledge earlier through the exercise of reasonable diligence.

141. The Pharmaceutical Defendants' misrepresentations deceived doctors and patients about the risks and benefits of long-term opioid use. Studies also reveal that many doctors and

patients are not aware of or do not understand these risks and benefits. Indeed, patients often report that they were not warned they might become addicted to opioids prescribed to them. Upon information and belief, as reported in January 2016, a 2015 survey of more than 1,000 opioid patients found that 4 out of 10 were not told opioids were potentially addictive.

142. The Pharmaceutical Defendants' deceptive marketing scheme caused and continues to cause doctors in Louisiana, and specifically in Plaintiff's Community, to prescribe opioids for chronic pain conditions such as back pain, headaches, arthritis, and fibromyalgia. Absent these Defendants' deceptive marketing scheme, these doctors would not have prescribed as many opioids. These Defendants' deceptive marketing scheme also caused and continues to cause patients to purchase and use opioids for their chronic pain believing they are safe and effective. Absent these Defendants' deceptive marketing scheme, fewer patients would be using opioids long-term to treat chronic pain, and those patients using opioids would be using less of them.

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

144. The escalating number of opioid prescriptions written by doctors who were deceived by the Pharmaceutical Defendants' deceptive marketing scheme is the cause of a correspondingly dramatic increase in opioid addiction, overdose, and death throughout the U.S., Louisiana, and in the Plaintiff's Community. In August 2016, the U.S. Surgeon General published an open letter to be sent to physicians nationwide, enlisting their help in combating this "urgent health crisis" and linking that crisis to deceptive marketing. He wrote the following:

...Nearly two decades ago, we were encouraged to be more aggressive about treating pain, often without enough training and support to do so safely. This coincided with heavy marketing of opioids to doctors. Many of us were even taught – incorrectly – that opioids are not addictive when prescribed for legitimate pain....¹⁰⁸

145. Scientific evidence demonstrates a strong correlation between opioid prescriptions and opioid abuse. In a 2016 report, the CDC explained that “[o]pioid pain reliever prescribing has quadrupled since 1999 and has increased in parallel with [opioid] overdoses.” Patients receiving prescription opioids for chronic pain account for the majority of overdoses. For these reasons, the CDC concluded that efforts to rein in the prescribing of opioids for chronic pain are critical “to reverse the epidemic of opioid drug overdose deaths and prevent opioid-related morbidity.”

146. Contrary to the Pharmaceutical Defendants’ misrepresentations, most opioid addiction begins with legitimately *prescribed* opioids, and therefore could have been prevented had Defendants’ representations to prescribers been truthful. In 2008, the majority of non-medical users (55.9 percent) obtained these drugs from a friend or relative for free (of which, 81.7 of these friends or relatives received drugs from one doctor). About 18 percent of non-medical users received these drugs from only one doctor. Only 4.3 percent got pain relievers from a drug dealer or other stranger, and 0.4 percent bought them on the Internet.¹⁰⁹

147. As alleged herein, the Pharmaceutical Defendants made and/or disseminated deceptive statements regarding material facts and further concealed material facts, in the course of manufacturing, marketing, and selling prescription opioids. The Pharmaceutical Defendants’ actions were intentional and/or unlawful. Such statements include, but are not limited to, those set out below and alleged throughout this Complaint.¹¹⁰

¹⁰⁸ <https://turnthetiderx.org/#>

¹⁰⁹ <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3328297/>

148. The Pharmaceutical Defendants made and/or disseminated deceptive statements, and concealed material facts in such a way to make their statements deceptive, including, but not limited to, the following:

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

- k. Developing and disseminating scientific studies that deceptively concluded opioids are safe and effective for the long-term treatment of chronic non-cancer pain and that opioids improve quality of life, while concealing contrary data;
- l. Assisting in the dissemination of literature written by pro-opioid KOLs that contained deceptive statements concerning the use of opioids to treat chronic noncancer pain;
- m. Creating, endorsing, and supporting the distribution of patient and prescriber education materials that misrepresented the data regarding the safety and efficacy of opioids for the long-term treatment of chronic non-cancer pain, including known rates of abuse and addiction and the lack of validation for long-term efficacy;
- n. Targeting veterans by sponsoring and disseminating patient education marketing materials that contained deceptive statements concerning the use of opioids to treat chronic non-cancer pain;
- o. Targeting the elderly by assisting in the distribution of guidelines that contained deceptive statements concerning the use of opioids to treat chronic non-cancer pain and misrepresented the risks of opioid addiction in this population;
- p. Exclusively disseminating misleading statements in education materials to hospital doctors and staff while purportedly educating them on new pain standards;
- q. Making deceptive statements concerning the use of opioids to treat chronic noncancer pain to prescribers through in-person detailing; and
- r. Withholding from law enforcement the names of prescribers believed to be facilitating the diversion of its opioid, while simultaneously marketing opioids to these doctors by disseminating patient and prescriber education materials and advertisements and CMEs they knew would reach these same prescribers.
- s. Creating and disseminating paid advertisement supplements in academic journals promoting chronic opioid therapy as safe and effective for long term use for high risk patients;
- t. Directly distributing and assisting in the dissemination of literature written by pro-opioid KOLs that contained deceptive statements concerning the use of opioids to treat chronic non-cancer pain, including the concept of pseudoaddiction;
- u. Disseminating deceptive statements concealing the true risk of addiction and promoting the deceptive concept of pseudoaddiction through internet sites;

- v. Directly distributing and assisting in the dissemination of literature written by pro-opioid KOLs that contained deceptive statements concerning the use of opioids to treat chronic non-cancer pain, including the concept of pseudoaddiction;
- w. Sponsoring and assisting in the distribution of publications that promoted the deceptive concept of pseudoaddiction, even for high-risk patients;
- x. Endorsing and assisting in the distribution of CMEs containing deceptive statements concerning the use of its opioids;
- y. Directing its marketing of opioids to a wide range of doctors, including general practitioners, neurologists, sports medicine specialists, and workers' compensation programs, serving chronic pain patients;
- z. Making deceptive statements concerning the use of its opioids to treat chronic non-cancer pain to prescribers through speakers' bureau events; and
- aa. Creating and disseminating advertisements that concealed the risk of addiction in the long-term treatment of chronic, non-cancer pain.

C. DISTRIBUTOR DEFENDANTS' WRONGFUL CONDUCT

1. The Distributor Defendants' conduct fostered and/or promoted Opioid Diversion

149. The supply chain for prescription opioids begins with the manufacture and packaging of the pills. The manufacturers then transfer the pills to distribution companies, including Defendants Cardinal, McKesson, and AmerisourceBergen, which together account for 85-90 % of all revenues from drug distribution in the United States, an estimated \$378.4 billion in 2015. The distributors then supply opioids to pharmacies, doctors, and other healthcare providers, which then dispense the drugs to patients.

150. Pharmaceutical Defendants and Distributor Defendants share the responsibility for controlling the availability of prescription opioids. Opioid "diversion" occurs whenever the supply chain of prescription opioids is broken, and the drugs are transferred from a legitimate channel of distribution or use, to an illegitimate channel of distribution or use. Diversion can occur at any

point in the opioid supply chain, including at the pharmacy level when prescriptions are filled for any reason other than a legitimate medical purpose.

151. For example, at the wholesale level of distribution, diversion occurs whenever distributors allow opioids to be lost or stolen in transit, or when distributors fill suspicious orders of opioids from buyers, retailers, or prescribers. Suspicious orders include orders of unusually large size, orders that are disproportionately large in comparison to the population of a community served by the pharmacy, orders that deviate from a normal pattern, and/or orders of unusual frequency and duration.

152. Diversion occurs at the pharmacies, including whenever a pharmacist fills a prescription despite having reason to believe it was not issued for a legitimate medical purpose or not in the usual course of practice. Some of the signs that a prescription may have been issued for an illegitimate medical purpose include when the patient seeks to fill multiple prescriptions from different doctors (a/k/a doctor shopping), when they travel great distances between the doctor or their residence and the pharmacy to get the prescription filled, when they present multiple prescriptions for the largest dose of more than one controlled substance, or when there are other "red flags" surrounding the transaction. These signs or "red flags" should trigger closer scrutiny of the prescriptions by the pharmacy and lead to a decision that the patient is not seeking the medication for purposes to treat a legitimate medical condition. In addition to diversion via prescription, opioids are also diverted from retail outlets when stolen by employees or others.

153. Diversion also occurs through the use of stolen or forged prescriptions at pharmacies, or the sale of opioids without prescriptions, including patients seeking prescription opioids under false pretenses.

154. Opioid diversion occurs in the United States at an alarming rate. In recent years,

the number of people who take prescription opioids for non-medical purposes is greater than the combined number of people who use tranquilizers, stimulants and sedatives.¹¹¹

155. The dramatic rise in heroin use in recent years is a direct result of prescription opioid diversion. The strongest risk factor for a heroin use disorder is prescription opioid use. In one national study covering the period 2008 to 2010, 77.4% of the participants reported using prescription opioids before initiating heroin use. Another study revealed that 75% of those who began their opioid abuse in the 2000s started with prescription opioid. The CDC has reported that people who are dependent on prescription opioid painkillers are 40 times more likely to become dependent on heroin. Heroin deaths are on a tragic upswing: In 2015, over 12,989 people died from heroin overdose-up more than 20% from approximately 10,574 overdose deaths in 2014.¹¹²

156. Plaintiff uniquely and significantly has been damaged by the effects of the Distributor Defendants' opioid diversion.

157. Defendants' opioid diversion diminishes the available workforce in Plaintiff's Community, decreases productivity, increases poverty, and consequently requires greater expenditures by Plaintiff in law-enforcement and other public services due to the disproportionate presence of opioids in Plaintiff's Community.

158. Distributor Defendants have a duty to exercise reasonable care under the circumstances. This involves a duty not to create a foreseeable risk of harm to others. Additionally, one who engages in affirmative conduct, and thereafter realizes or should realize that such conduct has created an unreasonable risk of harm to another, is under a duty to exercise reasonable care to prevent the threatened harm.

¹¹¹ <https://www.samhsa.gov/data/sites/default/files/NSDUH-FFR2-2015/NSDUH-FFR2-2015.htm>

¹¹² Wilson M. Compton, M.D., M.P.E., Christopher M. Jones, Pharm.D., M.P.H., and Grant T. Baldwin, Ph.D., M.P.H., *Relationship between Nonmedical Prescription-Opioid Use and Heroin Use*; N. Engl J Med 2016 374:154-163, DOI: 10.1056/NEJMra1508490, January 14, 2016. <http://www.nejm.org/doi/full/10.1056/NEJMra1508490>.

159. The Distributor Defendants owe a duty under both federal law (21 U.S.C. § 823, 21 CFR 1301.74) and Louisiana law (see, *e.g.*, 46 La. Admin. Code Pt XCI, § 313) to monitor, detect, investigate, refuse to fill, and report suspicious orders of prescription opioids originating from Plaintiff's Community as well as those orders which the Distributor Defendants knew or should have known were likely to be diverted into Plaintiff's Community.

160. The foreseeable harm from a breach of these duties is the diversion of prescription opioids for nonmedical purposes.

161. Each Distributor Defendant repeatedly and purposefully breached its duties under state and federal law. Such breaches are a direct and proximate cause of the widespread diversion of prescription opioids for nonmedical purposes into Plaintiff's Community.

162. The unlawful diversion of prescription opioids is a direct and proximate cause and/or substantial contributing factor to the opioid epidemic, prescription opioid abuse, addiction, morbidity and mortality in the State and in Plaintiff's Community. This diversion and the epidemic are direct causes of harms for which Plaintiff seeks to recover here.

163. The Distributor Defendants intentionally continued their conduct, as alleged herein, with knowledge that such conduct was creating the opioid nuisance and causing the harms and damages alleged herein.

164. The Distributor Defendants are also governed by the statutory requirements of the Controlled Substances Act ("CSA"), 21 U.S.C. § 801 *et seq.* and its implementing regulations. These requirements were enacted to protect society from the harms of drug diversion. The Distributor Defendants' violations of these requirements show that they failed to meet the relevant standard of conduct that society expects from them. The Distributor Defendants' repeated, unabashed, and prolific violations of these requirements show that they have acted in total reckless

disregard.

165. As under federal law, opioids are a Schedule II controlled substance under Louisiana law. *See* La. Rev. Stat. Ann. § 40:964. Opioids are categorized as “Schedule II” drugs because they have a “high potential for abuse” and the potential to cause “severe psychic or physical dependence” and/or “severe psychological ... dependence.” 21 U.S.C. § 812(b)(2)(A)-(C); *see also* La. Rev. Stat. Ann. § 40:961(29.1) (“[p]hysical dependence is an expected result of opioid use.”).

166. The CSA creates a legal framework for the distribution and dispensing of controlled substances. Congress passed the CSA partly out of a concern about “the widespread diversion of [controlled substances] out of legitimate channels into the illegal market.” H.R. Rep. No. 91-1444, 1970 U.S.C.C.A.N. at 4566, 4572.

167. Accordingly, the CSA acts as a system of checks and balances from the manufacturing level through delivery of the pharmaceutical drug to the patient or ultimate user. Every person or entity that manufactures, distributes, or dispenses opioids must obtain a “registration” with the DEA.¹¹³ Registrants at every level of the supply chain must fulfill their obligations under the CSA, otherwise controlled substances move from the legal to the illicit marketplace, and there is enormous potential for harm to the public.

168. As “registrants” under the CSA, the Distributor Defendants had a duty and responsibility to maintain effective controls against diversion, including a requirement that it review and monitor sales, and report suspicious orders to the DEA. Suspicious orders include orders of unusual size, orders deviating substantially from the normal pattern, and orders of unusual frequency. To comply with these requirements, distributors must know their customers,

¹¹³ 21 U.S.C. 823 (b); 28 C.F.R. §0.100.

report suspicious orders, conduct due diligence, and terminate orders if there are indications of diversion.

169. Federal regulations impose a non-delegable duty upon wholesale drug distributors to “design and operate a system to disclose to the registrant suspicious orders of controlled substances. The registrant [distributor] shall inform the Field Division Office of the Administration in his area of suspicious orders when discovered by the registrant. State regulations require that wholesale distributors maintain procedures to review excessive or suspicious purchases. *La. Admin. Code Pt XCI, § 313*.

170. “Suspicious orders” include orders of an unusual size, orders of unusual frequency or orders deviating substantially from a normal pattern. *See 21 CFR 1301.74(b)*. 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 wholesale distributor need not wait for a normal pattern to develop over time before determining whether a particular order is suspicious. The size of an order alone, regardless of whether it deviates from a normal pattern, is enough to trigger the wholesale distributor’s responsibility to report the order as suspicious. The determination of whether an order is suspicious depends not only on the ordering patterns of the particular customer but also on the patterns of the entirety of the wholesale distributor’s customer base and the patterns throughout the relevant segment of the wholesale distributor industry.

171. In addition to reporting all suspicious orders, distributors must also stop shipment on any order which is flagged as suspicious and only ship orders which were flagged as potentially suspicious if, after conducting due diligence, the distributor can determine that the order is not likely to be diverted into illegal channels. *See Southwood Pharm., Inc.*, 72 Fed. Reg. 36,487,

36,501 (Drug Enf't Admin. July 3, 2007); *Masters Pharmaceutical, Inc. v. Drug Enforcement Administration*, No. 15-11355 (D.C. Cir. June 30, 2017). Regardless, all flagged orders must be reported. *Id.*

172. These prescription drugs are regulated for the purpose of providing a “closed” system intended to reduce the widespread diversion of these drugs out of legitimate channels into the illicit market, while at the same time providing the legitimate drug industry with a unified approach to narcotic and dangerous drug control.¹¹⁴

173. Different entities supervise the discrete links in the chain that separate a consumer from a controlled substance. Statutes and regulations define each participant’s role and responsibilities.¹¹⁵

174. To prevent unauthorized users from obtaining opioids, the CSA creates a distribution monitoring system for controlled substances, including registration and tracking requirements imposed upon anyone authorized to handle controlled substances. The DEA's Automation of Reports and Consolidation Orders System ("ARCOS") is an automated drug reporting system that records and monitors the flow of Schedule II controlled substances from point of manufacture through commercial distribution channels to point of sale. ARCOS accumulates data on distributors' controlled substances, acquisition transactions, and distribution

¹¹⁴ See 1970 U.S.C.C.A.N. 4566, 4571-72.

¹¹⁵ Brief for Healthcare Distribution Management Association and National Association of Chain Drug Stores as Amici Curiae in Support of Neither Party, *Masters Pharm., Inc. v. U.S. Drug Enf't Admin.* (No. 15-1335) (D.C. Cir. Apr. 4, 2016), 2016 WL 1321983, at *22 [hereinafter Brief for HDMA and NACDS]. The Healthcare Distribution Management Association (HDMA or HMA)—now known as the Healthcare Distribution Alliance (HDA)—is a national, not-for-profit trade association that represents the nation’s primary, full-service healthcare distributors whose membership includes, among others: AmerisourceBergen Drug Corporation, Cardinal Health, Inc., and McKesson Corporation. See generally HDA, *About*, <https://www.healthcaredistribution.org/about>. The National Association of Chain Drug Stores (NACDS) is a national, not-for-profit trade association that represents traditional drug stores and supermarkets and mass merchants with pharmacies whose membership includes, among others: Walgreen Company, CVS Health, Rite Aid Corporation and Walmart. See generally NACDS, *Mission*, <https://www.nacds.org/about/mission>.

transactions, which are then summarized into reports used by the DEA to identify any diversion of controlled substances into illicit channels of distribution. Each person or entity that is registered to distribute ARCOS Reportable controlled substances must report acquisition and distribution transactions to the DEA.¹¹⁶

175. Acquisition and distribution transaction reports must provide data on each acquisition to inventory (identifying whether it is, e.g., by purchase or transfer, return from a customer, or supply by the Federal Government) and each reduction from inventory (identifying whether it is, e.g., by sale or transfer, theft, destruction or seizure by Government agencies) for each ARCOS Reportable controlled substance. 21 U.S.C. § 827(d) (l); 21 C.F.R. §§ 1304.33(e), (d). Inventory that has been lost or stolen must also be reported separately to the DEA within one business day of discovery of such loss or theft.

176. In addition to filing acquisition/distribution transaction reports, each registrant is required to maintain a complete, accurate, and current record of each substance manufactured, imported, received, sold, delivered, exported, or otherwise disposed of. 21 U.S.C. §§ 827(a)(3), 1304.21(a), 1304.22(b). It is unlawful for any person to negligently fail to abide by the recordkeeping and reporting requirements.

177. To maintain registration, distributors must also maintain effective controls against diversion of controlled substances into other than legitimate medical, scientific and industrial channels. When determining if a distributor has provided effective controls, the DEA Administrator refers to the security requirements set forth in §§ 130 1.72-1301.76 as standards for the physical security controls and operating procedures necessary to prevent diversion. 21 CFR §

¹¹⁶ As of the date of the filing of this Complaint, Plaintiff has not been able to access the ARCOS database. Plaintiff reserves the right to seek leave to amend or correct this Complaint based upon analysis of the ARCOS, IMS Health, and other data and upon further investigation and discovery.

1301.71.

178. For years the Distributor Defendants have known of the problems and consequences of opioid diversion in the supply chain, and have committed repeated violations of the laws and regulations of the United States as cited above consequently making them liable under Louisiana law.

179. To combat the problem of opioid diversion, the DEA has provided guidance to distributors on the requirements of suspicious order reporting in numerous venues, publications, documents, and final agency actions. Since 2006, the DEA has conducted one-on-one briefings with distributors regarding their downstream customer sales, due diligence responsibilities, and legal and regulatory responsibilities (including the responsibility to know their customers and report suspicious orders to the DEA). The DEA provided distributors with data on controlled substance distribution patterns and trends, including data on the volume of orders, frequency of orders, and percentage of controlled vs. non-controlled purchases. The distributors were given case studies, legal findings against other registrants, and ARCOS profiles of their customers whose previous purchases may have reflected suspicious ordering patterns. The DEA emphasized the "red flags" distributors should look for to identify potential diversion.¹¹⁷

180. Since 2007, the DEA has hosted no less than five conferences to provide opioid distributors with updated information about diversion trends. The Defendant Distributors attended at least one of these conferences, which allowed for questions and discussions. The DEA has participated in numerous meetings and events with the Healthcare Distribution Management Association (HDMA), now known as the Healthcare Distribution Alliance (HDA), an industry trade association for wholesalers and distributors. DEA representatives have provided guidance to

¹¹⁷ <https://www.deadiversion.usdoj.gov/>

the association concerning suspicious order monitoring, and the association has published guidance documents for its members on suspicious order monitoring, reporting requirements, and the diversion of controlled substances.

181. On September 27, 2006 and December 27, 2007, the DEA Office of Diversion Control sent letters to all registered distributors providing guidance on suspicious order monitoring of controlled substances and the responsibilities and obligations of the registrant to conduct due diligence on controlled substance customers as part of a program to maintain effective controls against diversion.

182. The September 27, 2006 letter reminded registrants that they were required by law to exercise due diligence to avoid filling orders that could be diverted into the illicit market. The DEA explained that as part of the legal obligation to maintain effective controls against diversion, the distributor was required to exercise due care in confirming the legitimacy of each and every order prior to filling. It also described circumstances that could be indicative of diversion including ordering excessive quantities of a limited variety of controlled substances while ordering few if any other drugs; disproportionate ratio of ordering controlled substances versus non-controlled prescription drugs; the ordering of excessive quantities of a limited variety of controlled substances in combination with lifestyle drugs; and ordering the same controlled substance from multiple distributors. The letter went on to describe what questions should be answered by a customer when attempting to make a determination if the order is indeed suspicious. The letter emphasized that:

“‘[t]hese questions [were] not all inclusive’” and that “‘the answer to any of the questions’” would not “‘necessarily determine whether a suspicious order is indicative of diversion.’”¹¹⁸

Finally, the letter concluded by advising that “‘[d]istributors should consider the totality of

¹¹⁸ Federal Register, Vol. 80, No. 178, p. 55421.

the circumstances when evaluating an order for controlled substances.”¹¹⁹

183. On December 27, 2007, the Office of Diversion Control sent a follow-up letter to DEA registrants providing guidance and reinforcing the legal requirements outlined in the September 2006 correspondence. The letter reminded registrants that suspicious orders must be reported when discovered and monthly transaction reports of excessive purchases did not meet the regulatory criteria for suspicious order reporting.

The letter further explained that a registrant’s “responsibility does not end merely with the filing of a suspicious order report” and that a “[r]egistrant[] 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.” *Id.* Continuing, the letter warned that “[r]eporting 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.” *Id.* The letter thus advised that a registrant which “routinely report[s] suspicious orders, yet fill[s] these orders without first determining that [the] order[s] [are] not being diverted ... may be failing to maintain effective controls against diversion” and engaging in acts which are “inconsistent with the public interest.” *Id.* At 2.¹²⁰

184. The Distributor Defendants’ own industry group, the Healthcare Distribution Management Association, published Industry Compliance Guidelines titled “Reporting Suspicious Orders and Preventing Diversion of Controlled Substances,” emphasizing the critical role of each member of the supply chain in distributing controlled substances.¹²¹

185. These industry guidelines stated: “At the center of a sophisticated supply chain, distributors are uniquely situated to perform due diligence in order to help support the security of controlled substances they deliver to their customers.”

186. Opioid distributors have admitted to the magnitude of the problem and, at least superficially, their legal responsibilities to prevent diversion. They have made statements assuring

¹¹⁹ *Id.*

¹²⁰ *Id.*

¹²¹ https://www.dea.gov/divisions/mia/2013/mia061113_appendixb.pdf

the public they are supposedly undertaking a duty to curb the opioid epidemic.

187. For example, a Cardinal executive claimed that Cardinal uses “advanced analytics” to monitor its supply chain. He further extolled that Cardinal was being “as effective and efficient as possible in constantly monitoring, identifying, and eliminating any *outside* criminal activity.” (*emphasis added*).

188. McKesson has publicly stated that it has a “best-in-class controlled substance monitoring program to help identify suspicious orders” and claimed it is “deeply passionate about curbing the opioid epidemic in our Country.”

189. These assurances, on their face, of identifying and eliminating criminal activity and curbing the opioid epidemic create a duty for the Distributor Defendants to take reasonable measures to do just that.

190. In addition to the obligations imposed by law, through their own words, representations, and actions, the Distributor Defendants have voluntarily, yet disingenuously, undertaken a duty to protect the public at large against diversion from their supply chains, and to curb the opioid epidemic.

191. The Distributors Defendants have knowingly or negligently allowed diversion. Their wrongful conduct and inaction have resulted in numerous civil fines and other penalties recovered by state and federal agencies- including actions by the DEA related to violations of the Controlled Substances Act. The following illustrates their intentional and wanton misconduct:

192. In 2008, Cardinal paid a \$34 million penalty to settle allegations about opioid diversion taking place at seven of its warehouses in the United States. In 2012, Cardinal reached an administrative settlement with the DEA relating to opioid diversion between 2009 and 2012 in multiple states. In December 2016, a Department of Justice press release announced a multi-

million dollar settlement with Cardinal for violations of the Controlled Substances Act. Upon information and belief, in connection with the investigations of Cardinal, the DEA uncovered evidence that Cardinal's own investigator warned Cardinal against selling opioids to certain pharmacies.

193. In May 2008, McKesson entered into a settlement with the DEA on claims that McKesson failed to maintain effective controls against diversion of controlled substances. McKesson allegedly failed to report suspicious orders from illegal Internet pharmacies around the Country, resulting in *millions of doses* of controlled substances being diverted. McKesson agreed to pay a \$13.25 million civil fine. At the time of the settlement, the acting Administrator of the DEA stated the following:

By failing to report suspicious orders for controlled substances that it received from rogue Internet pharmacies, the McKesson Corporation fueled the explosive prescription drug abuse problem we have in this country.

After the settlement, McKesson was supposed to implement tougher controls regarding opioid diversion. McKesson utterly failed. Upon information and belief, McKesson's system for detecting "suspicious orders" from pharmacies was so ineffective and dysfunctional that at one of its facilities in Colorado between 2008 and 2013, it filled more than 1.6 million orders, for tens of millions of controlled substances, but it reported just 16 orders as suspicious, all from a single consumer. In 2015, McKesson was in the middle of allegations concerning its "suspicious order reporting practices for controlled substances." Pursuant to a January 2017 Settlement Agreement and Release, McKesson agreed to a settlement agreement with the United States of America in the amount of \$150,000,000.00 "...in settlement of claims or potential claims made by the United States of America for failing to report suspicious orders of controlled substances..." In the Settlement Agreement, McKesson acknowledged that during the period January 1, 2009 through

January 17, 2017 it “did not identify or report to [the] DEA certain orders placed by certain pharmacies which should have been detected by McKesson as suspicious based on the guidance contained in the DEA Letters...”¹²²

194. In 2007, the DEA suspended the license of AmerisourceBergen to distribute controlled substances from a distribution center amid allegations that its distribution center had not maintained effective controls against diversion of controlled substances, specifically hydrocodone, by retail internet pharmacies. Again in 2012, AmerisourceBergen was implicated for failing to protect against diversion of controlled substances into non-medically necessary channels. It has been reported that AmerisourceBergen paid \$16 million to the State of West Virginia to settle claims that it failed to report suspicious orders for controlled substances.¹²³ Cardinal Health paid \$20 Million.¹²⁴

195. On May 24, 2019, it was reported that Morris & Dickson Company, LLC reached an agreement to pay the United States \$22 million in civil penalties to resolve claims that it violated the Controlled Substances Act by failing to report suspicious orders of hydrocodone and oxycodone.¹²⁵

196. Relying upon state laws and regulation, various State Boards of Pharmacy have directly disciplined the wholesale distributors of prescription opioids for failure to prevent diversion, a duty recognized under state laws and regulations.

197. As wholesale drug distributors, each Defendant was required under Louisiana law to first be licensed by the Louisiana Board of Pharmacy. La. Rev. Stat. Ann. § 40:973(A). To

¹²² See Administrative Memorandum of Agreement between the U.S. Dep’t of Justice, the Drug Enf’t Admin., and the McKesson Corp. (Jan. 17, 2017), <https://www.justice.gov/opa/press-release/file/928476/download>.

¹²³ <http://www.policymed.com/2017/02/drug-wholesalers-to-pay-36-million-over-west-virginia-pill-mill-claims.html>

¹²⁴ *Id.*

¹²⁵ DEA Press Release; May 24, 2019 (<https://www.dea.gov/press-releases/2019/05/24/dea-and-us-attorney-western-district-louisiana-announce-settlement-drug-0>)(last accessed 5/28/2019)

receive and maintain this license, each of the Defendant Wholesale Distributors assumed a duty to comply with “applicable state and local laws and regulations.” La. Rev. Stat. Ann. § 40:974(A)(2). To receive a license under the Louisiana Drug and Device Distributors Act, Defendant Wholesale Distributors had to meet “all applicable requirements under federal law and regulation.” La. Rev. Stat. Ann. § 37:3469; *see also* La. Rev. Stat. Ann. §§ 37:3467; 37:3472 (“Failure to comply with state and federal laws or the board’s regulations shall be prima facie evidence of a violation of this Chapter and shall subject the applicant or licensee either to disciplinary action ... or forfeiture of the license.”); La. Admin. Code Pt XCI, § 711.

198. The Louisiana State Board of Pharmacy has the authority to suspend or revoke a license issued to Wholesale Distributors who violate the Louisiana Controlled Dangerous Substance Law or any “state or federal laws pertaining to the manufacture, distribution or dispensing of controlled dangerous substances.” *La. Rev. Stat. Ann. § 40:975*. Except as authorized, it is unlawful to knowingly or intentionally “manufacture, distribute, or dispense” Schedule II drugs. *La. Rev. Stat. Ann. § 40:967(A)*.

199. The Louisiana Board of Drug and Device Distributors also can “deny, revoke or suspend a license” for “violation of any federal, state or local law or regulation relating to drugs.” *46 La. Admin. Code Pt XCI, § 711*.

200. Each Distributor Defendant was further required to register with the DEA, pursuant to the federal Controlled Substance Act. *See 21 U.S.C. § 823(b), (e); 28 C.F.R. § 0.100*. Each Distributor Defendant is a “registrant” as a wholesale distributor in the chain of distribution of Schedule II controlled substances with a duty to comply with all security requirements imposed under that statutory scheme.

201. Each Distributor Defendant has an affirmative duty under federal and Louisiana

law to act as a gatekeeper guarding against the diversion of the highly addictive, dangerous opioid drugs. Federal law requires that Distributors of Schedule II drugs, including opioids, must 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)*. Louisiana law requires that drug distributors shall “adhere to written policies and procedures, which shall be followed for the receipt, security, storage, inventory, and distribution of drugs or devices, including policies and procedures for identifying, recording, and reporting losses or thefts,” including, procedures to review suspicious purchases and to notify the board in writing after discovering any theft or diversion of a drug. *46 La. Admin. Code Pt XCI, § 313*; *see also La. Rev. Stat. Ann. § 40:974(A)(1) & (A)(4)*.

202. Although distributors have been penalized by law enforcement authorities, these penalties have not changed their conduct. They pay fines as a cost of doing business in an industry that generates billions of dollars in revenue and profit.

203. The Distributor Defendants have the ability and owe the duty to prevent opioid diversion, which presented a known or foreseeable risk of damage to Plaintiff and Plaintiff’s Community.

204. The Distributor Defendants have supplied massive quantities of prescription opioids in and around the geographic areas served by Plaintiff with the actual or constructive knowledge that the opioids were ultimately being consumed by citizens for non-medical purposes. Many of these shipments should have been stopped or investigated as suspicious orders, but the Distributor Defendants negligently or intentionally failed to do so.

205. Each Distributor Defendant knew or should have known that the amount of the opioids that it allowed to flow into the Plaintiff’s Community was far in excess of what could be

consumed for medically necessary purposes in the relevant communities (especially given that each Distributor Defendant knew it was not the only opioid distributor servicing Plaintiff's Community).

206. The Distributor Defendants negligently or intentionally failed to adequately control their supply lines to prevent diversion. A reasonably-prudent distributor of Schedule II controlled substances would have anticipated the danger of opioid diversion and protected against it by, for example, taking greater care in hiring, training, and supervising employees; providing greater oversight, security, and control of supply channels; looking more closely at the pharmacists and doctors who were purchasing large quantities of commonly-abused opioids in amounts greater than the populations in those areas would warrant; investigating demographic or epidemiological facts concerning the increasing demand for narcotic painkillers in and around the Plaintiff's Community; providing information to pharmacies and retailers about opioid diversion; and in general, simply following applicable statutes, regulations, professional standards, and guidance from government agencies and using a little bit of common sense.

207. On information and belief, the compensation the Distributor Defendants provided to certain of their employees was affected, in part, by the volume of their sales of opioids to pharmacies and other facilities servicing the patients and hospitals in the Plaintiff's Community, thus improperly creating incentives that contributed to and exacerbated opioid diversion and the resulting epidemic of opioid abuse.

208. It was reasonably foreseeable to the Distributor Defendants that their conduct in flooding the consumer market of the Plaintiff's Community and flooding its clinics and treatment facilities with highly-addictive opioids would allow opioids to fall into the hands of children, addicts, criminals, and other unintended users.

209. It was reasonably foreseeable to the Distributor Defendants that, when unintended users gain access to opioids, tragic preventable injuries would result, including addiction, overdoses, and death. It was also reasonably foreseeable that Plaintiff, its members and their families would suffer damage and injury as a result.

210. The Distributor Defendants knew or should have known that the opioids being diverted from their supply chains would contribute to the opioid costs of Plaintiff, and would create access to opioids by unauthorized users, which, in turn, perpetuates the cycle of addiction, demand, illegal transactions, economic ruin, and human tragedy.

211. The Distributor Defendants knew or should have known that a substantial amount of the opioids dispensed to individuals who are members of the Plaintiff's Tribe. It is foreseeable that filling suspicious orders for opioids will cause harm to Plaintiff, its members and their families.

212. The Distributor Defendants were aware of widespread prescription opioid abuse in the Plaintiff's Community, but they nevertheless persisted in a pattern of distributing commonly abused and diverted opioids in Plaintiff's Community and in such quantities, and with such frequency- that they knew or should have known these commonly abused controlled substances were not being prescribed and consumed for legitimate medical purposes.

213. If any of the Distributor Defendants adhered to effective controls to guard against diversion, Plaintiff, its members, and their families would have avoided significant damages and injuries.

214. The Distributor Defendants made substantial profits over the years based on the diversion of opioids affecting Plaintiff. Their participation and cooperation in a common enterprise has foreseeably caused damages to Plaintiff. The Distributor Defendants knew full well that

Plaintiff would be unjustly forced to bear the costs of these injuries and damages.

215. The Distributor Defendants' intentional distribution of excessive amounts of prescription opioids to communities such as Plaintiff's Community and/or its surrounding areas showed an intentional or reckless disregard for Plaintiff, its members, and their families. Their conduct poses a continuing economic threat to Plaintiff, its members, and their families.

216. The Distributor Defendants admit that they "have not only statutory and regulatory responsibilities to detect and prevent diversion of controlled prescription drugs, but undertake such efforts as responsible members of society."¹²⁶

217. The Distributor Defendants knew they were required to monitor, detect, and halt suspicious orders. Industry compliance guidelines established by the Healthcare Distribution Management Association, the trade association of pharmaceutical distributors, explain that distributors are "[a]t the center of a sophisticated supply chain" and therefore "are uniquely situated to perform due diligence in order to help support the security of the controlled substances they deliver to their customers." The guidelines set forth recommended steps in the "due diligence" process, and note in particular: If an order meets or exceeds a distributor's threshold, as defined in the distributor's monitoring system, or is otherwise characterized by the distributor as an order of interest, the distributor should not ship to the customer, in fulfillment of that order, any units of the specific drug code product as to which the order met or exceeded a threshold or as to which the order was otherwise characterized as an order of interest.¹²⁷

218. Each of the Distributor Defendants sold prescription opioids, including hydrocodone and/or oxycodone, to retailers in Plaintiff's Community and/or to retailers from

¹²⁶ See Brief of HDMA, 2012 WL 1637016, at *2.

¹²⁷ Healthcare Distribution Management Association (HDMA) Industry Compliance Guidelines: Reporting Suspicious Orders and Preventing Diversion of Controlled Substances, filed in *Cardinal Health, Inc. v. Holder*, No. 12-5061 (D.C. Cir. Mar. 7, 2012), Doc. No. 1362415 (App'x B).

which Defendants knew prescription opioids were likely to be diverted to Plaintiff's Community.

219. Each Distributor Defendant owes a duty to monitor and detect suspicious orders of prescription opioids.

220. Each Distributor Defendant owes a duty under federal and state law to investigate and refuse suspicious orders of prescription opioids.

221. Each Distributor Defendant owes a duty under federal and state law to report suspicious orders of prescription opioids.

222. Each Distributor Defendant owes a duty under federal and state law to prevent the diversion of prescription opioids into illicit markets in the State and Plaintiff's Community.

223. The foreseeable harm resulting from a breach of these duties is the diversion of prescription opioids for nonmedical purposes and subsequent plague of opioid addiction.

224. The foreseeable harm resulting from the diversion of prescription opioids for nonmedical purposes is abuse, addiction, morbidity and mortality in Plaintiff's Community and the damages caused thereby.

2. The Distributor Defendants Breached Their Duties.

225. Because distributors handle such large volumes of controlled substances, and are the first major line of defense in the movement of legal pharmaceutical controlled substances from legitimate channels into the illicit market, it is incumbent on distributors to maintain effective controls to prevent diversion of controlled substances. Should a distributor deviate from these checks and balances, the closed system collapses.¹²⁸

226. The sheer volume of prescription opioids distributed to pharmacies in the Plaintiff's Community, and/or to pharmacies from which the Distributor Defendants knew the opioids were

¹²⁸ See Rannazzisi Decl. ¶ 10, filed in *Cardinal Health, Inc. v. Holder*, No. 1:12-cv-00185-RBW (D.D.C. Feb. 10, 2012), ECF No. 14-2.

likely to be diverted into Plaintiff's Community, is excessive for the medical need of the community and suspicious. Some red flags are so obvious that no one who engages in the legitimate distribution of controlled substances can reasonably claim ignorance of them.¹²⁹

227. Upon information and belief, the Distributor Defendants failed to report "suspicious orders" originating from Plaintiff's Community, or which the Distributor Defendants knew were likely to be diverted to Plaintiff's Community, to the federal and state authorities, including the DEA and/or the state Board of Pharmacy.

228. Upon information and belief, the Distributor Defendants unlawfully filled suspicious orders of unusual size, orders deviating substantially from a normal pattern and/or orders of unusual frequency in Plaintiff's Community, and/or in areas from which the Distributor Defendants knew opioids were likely to be diverted to Plaintiff's Community and thus cause damage to Plaintiff, its members, and their families.

229. The Distributor Defendants breached their duty to monitor, detect, investigate, refuse and report suspicious orders of prescription opiates originating from Plaintiff's Community, and/or in areas from which the Distributor Defendants knew opioids were likely to be diverted to Plaintiff's Community.

230. The Distributor Defendants breached their duty to maintain effective controls against diversion of prescription opiates into other than legitimate medical, scientific, and industrial channels.

231. The Distributor Defendants breached their duty to "design and operate a system to disclose to the registrant suspicious orders of controlled substances" and failed to inform the authorities including the DEA of suspicious orders when discovered, in violation of their duties

¹²⁹ *Masters Pharmaceuticals, Inc.*, 80 Fed. Reg. 55,418-01, 55,482 (Sept. 15, 2015) (citing *Holiday CVS, L.L.C., d/b/a CVS/Pharmacy Nos. 219 and 5195*, 77 Fed. Reg. 62,316, 62,322 (2012)).

under federal and state law.

232. The Distributor Defendants breached their duty to exercise due diligence to avoid filling suspicious orders that might be diverted into channels other than legitimate medical, scientific and industrial channels.¹³⁰

233. The federal and state laws at issue here are public safety laws.

234. The Distributor Defendants' violations of public safety statutes constitute prima facie evidence of negligence under State law.

235. The Distributor Defendants supplied prescription opioids to obviously suspicious physicians and pharmacies, enabled the illegal diversion of opioids, aided criminal activity, and disseminated massive quantities of prescription opioids into the black market.

236. The unlawful conduct by the Distributor Defendants is purposeful and intentional. The Distributor Defendants refuse to abide by the duties imposed by federal and state law which are required to legally acquire and maintain a license to distribute prescription opiates.

237. The Distributor 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.

238. The Distributor Defendants' repeated shipments of suspicious orders, over an extended period of time, in violation of public safety statutes, and without reporting the suspicious orders to the relevant authorities demonstrates wanton, willful, or reckless conduct or criminal indifference to civil obligations affecting the rights of others.

3. The Distributor Defendants Have Sought to Avoid and Have Misrepresented Their Purported Compliance with Their Legal Duties.

239. The Distributor Defendants have repeatedly misrepresented their compliance with

¹³⁰ See *Cardinal Health, Inc. v. Holder*, 846 F. Supp. 2d 203, 206 (D.D.C. 2012).

their legal duties under state and federal law and have wrongfully and repeatedly disavowed those duties in an effort to mislead regulators and the public regarding the Distributor Defendants' compliance with their legal duties.

240. Distributor Defendants have refused to recognize any duty beyond *reporting* suspicious orders. In *Masters Pharmaceuticals*, the HDMA, a trade association run by the Distributor Defendants, and the NACDS submitted amicus briefs regarding the legal duty of wholesale distributors. Inaccurately denying the legal duties that the wholesale drug industry has been tragically recalcitrant in performing, they argued as follows:

- a. The Associations complained that the “DEA has required distributors not only to report suspicious orders, but to *investigate* orders (e.g., by interrogating pharmacies and physicians) and take action to *halt* suspicious orders before they are filled.”¹³¹
- b. The Associations argued that, “DEA now appears to have changed its position to require that distributors not only *report* suspicious orders, but *investigate* and *halt* suspicious orders. Such a change in agency position must be accompanied by an acknowledgment of the change and a reasoned explanation for it. In other words, an agency must display awareness that it *is* changing position and show that there are good reasons for the new policy. This is especially important here, because imposing intrusive obligations on distributors threatens to disrupt patient access to needed prescription medications.”¹³²
- c. The Associations alleged (inaccurately) that nothing “requires distributors to investigate the legitimacy of orders, or to halt shipment of any orders deemed to be suspicious.”¹³³
- d. The Association complained that the purported “practical infeasibility of requiring distributors to investigate and halt suspicious orders (as well as report them) underscores the importance of ensuring that DEA has complied with the APA before attempting to impose such duties.”¹³⁴
- e. The Associations alleged (inaccurately) that “DEA’s regulations sensibly impose a duty on distributors simply to *report* suspicious orders, but left it to

¹³¹ Brief for HDMA and NACDS, 2016 WL 1321983, at *4–5.

¹³² *Id.* at *8 (citations and quotation marks omitted).

¹³³ *Id.* at *14.

¹³⁴ *Id.* at *22.

DEA and its agents to investigate and halt suspicious orders.”¹³⁵

- f. Also inaccurately, the Associations argued that, “[i]mposing a duty on distributors – which lack the patient information and the necessary medical expertise – to investigate and halt orders may force distributors to take a shot-in-the-dark approach to complying with DEA’s demands.”¹³⁶

241. The positions taken by the trade groups is emblematic of the position taken by the Distributor Defendants in an attempt to deny their legal obligations to prevent diversion of the dangerous drugs.¹³⁷

242. The Court of Appeals for the District of Columbia recently issued its opinion affirming that a wholesale drug distributor does, in fact, have duties beyond reporting. *Masters Pharm., Inc. v. Drug Enf’t Admin.*, 861 F.3d 206 (D.C. Cir. 2017). The D.C. Circuit Court upheld the revocation of Master Pharmaceutical’s license and determined that DEA regulations require that in addition to reporting suspicious orders, distributors must “decline to ship the order, or conduct some ‘due diligence’ and—if it is able to determine that the order is not likely to be diverted into illegal channels—ship the order.” *Id.* at 212. Master Pharmaceutical was in violation of legal requirements because it failed to conduct necessary investigations and filled suspicious orders. *Id.* at 218–19, 226. A distributor’s investigation must dispel all the red flags giving rise to suspicious circumstances prior to shipping a suspicious order. *Id.* at 226. The Circuit Court also rejected the argument made by the HDMA and NACDS (quoted above), that, allegedly, the DEA had created or imposed new duties. *Id.* at 220.

243. Because of the Distributor Defendants’ refusal to abide by their legal obligations, the DEA has repeatedly taken administrative action to attempt to force compliance. For example,

¹³⁵ *Id.* at *24–25.

¹³⁶ *Id.* at *26.

¹³⁷ See Brief of HDMA, 2012 WL 1637016, at *3 (arguing the wholesale distributor industry “does not know the rules of the road because” they claim (inaccurately) that the “DEA has not adequately explained them”).

in May 2014, the United States Department of Justice, Office of the Inspector General, Evaluation and Inspections Divisions, reported that the DEA issued final decisions in 178 registrant actions between 2008 and 2012.¹³⁸ Upon information and belief, the Office of Administrative Law Judges issued a recommended decision in a total of 117 registrant actions before the DEA issued its final decision, including 76 actions involving orders to show cause and 41 actions involving immediate suspension orders.¹³⁹ These actions include the following:

- a. On April 24, 2007, the DEA issued an *Order to Show Cause and Immediate Suspension Order* against the AmerisourceBergen Orlando, Florida distribution center (“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 the Cardinal Health Auburn, Washington Distribution Center (“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 the Cardinal Health Lakeland, Florida Distribution Center (“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 the Cardinal Health Swedesboro, New Jersey Distribution Center (“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 Stafford, Texas Distribution Center (“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

¹³⁸ Evaluation and Inspections Div., Office of the Inspector Gen., U.S. Dep’t of Justice, *The Drug Enforcement Administration’s Adjudication of Registrant Actions* 6 (2014), <https://oig.justice.gov/reports/2014/e1403.pdf>.

¹³⁹ *Id.*

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

244. Rather than abide by their non-delegable duties under public safety laws, the Distributor Defendants, individually and collectively through trade groups in the industry, pressured the U.S. Department of Justice to “halt” prosecutions and lobbied Congress to strip the DEA of its ability to immediately suspend distributor registrations. The result was a “sharp drop in enforcement actions” and the passage of the “Ensuring Patient Access and Effective Drug Enforcement Act” which, ironically, raised the burden for the DEA to revoke a distributor’s license from “imminent harm” to “immediate harm” and provided the industry the right to “cure” any

violations of law before a suspension order can be issued.¹⁴⁰

245. In addition to taking actions to limit regulatory prosecutions and suspensions, the Distributor Defendants undertook to fraudulently convince the public that they were complying with their legal obligations, including those imposed by licensing regulations. Through such statements, the Distributor Defendants attempted to assure the public they were working to curb the opioid epidemic.

246. For example, a Cardinal Health executive claimed that it uses “advanced analytics” to monitor its supply chain, and represented that it was being “as effective and efficient as possible in constantly monitoring, identifying, and eliminating any outside criminal activity.”¹⁴¹ Given the sales volumes and the company’s history of violations, this executive was either not telling the truth, or, if Cardinal Health had such a system, it ignored the results.

247. Similarly, Defendant McKesson publicly stated that it has a “best-in-class controlled substance monitoring program to help identify suspicious orders,” and claimed it is “deeply passionate about curbing the opioid epidemic in our country.”¹⁴² Again, given McKesson’s historical conduct, this statement is either false, or the company ignored outputs of the monitoring program.

¹⁴⁰ See Lenny Bernstein & Scott Higham, *Investigation: The DEA Slowed Enforcement While the Opioid Epidemic Grew Out of Control*, Wash. Post, Oct. 22, 2016, https://www.washingtonpost.com/investigations/the-dea-slowed-enforcement-while-the-opioid-epidemic-grew-out-of-control/2016/10/22/aea2bf8e-7f71-11e6-8d13-d7c704ef9fd9_story.html; Lenny Bernstein & Scott Higham, *Investigation: U.S. Senator Calls for Investigation of DEA Enforcement Slowdown Amid Opioid Crisis*, Wash. Post, Mar. 6, 2017, https://www.washingtonpost.com/investigations/us-senator-calls-for-investigation-of-dea-enforcement-slowdown/2017/03/06/5846ee60-028b-11e7-b1e9-a05d3c21f7cf_story.html; Eric Eyre, *DEA Agent: “We Had No Leadership” in WV Amid Flood of Pain Pills*, Charleston Gazette-Mail, Feb. 18, 2017, <http://www.wvgazettemail.com/news/20170218/dea-agent-we-had-no-leadership-in-wv-amid-flood-of-pain-pills->.

¹⁴¹ Lenny Bernstein et al., *How Drugs Intended for Patients Ended Up in the Hands of Illegal Users: “No One Was Doing Their Job,”* Wash. Post, Oct. 22, 2016, https://www.washingtonpost.com/investigations/how-drugs-intended-for-patients-ended-up-in-the-hands-of-illegal-users-no-one-was-doing-their-job/2016/10/22/10e79396-30a7-11e6-8ff7-7b6c1998b7a0_story.html.

¹⁴² Scott Higham et al., *Drug Industry Hired Dozens of Officials from the DEA as the Agency Tried to Curb Opioid Abuse*, Wash. Post, Dec. 22, 2016, https://www.washingtonpost.com/investigations/key-officials-switch-sides-from-dea-to-pharmaceutical-industry/2016/12/22/55d2e938-c07b-11e6-b527-949c5893595e_story.html.

248. By misleading the public about the effectiveness of their controlled substance monitoring programs, the Distributor Defendants successfully concealed the facts sufficient to arouse suspicion of the claims that the Plaintiff now asserts. The Plaintiff did not know of the existence or scope of Defendants' industry-wide fraud and could not have acquired such knowledge earlier through the exercise of reasonable diligence.

249. Meanwhile, the opioid epidemic rages unabated in the Nation, the State, and in Plaintiff's Community, where it continues to damage the Plaintiffs, its members, and their families.

250. The epidemic still rages because the fines and suspensions imposed by the DEA do not change the conduct of the industry. The distributors, including the Distributor Defendants, pay fines as a cost of doing business in an industry that generates billions of dollars in annual revenue. They hold multiple DEA registration numbers and when one facility is suspended, they simply ship from another facility.

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

252. The Distributor Defendants have abandoned their duties imposed under federal and state law, taken advantage of a lack of DEA law enforcement, and abused the privilege of distributing controlled substances in the State and Plaintiff's Community, thus causing damage to Plaintiffs, its members, and their families.

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

253. As the Pharmaceutical Defendants' efforts to expand the market for opioids increased so have the rates of prescription and sale of their products — and the rates of opioid-

related substance abuse, hospitalization, and death among the people of the State and the Plaintiff's Community. The Distributor Defendants have continued to unlawfully ship these massive quantities of opioids into communities like the Plaintiff's Community, fueling the epidemic.

254. There is a "parallel relationship between the availability of prescription opioid analgesics through legitimate pharmacy channels and the diversion and abuse of these drugs and associated adverse outcomes."¹⁴³

255. Opioid analgesics are widely diverted and improperly used, and the widespread use of the drugs has resulted in a national epidemic of opioid overdose deaths and addictions.¹⁴⁴

256. The epidemic is "directly related to the increasingly widespread misuse of powerful opioid pain medications."¹⁴⁵

257. The increased abuse of prescription painkillers along with growing sales has contributed to a large number of overdoses and deaths.¹⁴⁶

258. As shown above, the opioid epidemic has escalated in Plaintiff's Community with devastating effects. Substantial opiate-related substance abuse, hospitalization and death mirrors Defendants' increased distribution of opiates.

259. Because of the well-established relationship between the use of prescription opiates and the use of non-prescription opioids, like heroin, the massive distribution of opioids to Plaintiffs' Community and areas from which such opioids are being diverted into Plaintiff's Community, has caused the Defendant-caused opioid epidemic to include heroin addiction, abuse,

¹⁴³ See Richard C. Dart et al., *Trends in Opioid Analgesic Abuse and Mortality in the United States*, 372 N. Eng. J. Med. 241 (2015).

¹⁴⁴ See Nora D. Volkow & A. Thomas McLellan, *Opioid Abuse in Chronic Pain—Misconceptions and Mitigation Strategies*, 374 N. Eng. J. Med. 1253 (2016).

¹⁴⁵ See Robert M. Califf et al., *A Proactive Response to Prescription Opioid Abuse*, 374 N. Eng. J. Med. 1480 (2016).

¹⁴⁶ See Press Release, Ctrs. for Disease Control and Prevention, U.S. Dep't of Health and Human Servs., Prescription Painkiller Overdoses at Epidemic Levels (Nov. 1, 2011), https://www.cdc.gov/media/releases/2011/p1101_flu_pain_killer_overdose.html.

and death.

260. Prescription opioid abuse, addiction, morbidity, and mortality are hazards to public health and safety in the State and in Plaintiff's Community, and thus to Plaintiff, its members, and their families.

261. Heroin abuse, addiction, morbidity, and mortality are hazards to public health and safety in the State and in Plaintiff's Community.

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

263. The unlawful diversion of prescription opioids is a direct and proximate cause of, and/or substantial factor leading to, the opioid epidemic, prescription opioid abuse, addiction, morbidity and mortality in the State and in Plaintiff's Community. This diversion and the epidemic are direct causes of foreseeable harms incurred by the Plaintiff, its members, and their families.

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

265. Plaintiff seeks economic damages from the Defendants as reimbursement for the costs associated with past efforts to eliminate the hazards to public health and safety.

266. Plaintiff seeks economic damages from the Defendants to pay for the cost to permanently eliminate the hazards to public health and safety and abate the temporary public nuisance.

267. To eliminate the hazard to public health and safety, and abate the public nuisance, a “multifaceted, collaborative public health and law enforcement approach is urgently needed.”¹⁴⁷

268. A comprehensive response to this crisis must focus on preventing new cases of opioid addiction, identifying early opioid-addicted individuals, and ensuring access to effective opioid addiction treatment while safely meeting the needs of patients experiencing pain.¹⁴⁸

269. These community-based problems require community-based solutions that have been limited by “budgetary constraints at the state and Federal levels.”¹⁴⁹

270. Having profited enormously through the aggressive sale, misleading promotion, and irresponsible distribution of opiates, Defendants should be required to take responsibility for the financial burdens their conduct has inflicted upon the Plaintiff and Plaintiff’s Community, including its members, and their families.

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

1. Continuing Conduct.

271. Plaintiff contends that it, its members and their families continue to suffer harm from the unlawful actions by the Defendants.

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

¹⁴⁷ See Rose A. Rudd et al., *Increases in Drug and Opioid Overdose Deaths—United States, 2000–2014*, 64 Morbidity & Mortality Wkly. Rep. 1378 (2016), at 1145.

¹⁴⁸ See Johns Hopkins Bloomberg School of Public Health, *The Prescription Opioid Epidemic: An Evidence-Based Approach* (G. Caleb Alexander et al. eds., 2015), http://www.jhsph.edu/research/centers-and-institutes/center-for-drug-safety-and-effectiveness/research/prescription-opioids/JHSPH_OPIOID_EPIDEMIC_REPORT.pdf.

¹⁴⁹ See Office of Nat’l Drug Control Policy, Exec. Office of the President, *Epidemic: Responding to America’s Prescription Drug Abuse Crisis* (2011), https://www.ncjrs.gov/pdffiles1/ondcp/rx_abuse_plan.pdf.

The public nuisance remains unabated. The conduct causing the damages remains unabated.

2. Equitable Estoppel and Fraudulent Concealment.

273. Defendants are equitably estopped from relying upon a statute of limitations defense because they undertook active efforts to deceive Plaintiff, its members and their families and/or doctors and patients in Plaintiff's Community and to purposefully conceal their unlawful conduct and fraudulently assure the public, including the State, the Plaintiff and its members and their families, that they were undertaking efforts to comply with their obligations under the state and federal controlled substances laws, all with the goal of protecting their registered manufacturer or distributor status in the State and to continue generating profits. Notwithstanding the allegations set forth above, the Defendants affirmatively assured the public, including the State, the Plaintiff and its members and their families, that they were working to curb the opioid epidemic.

274. For example, a Cardinal Health executive claimed that it uses "advanced analytics" to monitor its supply chain, and assured the public it was being "as effective and efficient as possible in constantly monitoring, identifying, and eliminating any outside criminal activity."¹⁵⁰

275. Moreover, in furtherance of their effort to affirmatively conceal their conduct and avoid detection, the Distributor Defendants, through HDMA and NACDS, filed an amicus brief in *Masters Pharmaceuticals*, which made the following statements:¹⁵¹

- a. "HDMA and NACDS members not only have statutory and regulatory responsibilities to guard against diversion of controlled prescription drugs, but undertake such efforts as responsible members of society."
- b. "DEA regulations that have been in place for more than 40 years require distributors to report suspicious orders of controlled substances to DEA based on information readily available to them (e.g., a pharmacy's placement of unusually frequent or large orders)."
- c. "Distributors take seriously their duty to report suspicious orders,

¹⁵⁰ Bernstein et al., *supra*.

¹⁵¹ Brief for HDMA and NACDS, 2016 WL 1321983, at *3-4, *25.

utilizing both computer algorithms and human review to detect suspicious orders based on the generalized information that is available to them in the ordering process.”

- d. “A particular order or series of orders can raise red flags because of its unusual size, frequency, or departure from typical patterns with a given pharmacy.”
- e. “Distributors also monitor for and report abnormal behavior by pharmacies placing orders, such as refusing to provide business contact information or insisting on paying in cash.”

276. Through the above statements made on their behalf by their trade associations, and other similar statements assuring their continued compliance with their legal obligations, the Distributor Defendants not only acknowledged that they understood their obligations under the law, but they further affirmed that their conduct was in compliance with those obligations.

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

278. Defendants also concealed from Plaintiff the existence of Plaintiff’s claims by hiding their lack of cooperation with law enforcement and affirmatively seeking to convince the

public that their legal duties to report suspicious sales had been satisfied through public assurances that they were working to curb the opioid epidemic. They publicly portrayed themselves as committed to working diligently with law enforcement and others to prevent diversion of these dangerous drugs and curb the opioid epidemic, and they made broad promises to change their ways insisting they were good corporate citizens. These repeated misrepresentations misled regulators, prescribers and the public, including Plaintiff, and deprived Plaintiff of actual or implied knowledge of facts sufficient to put Plaintiff on notice of potential claims.

279. The Defendants have also concealed and prevented discovery of information, including data from the ARCOS database that will confirm their identities and the extent of their wrongful and illegal activities. (See *supra*, footnote 108).

280. Defendants intended that their actions and omissions would be relied upon, including by Plaintiff and its members and their families. Plaintiff and Plaintiff's members and their families did not know, and did not have the means to know, the truth due to Defendants' actions and omissions.

281. The Plaintiff and its members and their families reasonably relied on Defendants' affirmative statements regarding their purported compliance with their obligations under the law and consent orders.

282. The Plaintiff's claims are further subject to equitable tolling, stemming from Defendants knowingly and fraudulently concealing the facts alleged herein. As alleged herein, Defendants knew of the wrongful acts set forth above, and had material information pertinent to their discovery, and concealed them from the Plaintiff and its members and their families. As a result of Defendants' continuing wrongful conduct, Plaintiff and its members and their families did not know the nature, scope and magnitude of Defendants' misconduct, and its full impact on

Plaintiff and its members and their families; nor could Plaintiff nor its members and their families have acquired such knowledge through the exercise of reasonable diligence.

283. Under the Louisiana doctrine of *contra non valentem agere nulla currit praescriptio*, the prescriptive period, i.e. the statute of limitations, does not run on the any causes of action asserted herein because Defendants have concealed information and misled the Plaintiff and Plaintiff's Community. Defendants are estopped from asserting any statute of limitations or prescriptive period as a defense because they intentionally concealed facts and engaged in fraudulent practices that prevented Plaintiff from discovering their wrongful conduct.

284. In light of their statements to the media, in legal filings, and in settlements, it is clear that Defendants had actual or constructive knowledge that their conduct was deceptive, in that they consciously concealed the schemes set forth herein.

285. Defendants continually and secretly engaged in their scheme to avoid compliance with their legal obligations. Only Defendants and their agents knew, or could have known, about Defendants' unlawful actions because Defendants made deliberate efforts to conceal their conduct. As a result of the above, the Plaintiff was unable to obtain vital information bearing on its claims absent any fault or lack of diligence on its part.

IV. LEGAL CAUSES OF ACTION

COUNT I PUBLIC NUISANCE (Against all Defendants)

286. The allegations set forth in this Complaint establish the liability of the Defendants unto Plaintiff under numerous causes of action set forth hereinafter. To the extent that any causes of action may be deemed to be inconsistent with any other causes of action, they shall be deemed to be pled in the alternative.

287. Plaintiff incorporates by reference all other paragraphs of this Complaint as if fully set forth here and further alleges as follows:

288. The opioid epidemic in the State, including *inter alia* in Plaintiff's Community, remains an immediate hazard to public health and safety.

289. The opioid epidemic in Plaintiff's Community is a continuous public nuisance and remains unabated.

290. Louisiana has found that a prohibited activity under its public nuisance statutes can include the illegal manufacture, sale or distribution of, or possession with intent to manufacture, sell, or distribute, a controlled dangerous substance, which include opiates. La. Rev. Stat. Ann. §§ 13:4711(4)(b); La. Rev. Stat. Ann. § 40:961 (26), (27). Plaintiff has the right and the power to suppress nuisances. *See City of Shreveport v. Leiderkrantz Soc.*, 130 La. 802, 806, 58 So. 578, 579 (1912); *Board of Aldermen of Opelousas v. Norman*, 51 La. Ann. 736, 738-39, 26 So. 401, 402 (1899); *see also* La. Rev. Stat. Ann. § 13:4712 (governing authority of city-parish has authority to seek an injunction or order of abatement).

291. Each Defendant is liable for public nuisance because its conduct at issue has caused an unreasonable and substantial interference with a right common to the general public, which includes Plaintiff, its members, and their families, which is the proximate cause of, and/or substantial factor leading to, Plaintiff's injury. *See* Restatement Second, Torts § 821B.

292. In addition, Defendants McKesson and Morris & Dickson have violated Louisiana's public nuisance statutes by conducting, carrying on and knowingly permitting prohibited activities at its distribution centers in St. Rose, Louisiana (McKesson) and Shreveport, Louisiana and Jefferson Parish, Louisiana (Morris & Dickson). *See* La. Rev. Stat. Ann. § 13:4711.

293. By causing dangerously addictive drugs to flood the Plaintiff's community, and to

be diverted for illicit purposes, in contravention of federal and state law, each Defendant has injuriously affected rights common to the general public, specifically including the rights of the members of the Plaintiff's Community to public health, public safety, public peace, public comfort, and public convenience. The public nuisance caused by Defendants' diversion of dangerous drugs has caused substantial annoyance, inconvenience, and injury to the public, including Plaintiff, its members and their families.

294. By selling dangerously addictive opioid drugs diverted from a legitimate medical, scientific, or industrial purpose, Defendants have committed a course of conduct that detrimentally affects the safety, health, and morals of the members of Plaintiff's tribe and their families.

295. By failing to maintain a closed system that guards against diversion of dangerously addictive drugs for illicit purposes, Defendants injuriously affected public rights, including the right to public health, public safety, public peace, and public comfort of the members of Plaintiff's tribe, and their families.

296. Plaintiff alleges that Defendants' wrongful and illegal actions have created a public nuisance. Each Defendant is liable for public nuisance because its conduct at issue has caused an unreasonable interference with a right common to the general public.

297. The Defendants have intentionally and/or unlawfully created a nuisance.

298. Defendants intentionally, unlawfully, and recklessly have manufactured, marketed, distributed, and/or sold prescription opioids that Defendants knew, or reasonably should have known would be diverted, causing widespread distribution of prescription opioids in and/or to Plaintiff's Community, resulting in addiction and abuse, an elevated level of crime, death and injuries to the members of Plaintiff's tribe and their families, a higher level of fear, discomfort and inconvenience to the residents of Plaintiff's Community, and direct costs to Plaintiff's Community.

299. Defendants have unlawfully and/or intentionally caused and permitted dangerous drugs under their control to be diverted such as to injure the Plaintiff and the members of its tribe and their families.

300. Defendants have unlawfully and/or intentionally distributed opioids or caused opioids to be distributed without maintaining effective controls against diversion. Such conduct was illegal. Defendants' failures to maintain effective controls against diversion include Defendants' failure to effectively monitor for suspicious orders, report suspicious orders, and/or stop shipment of suspicious orders.

301. Defendants' conduct in illegally distributing and selling prescription opioids, or causing such opioids to be distributed and sold, where Defendants knew, or reasonably should have known, such opioids would be diverted and possessed and/or used illegally in Plaintiff's Community is of a continuing nature.

302. Defendants' actions have been of a continuing nature and have produced, and continue to produce, a significant effect upon the public's rights, including the public's right to health and safety.

303. A violation of any rule or law controlling the distribution of a drug of abuse in Plaintiff's Community and the State is a public nuisance.

304. Defendants' distribution of opioids while failing to maintain effective controls against diversion was proscribed by statute and regulation.

305. Defendants' ongoing conduct produces an ongoing nuisance, as the prescription opioids that they allow and/or cause to be illegally distributed and possessed in Plaintiff's Community will be diverted, leading to abuse, addiction, crime, and public health costs.

306. Because of the continued use and addiction caused by these illegally distributed

opioids, the Plaintiff's members and their families will continue to fear for their health, safety and welfare, and will be subjected to conduct that creates a disturbance and reasonable apprehension of danger to person and property.

307. Defendants know, or reasonably should know, that their continuing wrongful conduct, as alleged herein, will have an ongoing detrimental effect upon the public health, safety and welfare of the Plaintiff's members and their families, and their ability to be free from disturbance and reasonable apprehension of danger to person and property.

308. Defendants know, or reasonably should know, that their continuing wrongful conduct, as alleged herein, causes a continuous unreasonable invasion of the right of the Plaintiff's members and their families to health, safety and welfare and their ability to be free from disturbance and reasonable apprehension of danger to person and property.

309. Defendants are (or should be) aware, of the unreasonable interference that their conduct has caused in and around Plaintiff's Community. Defendants are in the business of manufacturing, marketing, selling, and/or distributing prescription drugs, including opioids, which are specifically known to Defendants to be dangerous under federal and state law. *See, e.g.*, 21 U.S.C. § 812 (b)(2).

310. Defendants' continuing wrongful conduct, as alleged herein, in marketing, distributing, and selling prescription opioids which the defendants know, or reasonably should know, will likely be diverted for non- legitimate, non-medical use, creates a strong likelihood that these illegal distributions of opioids causes, has caused, and will cause death and injuries to Plaintiff's members and their families and otherwise significantly and unreasonably interfere with public health, safety and welfare, and with their right to be free from disturbance and reasonable apprehension of danger to person and property.

311. It is, or should be, reasonably foreseeable to defendants that their continuing wrongful conduct, as alleged herein, causes, has caused, and will cause deaths and injuries to members of Plaintiff's tribe and their families, and will otherwise significantly and unreasonably interfere with public health, safety and welfare, and with their right to be free from disturbance and reasonable apprehension of danger to person and property.

312. The prevalence and availability of diverted prescription opioids in the hands of irresponsible persons and persons with criminal purposes and around the members of the tribe and their families not only causes deaths and injuries, but also creates a palpable climate of fear among residents in Plaintiff's Community where opioid diversion, abuse, addiction are prevalent and where diverted opioids tend to be used frequently.

313. Defendants' continuing wrongful conduct, as alleged herein, conduct makes it easier for persons to divert prescription opioids, constituting a dangerous threat to the Plaintiff's members and their families.

314. Defendants' actions are, and have been, at the least, a substantial factor in opioids becoming widely available and widely used for non-medical purposes. Because of Defendants' special positions within the closed system of opioid distribution, without Defendants' actions, opioid use would not have become so widespread, and the enormous public health hazard of prescription opioid and heroin overuse, abuse, and addiction that now exists would have been averted.

315. The presence of diverted prescription opioids in and around Plaintiff's Community, and the consequence of prescription opioids having been diverted in Plaintiff's Community, has, upon information and belief, and proximately caused significant increases in costs, greatly in excess of the norm, to the Plaintiff and to Plaintiff's Community needed to enforce the law, equip

its police force and treat the victims of opioid abuse and addiction.

316. Stemming the flow of illegally distributed prescription opioids, and abating the nuisance caused by the illegal flow of opioids, will help to alleviate this problem, save lives, prevent injuries and make Plaintiff's Community a safer place to live for its members and their families.

317. Defendants' continuing wrongful conduct as alleged herein is a direct and proximate cause of and/or a substantial contributing factor to opioid addiction and abuse in Plaintiff's Community, costs borne by Plaintiff's members and their families, the Plaintiff, and Plaintiff's Community and a significant and unreasonable interference with public health, safety and welfare, and with the public's right to be free from disturbance and reasonable apprehension of danger to person and property.

318. Defendants' continuing wrongful conduct as alleged herein constitutes a public nuisance and, if unabated, will continue to threaten the health, safety and welfare of the members of Plaintiff's tribe and their families, creating an atmosphere of fear and addiction that tears at the residents' sense of well-being and security. Plaintiff has a clearly ascertainable right to abate conduct that perpetuates this nuisance.

319. Defendants created an intentional nuisance which remains unabated. Defendants' actions created and expanded the abuse of opioids, which are dangerously addictive, and the ensuing associated plague of prescription opioid and heroin addiction. Defendants knew the dangers to public health and safety that diversion of opioids would create in and around the Tribe and among Plaintiff's members and their families; however, Defendants intentionally and/or unlawfully failed to maintain effective controls against diversion through proper monitoring, reporting and refusal to fill suspicious orders of opioids. Defendants intentionally and/or

unlawfully distributed opioids or caused opioids to be distributed without reporting or refusing to fill suspicious orders or taking other measures to maintain effective controls against diversion. Defendants intentionally and/or unlawfully continued to ship and failed to halt suspicious orders of opioids, or caused such orders to be shipped. Defendants intentionally and/or unlawfully marketed opioids in manners they knew to be false and misleading. Such actions were inherently dangerous.

320. Defendants knew that prescription opioids have a high likelihood of being diverted. It was foreseeable to Defendants that where Defendants distributed prescription opioids or caused such opioids to be distributed without maintaining effective controls against diversion, including monitoring, reporting, and refusing shipment of suspicious orders, that the opioids would be diverted, and create an opioid abuse nuisance in and around the Tribe and to Plaintiff and its members and their families.

321. Defendants' actions also created a nuisance by acting recklessly, negligently and/or carelessly, in breach of their duties to maintain effective controls against diversion, thereby creating an unreasonable risk of harm.

322. Defendants acted with actual malice because Defendants acted with a conscious disregard for the rights and safety of other persons, and said actions have a great probability of causing substantial harm.

323. The Plaintiff further seeks to abate the nuisance created by the Defendants' unreasonable, unlawful, intentional, ongoing, continuing, and persistent actions and omissions, which have unreasonably interfered with the following common rights of the members and families of the Four Winds Cherokee Tribe:

- a. To be free from reasonable apprehension of danger to person and property;

- b. To be free from the spread of disease within the community including the disease of addiction and other diseases associated with widespread illegal opioid use;
- c. To be free from the negative health and safety effects of widespread illegal drug sales on premises in and around the Tribe;
- d. To be free from blights on the community created by areas of illegal drug use and opioid sales;
- e. The right to live or work in a community in which local businesses do not profit from using their premises to sell products that serve the criminal element and to foster a secondary market of illegal transactions; and
- f. The right to live or work in a community in which community members are not under the influence of narcotics unless they have a legitimate medical need to use them.

324. The public nuisance created by Defendants' actions is substantial and unreasonable.

It has caused and continues to cause significant harm to the Plaintiff, its members and their families, and the harm inflicted outweighs any offsetting benefit. The staggering rates of opioid and heroin use resulting from the Defendants' abdication of their gatekeeping and diversion prevention duties, and the Pharmaceutical Defendants' fraudulent marketing activities, have created hazards to public health and safety within the Tribe's communities, which have caused harm to the Plaintiff and its communities that includes, but is not limited to the following:

- a. The high rates of use leading to unnecessary opioid abuse, addiction, overdose, injuries, and deaths.
- b. Easy access to prescription opioids by children and teenagers, which are now a recreational drug of choice among teenagers, has hindered the preservation of the Tribe's heritage by placing the Tribe's youth at risk.
- c. The Tribe has further suffered from the public nuisance arising from Defendants' abdication of their gate-keeper duties and fraudulent promotions. The emotional and financial costs upon Tribe members forced to care for loved ones addicted to or injured by opioids, and the loss of companionship, wages, or other support from family members who have used, abused, become addicted to, overdosed on, or been killed by opioids has placed burden on the Tribe as a whole.

- d. Increased health care costs caused by the opioid epidemic have hindered the productivity and functioning of the Tribe.
- e. The Tribe has lost the value of productive and healthy members.
- f. Defendants' conduct created an abundance of drugs available for criminal use and fueled a new wave of addiction, abuse, and injury.
- g. Defendants' dereliction of duties and/or fraudulent misinformation campaign pushing dangerous drugs resulted in a diverted supply of narcotics to sell, and the ensuing demand of addicts to buy them. More prescription opioids sold by Defendants led to more addiction, with many addicts turning from prescription opioids to heroin. People addicted to opioids frequently require increasing levels of opioids, and many turned to heroin as a foreseeable result.
- h. The diversion of opioids into the secondary, criminal market and the increased number of individuals who abuse or are addicted to opioids increased the demands on health care services and law enforcement within the Tribe's communities.
- i. The significant and unreasonable interference with the public rights caused by Defendants' conduct taxed the human, medical, public health, law enforcement, and financial resources of the Plaintiff.
- j. Defendants' interference with the comfortable enjoyment of life within the Plaintiff's Community, is unreasonable because there is little social utility to opioid diversion and abuse, and any potential value is outweighed by the gravity of the harm inflicted by Defendants' actions.

325. Plaintiff seeks recovery of economic losses (direct, incidental, or consequential pecuniary losses) resulting from the public nuisance created by Defendants' wrongful conduct, as alleged herein, including but not limited to fraudulent activity and fraudulent misrepresentations.

326. Plaintiff seeks all legal and equitable relief as allowed by law, including *inter alia* injunctive relief, expenses to abate the nuisance, restitution, disgorgement of profits, compensatory damages, civil penalties, investigative costs and all damages allowed by law to be paid by the Defendants, including but not limited to attorney fees and costs, and pre- and post-judgment interest.

327. Defendants' misconduct alleged herein is ongoing and persistent.

328. The Defendants’ continuing wrongful conduct as alleged herein has foreseeably caused, and continues to cause, damage to the Plaintiff and its tribe members and their families, such as but not limited to the following:

- a. Costs associated with past efforts to eliminate the hazards to public health and safety;
- b. Costs associated with permanently eliminating the hazards to public health and safety and abate the public nuisance;
- c. Costs of rehabilitation and medical treatment for substance abuse;
- d. Costs associated with treatment of members necessary to cope with short and long-term emotional and physical damage;
- e. Costs associated with long-term opioid abuse treatment;
- f. Costs associated with foster care and/or adoption.
- g. Costs for providing mental-health services, treatment, counseling, rehabilitation services, and social services to victims of the opioid epidemic and their families;
- h. Costs for providing treatment of infants within the Tribe born with opioid-related medical conditions, or born dependent on opioids due to drug use by mother during pregnancy;
- i. Costs associated with providing care for children whose parents suffer from opioid-related disability or incapacitation, including foster care and other social services cost;
- j. Losses caused by diminished property values within Tribe Communities;
- k. Other costs or increased costs associated with opioid addiction.

COUNT II
LOUISIANA PRODUCTS LIABILITY ACT
La. Rev. Stat. Ann. §§ 9:2800.51, *et seq.*
(Against Pharmaceutical Defendants)

329. Plaintiff incorporates by reference all other paragraphs of this Complaint as if fully set forth herein and further alleges as follows.

330. Pursuant to the Louisiana Product Liability Act, a “manufacturer of a product shall

be liable to a claimant for damage proximately caused by a characteristic of the product that renders the product unreasonably dangerous when such damage arose from a reasonably anticipated use of the product by the claimant or another person or entity.” La. Rev. Stat. Ann. § 9:2800.54(A).

331. A product is “unreasonably dangerous” if, *inter alia*, “an adequate warning about the product has not be provided.” La. Rev. Stat. Ann. § 9:2800.54(B).

332. Pursuant to section 9:2800.57, a “product is unreasonably dangerous because an adequate warning about the product has not been provided if, at the time the product left its manufacturer's control, the product possessed a characteristic that may cause damage and the manufacturer failed to use reasonable care to provide an adequate warning of such characteristic and its danger to users and handlers of the product.” La. Rev. Stat. Ann. § 9:2800.57.

333. An adequate warning is one “that would lead an ordinary reasonable user or handler of a product to contemplate the danger in using or handling the product and either to decline to use or handle the product or, if possible, to use or handle the product in such a manner as to avoid the damage.” La. Rev. Stat. Ann. § 9:2800.53(9).

334. The Pharmaceutical Defendants, at all times, have manufactured and sold prescription opioids.

335. The Pharmaceutical Defendants had a duty to provide doctors serving the Tribe’s Community and patients, including members of the Tribe and their families, with accurate information regarding the risks of prescription opioids.

336. The Pharmaceutical Defendants had a duty to warn doctors serving the Tribe’s Community and patients, including members of the Tribe and their families, about the risks of prescription opioids.

337. The Pharmaceutical Defendants, at all times, purported to warn or purported to

inform prescribers and users regarding the benefits and risks associated with the use of prescription opioid drugs.

338. However, these warnings were inadequate.

339. 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.

340. As alleged herein, the Pharmaceutical Defendants also wrongfully misrepresented that the opioids were safe and effective when such representations were untrue, false, and misleading.

341. As set forth herein, the Pharmaceutical Defendants made deceptive representations about the use of opioids to treat chronic pain. Each Pharmaceutical Defendant also omitted or concealed material facts and failed to correct prior misrepresentations and omissions about the risks and benefits of opioids. Each Pharmaceutical Defendant's omissions rendered even their seemingly truthful statements about opioids deceptive.

342. As set forth herein, each Pharmaceutical Defendant has conducted, and continues to conduct, a marketing scheme designed to persuade doctors serving the Tribe's Community and patients, including members of the Tribe and their families, that opioids can and should be used for chronic pain. In connection with this scheme, each Pharmaceutical Defendant spent, and continues to spend, millions of dollars on promotional activities and materials that falsely deny or trivialize the risks of opioids while overstating the benefits of using them for chronic pain.

343. As set forth herein, the Pharmaceutical Defendants have made false and misleading claims, including, *inter alia*, that addiction to opioids is rare; downplaying the serious risk of opioid addiction and abuse; creating and promoting the misleading concept of "pseudoaddiction"

and advocating that the signs of addiction should be treated with more opioids; exaggerating the effectiveness of screening tools to prevent addiction; claiming that opioid dependence and withdrawal are easily managed; mischaracterizing the difficulty of discontinuing opioid therapy; denying the risks of higher opioid dosages; and exaggerating the effectiveness of “abuse-deterrent” opioid formulations to prevent abuse and addiction; and touting the Pharmaceutical Defendants have also falsely touted the benefits of long-term opioid use, including the supposed ability of opioids to improve function and quality of life.

344. The Pharmaceutical Defendants disseminated these messages directly, through their sales representatives, in speaker groups led by physicians the Pharmaceutical Defendants recruited for their support of their marketing messages, and through unbranded marketing and industry-funded Front Groups.

345. The Pharmaceutical Defendants’ warnings about prescription opioids were inadequate because they failed to give doctors who serve the Tribe’s community and patients, including Tribe members and their families, the information needed to contemplate and understand the dangers opioids posed. In fact, the Pharmaceutical Defendants’ statements and actions purported to inform doctors, patients, Plaintiff and Plaintiff’s Community that prescription opioids were safe when they were not, or at least were safer than they actually were.

346. The Pharmaceutical Defendants knew at all times that the prescription opioids that left their control had characteristics, *inter alia*, such as a far greater likelihood for addiction, that could cause damage, and failed to use reasonable care to adequately warn doctors who serve the Tribe’s community and patients, including Tribe members and their families, of these dangers.

347. This failure to warn doctors and patients within the Tribe’s community, including Tribe members and their families, of the dangers of prescription opioids made the Pharmaceutical

Defendants' product unreasonably dangerous under the Louisiana Products Liability Act.

348. Moreover, the Pharmaceutical Defendants specifically failed to warn doctors of the risks associated with the use of prescription opioids and instead conducted a marketing scheme designed to persuade doctors that opioids can and should be used for chronic pain and trivialized the risks of opioids. These risks were not otherwise known to doctors because the Pharmaceutical Defendants informed them, via scientific publications, treatment guidelines, CME programs, and medical conferences and seminars, that opioids were safer than they in fact were.

349. If the Pharmaceutical Defendants had properly warned doctors about the dangers of prescription opioids, doctors would have changed their actions in prescribing opioids to certain patients, in the amounts of prescription opioids they prescribed, and in identifying and treating signs of addiction. But for the Pharmaceutical Defendants' misrepresentations and failure to warn doctors about the actual risks of prescription opioids, doctors would have recognized the risks associated with these drugs, prescribed them less or not at all, and understood the signs of addiction.

350. If the Pharmaceutical Defendants had properly warned about the dangers of prescription opioids, doctors and patients would have used opioids in such a manner as to avoid the risks of, *inter alia*, addiction, over-prescription, and prescription for chronic pain and other non-indicated conditions.

351. The injuries alleged by Plaintiff herein were sustained as a direct and proximate result of the Pharmaceutical Defendants' failure to provide adequate warnings about the dangers of prescription opioids to doctors who serve the Tribe's community and patients, including Tribe members and their families.

352. Plaintiff and Plaintiff's Community's injuries, as alleged herein, were directly

caused by the Pharmaceutical Defendants' failure to warn.

353. Plaintiff and Plaintiff's Community's injuries, as alleged herein, arose from foreseeable and reasonably anticipated uses of prescription opioids.

354. Plaintiff seeks recovery of economic losses (direct, incidental, or consequential pecuniary losses) resulting from Defendants' violations of Louisiana Product Liability Act, as alleged herein, including but not limited to their failure to provide adequate warnings about the dangers of prescription opioids. La. Rev. Stat. Ann. § 9:2800.53(5).

355. The damages available to the Plaintiff include, *inter alia*, recoupment of governmental costs in excess of the norm, as a result of Defendants' failure to warn. Defendants' conduct is ongoing and persistent, and the Plaintiff seeks all damages flowing from Defendants' conduct.

356. Plaintiff seeks all legal and equitable relief as allowed by law including *inter alia* restitution, compensatory damages, attorney fees and costs, and pre- and post-judgment interest.

357. Defendants' misconduct alleged herein is ongoing and persistent.

358. As a result of Defendants' continuing wrongful conduct as alleged herein, including but not limited to its failure to warn, has foreseeably caused, and continues to cause, damage to Plaintiff its tribe members and their families, such as but not limited to the following:

- a. Costs associated with past efforts to eliminate the hazards to public health and safety;
- b. Costs associated with permanently eliminating the hazards to public health and safety and abate the public nuisance;
- c. Costs of rehabilitation and medical treatment for substance abuse;
- d. Costs associated with treatment of members necessary to cope with short and long-term emotional and physical damage;
- e. Costs associated with long-term opioid abuse treatment;

- f. Costs associated with foster care and/or adoption.
- g. Costs for providing mental-health services, treatment, counseling, rehabilitation services, and social services to victims of the opioid epidemic and their families;
- h. Costs for providing treatment of infants within the Tribe born with opioid-related medical conditions, or born dependent on opioids due to drug use by mother during pregnancy;
- i. Costs associated with providing care for children whose parents suffer from opioid-related disability or incapacitation, including foster care and other social services cost;
- j. Losses caused by diminished property values within Tribe Communities;
- k. Other costs or increased costs associated with opioid addiction.

COUNT III
LOUISIANA UNFAIR TRADE PRACTICES AND CONSUMER PROTECTION LAW
La. Rev. Stat. Ann. §§ 51:1401, *et seq.*
(Against All Defendants)

359. Plaintiff incorporates by reference all other paragraphs of this Complaint, as if fully set forth herein and further alleges as follows.

360. Plaintiff brings this count under the Louisiana Unfair Trade Practices Act (“LUTPA”), La. Rev. Stat. Ann. §§ 51:1401 *et seq.* as Plaintiff is a “legal entity” and therefore a “person” under the definitions of the LUTPA. *See* La. Rev. Stat. Ann. § 51:1402(8). Section 51:1409(A) allows any person who suffers any ascertainable loss of money or property “as a result of the use or employment by another person of an unfair or deceptive method, act, or practice declared unlawful by R.S. 51:1405” to bring an action to recover actual damages.

361. Under the LUTPA, “unfair or deceptive acts or practices in the conduct of any trade or commerce are hereby declared unlawful.” La. Rev. Stat. Ann. § 51:1405.

362. Defendants' practices as described herein are unfair and deceptive practices that violate LUTPA because the practices were and are intended to deceive consumers and occurred

and continue to occur in the course of conduct involving trade and commerce in Plaintiff's Community.

363. At all relevant times, the Pharmaceutical Defendants, directly, and/or through their control of third parties, and/or by aiding and abetting third parties, violated LUTPA, as set forth above, by making and disseminating untrue, false, and misleading statements to prescribers and consumers in the Tribe and in Plaintiff's Community to promote the sale and use of opioids to treat chronic pain, or by causing untrue, false, and misleading statements about opioids to be made or disseminated to prescribers and consumers in the Tribe and in Plaintiff's Community in order to promote the sale and use of opioids to treat chronic pain. By virtue of the continuous wrongful acts as alleged herein, the Pharmaceutical Defendants engaged in methods, act and practices with the intent to defraud health care providers and prescribers. These untrue, false, and misleading statements included, but were not limited to:

- a. Misrepresenting the truth about how opioids lead to addiction;
- b. Misrepresenting that opioids improve function;
- c. Misrepresenting that addiction risk can be managed;
- d. Misleading doctors, patients, and payors through the use of misleading terms like "pseudoaddiction;"
- e. Falsely claiming that withdrawal is simply managed;
- f. Misrepresenting that increased doses pose no significant additional risks;
- g. Falsely omitting or minimizing the adverse effects of opioids and overstating the risks of alternative forms of pain treatment.

364. As set forth herein the Distributor Defendants also committed repeated and willful unfair or deceptive acts or practices in the conduct of commerce.

365. As set forth herein, each Distributor Defendant failed to report and/or prevent the diversion of highly addictive prescription drugs to illegal sources.

366. Because of the dangerously addictive nature of these drugs, the Distributor Defendants' marketing, sales, and/or distribution practices unlawfully caused an opioid and heroin plague and epidemic which continues to rage in the State and in Plaintiff's Tribal Community. Each Distributor Defendant had a non-delegable duty to guard against and prevent the diversion of prescription opioids to other than legitimate medical, scientific, and industrial channels.

367. The Distributor Defendants failed to disclose the material facts that *inter alia* they were not in compliance with laws and regulations requiring that they maintain a system to prevent diversion, protect against addiction and severe harm, and specifically monitor, investigate, report, and refuse suspicious orders. But for these material factual omissions, the Distributor Defendants would not have been able to sell opioids, and the Distributor Defendants would not have been able to receive and renew licenses to sell opioids.

368. As set forth hereinabove, the Distributor Defendants' deceptive trade practices specifically include, but are not necessarily limited to, the following:

- a. The practice of not monitoring for suspicious orders of prescription opioids;
- b. The practice of not detecting suspicious orders of prescription opioids;
- c. The practice of not investigating suspicious orders of prescription opioids;
- d. The practice of filling, or failing to refuse fulfillment of, suspicious orders of prescription opioids;
- e. The practice of not reporting suspicious orders of prescription opioids;
- f. The practice of rewarding increases in prescription opioid sales; and/or
- g. The practice of falsely misrepresenting to the public that Defendants were complying with their legal obligations.

369. The Distributor Defendants' unfair, and deceptive actions, concealments, and omissions were reasonably calculated to deceive the public, Plaintiff's Tribal Community, Plaintiff, its members and their families.

370. As described more specifically above, the Distributor Defendants' representations, concealments, and omissions constitute a willful course of conduct which continues to this day.

371. The damages which Plaintiff seeks to recover were sustained as a direct and proximate cause of the Defendants' intentional and/or unlawful actions and omissions.

372. The Defendants' actions and omissions in the course of marketing, selling, and/or distributing opioids constitute deceptive trade practices under the LUTPA.

373. Louisiana state law prohibits representing that goods or services have sponsorship, approval, characteristics, uses, or benefits that they do not have. State law further prohibits representing that goods are of a standard, quality, or grade if they are of another.

374. The Defendants egregiously, knowingly, willfully and/or unlawfully engaged in the deceptive trade practices described herein.

375. The Defendants' unfair practices, as described above, violated public policies under both federal law (21 U.S.C. § 823, 21 U.S.C. § 801; 21 C.F.R. 1301.74) and Louisiana law (*e.g.* 46 La. Admin. Code. Pt XCI, § 313; *see also* La. Rev. Stat. Ann. § 40:974(A)(1) & (A)(4)), to maintain effective controls against diversion and to monitor, detect, investigate, refuse to fill, and report suspicious orders of prescription opioids originating from the State and in Plaintiff's Community, as well as those orders which the Defendants knew or should have known were likely to be diverted into the State and Plaintiff's Tribal Community. Nevertheless, by engaging in the conduct alleged above, the Defendants actively worked to conceal the risk of addiction related to opioids from Louisiana patients and prescribers in the hopes of selling greater quantities of their

dangerous drugs. The Defendants also worked to undermine public policy, enshrined by regulations contained in state and federal law, that is aimed at ensuring honest marketing and safe and appropriate use of pharmaceutical drugs.

376. As set forth herein, all Defendants have violated the CSA. Each violation of the CSA is also a violation of LUTPA.¹⁵²

377. The Defendants egregiously, knowingly and willfully engaged in the deceptive trade practices described herein.

378. La. R.S. § 51:1409(A) allows any person (including any legal entity, pursuant to La. R.S. § 51:1402(8)) who suffers "any ascertainable loss of money or movable property, corporeal or incorporeal, as a result of the use or employment of an unfair or deceptive method, or practice declared unlawful by R.S. § 51:1405" to bring an action to recover actual damages.

379. Section 51:1409(A) of the LUTPA empowers this Court to grant treble damages, as well as costs and attorney fees against the Defendants, if the Court finds that Defendants knowingly engaged in an unfair or deceptive trade practice.

380. Plaintiff, its member and their families have been damaged, and is likely to be further damaged in the future, by the continuing deceptive trade practices of Defendants' as alleged herein. Plaintiff seeks recovery of economic losses (direct, incidental, or consequential pecuniary losses) resulting from the Defendants' deceptive and unfair trade practices.

381. Plaintiff seeks all legal and equitable relief as allowed by law, including *inter alia* restitution, disgorgement of profits, compensatory damages, treble damages, attorney fees and costs, and pre- and post-judgment interest.

382. Defendants' misconduct alleged herein is ongoing and persistent.

¹⁵² La. R.S. 51:1401, *et seq.*

383. The Defendants' continuing wrongful conduct as alleged herein, including but not limited to its deceptive and unfair trade practices, has foreseeably caused, and continues to cause, damage to Plaintiff its tribe members and their families, such as but not limited to the following:

- a. Costs associated with past efforts to eliminate the hazards to public health and safety;
- b. Costs associated with permanently eliminating the hazards to public health and safety and abate the public nuisance;
- c. Costs of rehabilitation and medical treatment for substance abuse;
- d. Costs associated with treatment of members necessary to cope with short and long-term emotional and physical damage;
- e. Costs associated with long-term opioid abuse treatment;
- f. Costs associated with foster care and/or adoption.
- g. Costs for providing mental-health services, treatment, counseling, rehabilitation services, and social services to victims of the opioid epidemic and their families;
- h. Costs for providing treatment of infants within the Tribe born with opioid-related medical conditions, or born dependent on opioids due to drug use by mother during pregnancy;
- i. Costs associated with providing care for children whose parents suffer from opioid-related disability or incapacitation, including foster care and other social services cost;
- j. Losses caused by diminished property values within Tribe Communities;
- k. Other costs or increased costs associated with opioid addiction.

COUNT IV
NEGLIGENCE AND NEGLIGENT MISREPRESENTATION
(Against All Defendants)

384. Plaintiff incorporates by reference all other paragraphs of this Complaint as if fully set forth here and further alleges as follows.

385. Plaintiff seeks recovery of economic damages which were the foreseeable result of

the Distributor Defendants' intentional and/or unlawful actions and omissions.

386. Defendants violated Louisiana Civil Code articles 2315 and 2316 by their negligence and negligent misrepresentations. La. Civ. Code Ann. art. 2315; La. Civ. Code Ann. art. 2316.

387. Article 2315 of the Louisiana Civil Code states that "Every act whatever of man that causes damage to another obliges him by whose fault it happened to repair it."

388. Article 2316 the Louisiana Civil Code states that "Every person is responsible for the damage he occasions not merely by his act, but by his negligence, his imprudence, or his want of skill."

389. Each Defendant had an obligation to exercise reasonable care in marketing, selling, and/or distributing highly dangerous opioid drugs within the State of Louisiana and Plaintiff's Tribal Community.

390. Each Defendant had an obligation to exercise due care in marketing, selling, and distributing highly dangerous opioid drugs within the State and Plaintiff's Community.

391. Each Defendant owed a duty to the Plaintiff, and its members, because the injury was foreseeable, and in fact foreseen, by the Defendants.

392. Reasonably prudent manufacturers and/or distributors 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 associated with those communities, such as the Plaintiff. The closed system of opioid distribution whereby wholesale distributors are the gatekeepers between manufacturers and pharmacies, and wherein all links in the chain have a duty to prevent diversion, exists for the purpose of controlling dangerous substances such as opioids and preventing diversion and abuse.

393. The escalating amounts of addictive drugs flowing through Defendants' businesses, and the sheer volume of these prescription opioids, further alerted Defendants that addiction was fueling increased consumption and that legitimate medical purposes were not being served.

394. As described above in allegations expressly incorporated herein, Distributor Defendants breached their duties to exercise due care in the business of wholesale distribution of dangerous opioids, which are Schedule II Controlled Substances, by failing to monitor for, failing to report, and filling highly suspicious orders time and again. Because the very purpose of these duties was to prevent the resulting harm – diversion of highly addictive drugs for non- medical purposes – the causal connection between Distributor Defendants' breach of duties and the ensuing harm was entirely foreseeable.

395. As described elsewhere in the Complaint in allegations expressly incorporated herein, Distributor Defendants misrepresented their compliance with their duties under the law and concealed their noncompliance and shipments of suspicious orders of opioids to Plaintiff's Tribal Community and destinations from which they knew opioids were likely to be diverted into Plaintiff's Tribal Community, in addition to other misrepresentations alleged and incorporated herein.

396. The Defendants breached their duties to prevent diversion and report and halt suspicious orders, and they misrepresented their compliance with their legal duties.

397. The Defendants' breaches were intentional and/or unlawful, and their conduct was willful, wanton, malicious, reckless, oppressive, and/or fraudulent.

398. The causal connection between the Defendants' breaches of their duties and misrepresentations and the ensuing harm was entirely foreseeable.

399. The Defendants' breaches of their duties and misrepresentations were the cause-in-

fact of Plaintiff's injuries.

400. The risk of harm to Plaintiff and Plaintiff's Community and the harm caused were within the scope of protection afforded by the Defendants' duty to exercise due and reasonable care in marketing, selling, and/or distributing highly dangerous opioid drugs in the State and Plaintiff's Community. The Defendants' substandard conduct was a legal cause of the Plaintiff's injuries.

401. As described above in allegations expressly incorporated herein, the Defendants' breaches of duty and misrepresentations caused, bears a causal connection with, and/or proximately resulted in the damages sought herein.

402. The Defendants' unlawful and/or intentional actions as described herein create a rebuttable presumption of negligence and negligent misrepresentation under State law.

403. Plaintiff seeks recovery of economic losses (direct, incidental, or consequential pecuniary losses) resulting from the Defendants' actions and omissions.

404. Plaintiff seeks all legal and equitable relief as allowed by law, including *inter alia* injunctive relief, restitution, disgorgement of profits, compensatory damages, and all damages allowed by law to be paid by the Defendants, attorney fees and costs, and pre- and post-judgment interest.

405. Defendants' misconduct alleged herein is ongoing and persistent.

406. The Defendants' continuing wrongful conduct as alleged herein, including but not limited to its negligence and/or negligent misrepresentations has foreseeably caused, and continues to cause, damage to Plaintiff, its tribe members and their families, such as but not limited to the following:

- a. Costs associated with past efforts to eliminate the hazards to public health and safety;

- b. Costs associated with permanently eliminating the hazards to public health and safety and abate the public nuisance;
- c. Costs of rehabilitation and medical treatment for substance abuse;
- d. Costs associated with treatment of members necessary to cope with short and long-term emotional and physical damage;
- e. Costs associated with long-term opioid abuse treatment;
- f. Costs associated with foster care and/or adoption.
- g. Costs for providing mental-health services, treatment, counseling, rehabilitation services, and social services to victims of the opioid epidemic and their families;
- h. Costs for providing treatment of infants within the Tribe born with opioid-related medical conditions, or born dependent on opioids due to drug use by mother during pregnancy;
- i. Costs associated with providing care for children whose parents suffer from opioid-related disability or incapacitation, including foster care and other social services cost;
- j. Losses caused by diminished property values within Tribe Communities;
- k. Other costs or increased costs associated with opioid addiction.

COUNT V
FRAUD AND FRAUDULENT MISREPRESENTATION
(Against All Defendants)

407. Plaintiff incorporates by reference all other paragraphs of this Complaint as if fully set forth here and further alleges as follows.

408. Under Louisiana law, “Fraud is a misrepresentation or a suppression of the truth made with the intention either to obtain an unjust advantage for one party or to cause a loss or inconvenience to the other. Fraud may also result from silence or inaction.” La. Civ. Code Ann. Art. 1953. The “Revision Comments” to the said statute explain that “Fraud, like its French equivalent ‘*dol*,’ need not be a criminal act. Intentional fault of a quasi-delictual nature suffices to

constitute the kind of fraud that vitiates a party's consent." Revision Comments at Paragraph (c).

409. Under Louisiana law, delictual fraud or intentional misrepresentation consists of: 1) a misrepresentation of material fact, 2) made with the intent to deceive and 3) causing justifiable reliance and resultant injury. *Becnel v. Grodner*, 2007-1041 (La. App. 4 Cir. 4/2/08), 982 So.2d 891, 894.

410. As set forth herein the Defendants, with the intent to deceive and/or obtain an unjust advantage and/or to cause damage to patients, doctors, payors, and local governments such as Plaintiff, made knowingly false statements and omitted and/or concealed information. The Defendants acted intentionally and/or unlawfully. These actions and omissions constitute fraud, as that term is defined in La. Civ. Code Ann. Art. 1953.

411. As alleged herein the Defendants made false statements regarding their compliance with state and federal law regarding their duties to prevent diversion, their duties to monitor, report and halt suspicious orders, and/or concealed their noncompliance with these requirements.

412. As alleged herein the Defendants knowingly and/or intentionally made representations that were false. The Defendants had a duty to disclose material facts and concealed them. These false representations and concealed facts were material to the conduct and actions at issue. The Defendants made these false representations and concealed facts with knowledge of the falsity of their representations, and did so with the intent of misleading Plaintiff, including members of Plaintiff's Tribal Community and their families.

413. These false representations and concealments were reasonably calculated to deceive the Plaintiff, including members of Plaintiff's Tribal Community and their families, and the physicians who prescribed opioids for persons in Plaintiff's Tribal Community. These false representations and concealments were made with the intent to deceive, and did in fact deceive the

Plaintiff, Tribe members and their families and physicians within Plaintiff's Tribal Community.

414. Plaintiff, Plaintiff's Tribal Community, and the physicians who prescribed opioids reasonably relied on these false representations and concealments of material fact.

415. But for the aforementioned fraudulent conduct of the Defendants [which is ongoing], and the detrimental reliance thereon of doctors, prescribers and patients in the Plaintiff's Community, there would not be a massive opioid addiction epidemic that extends into the Plaintiff's Community. However, as a result of the Defendants continuous fraudulent actions alleged herein, Plaintiff has suffered, and continues to suffer damages, including but not limited to the damages described herein.

416. The injuries alleged by Plaintiff herein were sustained as a direct and proximate cause of the Defendants' fraudulent conduct.

417. Plaintiff seeks recovery of economic losses (direct, incidental, or consequential pecuniary losses) resulting from Defendants' fraudulent activity, including fraudulent misrepresentations and fraudulent concealment.

418. Plaintiff seeks all legal and equitable relief as allowed by law, including *inter alia* injunctive relief, restitution, disgorgement of profits, compensatory damages, attorney fees, investigative costs and expenses, and all damages allowed by law to be paid by the Defendants, and costs, and pre- and post-judgment interest.

419. Defendants' misconduct alleged herein is ongoing and persistent.

420. The Defendants' continuing wrongful conduct as alleged herein, including but not limited to its fraud and fraudulent misrepresentations, has foreseeably caused, and continues to cause, damage to Plaintiff, its tribe members and their families, such as but not limited to the following:

- a. Costs associated with past efforts to eliminate the hazards to public health and safety;
- b. Costs associated with permanently eliminating the hazards to public health and safety and abate the public nuisance;
- c. Costs of rehabilitation and medical treatment for substance abuse;
- d. Costs associated with treatment of members necessary to cope with short and long-term emotional and physical damage;
- e. Costs associated with long-term opioid abuse treatment;
- f. Costs associated with foster care and/or adoption.
- g. Costs for providing mental-health services, treatment, counseling, rehabilitation services, and social services to victims of the opioid epidemic and their families;
- h. Costs for providing treatment of infants within the Tribe born with opioid-related medical conditions, or born dependent on opioids due to drug use by mother during pregnancy;
- i. Costs associated with providing care for children whose parents suffer from opioid-related disability or incapacitation, including foster care and other social services cost;
- j. Losses caused by diminished property values within Tribe Communities;
- k. Other costs or increased costs associated with opioid addiction.

COUNT VI
FALSE ADVERTISING
La. Rev. Stat. Ann. §§ 40:625
(Against all Defendants)

421. Plaintiff incorporates by reference all previous allegations within the preceding paragraphs as if fully set forth herein, and further alleges as follows:

422. Louisiana Revised Statute § 40:625(A) provides that:

An advertisement of a food, drug, device, or cosmetic is false if it is false or misleading in any particular regarding the food, drug, device, or cosmetic. Any representation concerning any effect of a drug or device is false under this Sub-section if it is not supported by demonstrable scientific facts or substantial and reliable medical or scientific opinion.

423. “Advertisement” includes all representations of fact or opinion disseminated to the public in any manner or by any means other than by the labeling.¹⁵³

424. Defendants violated La. Rev. Stat. Ann. §40:625 as they engaged in false advertising in the conduct of a business, trade or commerce in this State.

425. As set forth herein, Defendants, directly and through third parties, violated La. Rev. Stat. Ann. §40:625 by making and disseminating untrue, false and misleading advertisements to consumers in this State and in Plaintiff’s Tribal Community promoting the sale and use of opioids to treat chronic pain, and by causing untrue, false, and misleading advertisements about opioids to be made or disseminated to them and other Louisiana consumers in order to promote the sale and use of opioids to treat chronic pain. These untrue, false, and misleading statements in advertisements and other patient brochures included, but were not limited to:

- a. Misrepresenting the truth about how opioids lead to addiction;
- b. Misrepresenting that opioids improve function;
- c. Misrepresenting that addiction risk can be managed;
- d. Misleading patients through the use of terms like "pseudoaddiction";
- e. Falsely claiming that withdrawal is simply managed;
- f. Misrepresenting that increased doses pose no significant additional risks;
- g. Falsely omitting or minimizing the adverse effects of opioids and overstating the risks of alternative forms of pain treatment.

426. At all times relevant to this Complaint, Defendants, directly, and through third

¹⁵³ La. Rev. Stat. Ann. § 40:602(1).

parties, and by aiding and abetting third parties, also violated La. R.S. § 40:625 through misleading advertisements in various marketing channels, including but not limited to: advertisements, brochures, and other patient education materials that omitted or concealed material facts to promote the sale and use of opioids to treat chronic pain. Defendants repeatedly failed to disclose or minimized material facts about the risks of opioids, including the risk of addiction, and their risks compared to alternative treatments. Such material omissions were deceptive and misleading in their own right, and further rendered even otherwise truthful statements about opioids untrue, false, and misleading, creating a misleading impression of the risks, benefits, and superiority of opioids for treatment of chronic pain.

427. Defendants knew at the time of making or disseminating these misstatements and material omissions, or causing these misstatements and material omissions statements to be made or disseminated, that they were untrue, false, or misleading and therefore likely to deceive the public. In addition, Defendants knew or should have known that their marketing and promotional efforts created an untrue, false, and misleading impression of the risks, benefits, and superiority of opioids. This conduct remains ongoing.

428. In sum, Defendants: (a) directly engaged in untrue, false, and misleading advertising; (b) disseminated the untrue, false, and misleading advertisements through third parties; and (c) aided and abetted the untrue, false, and misleading advertising by third parties.

429. All of this conduct, separately and collectively, was intended to deceive Louisiana consumers, including Plaintiff's members and Tribal Community.

430. Defendants' misconduct alleged herein is ongoing and persistent.

431. The Defendants' continuing wrongful conduct as alleged herein, including but not limited to its false advertising, has foreseeably caused, and continues to cause, damage to Plaintiff,

its tribe members and their families, such as but not limited to the following:

- a. Costs associated with past efforts to eliminate the hazards to public health and safety;
- b. Costs associated with permanently eliminating the hazards to public health and safety and abate the public nuisance;
- c. Costs of rehabilitation and medical treatment for substance abuse;
- d. Costs associated with additional care and needs for children within the Tribe born addicted to prescription opioids and other controlled substances;
- e. Costs associated with treatment of members necessary to cope with short and long-term emotional and physical damage;
- f. Costs associated with long-term opioid abuse treatment;
- g. Costs associated with foster care and/or adoption.
- h. Costs for providing mental-health services, treatment, counseling, rehabilitation services, and social services to victims of the opioid epidemic and their families;
- i. Costs for providing treatment of infants born with opioid-related medical conditions, or born dependent on opioids due to drug use by mother during pregnancy;
- j. Costs associated with providing care for children whose parents suffer from opioid-related disability or incapacitation, including foster care and other social services cost;
- k. Losses caused by diminished property values within Tribe Communities in the form of decreased business investment and tax revenue.
- l. Other increased costs associated with opioid addiction.

COUNT VII
MISBRANDING DRUGS OR DEVICES
La. Rev. Stat. Ann. §40:617
(All Defendants)

432. Plaintiff incorporates by reference all previous allegations within the preceding paragraphs as if fully set forth herein, and further alleges as follows:

433. Louisiana Revised Statute § 40:617(A)(2) provides that a drug is considered

misbranded if it "is dangerous to health under the conditions of use prescribed in the labeling or advertising thereof...."

434. Additionally, in Louisiana, a manufacturer illegally "misbrands" a drug if the drug's labeling is false or misleading.¹⁵⁴

435. "Labeling" includes all labels and other written, printed, and graphic matter, in any form whatsoever, accompanying any drug.¹⁵⁵

436. Any representation concerning any effect of a drug is considered false if the representation is not supported by demonstrable scientific facts, or substantial and reliable medical or scientific opinion.¹⁵⁶

437. The Defendants violated La. R.S. § 40:617, because they misbranded drugs in the conduct of a business, trade or commerce in this state.

438. By falsely promoting the message, *inter alia*, that opioids were unlikely to lead to addiction; that the rare incidence of addiction could be easily managed; that opioids were appropriate and first-line treatment for chronic pain; that withdrawal is easily managed; that increased doses of opioids posed no additional risks; and by falsely omitting or minimizing the adverse effects of opioids, the Defendants promoted a product that was dangerous to health under the conditions and use prescribed in their advertisements and marketing and therefore misbranded.

439. The Defendants also violated La. R.S. § 40:617, because said Defendants promoted a product through advertising and marketing was not supported by demonstrable scientific facts or substantial and reliable medical or scientific opinion, thereby rendered their drugs misbranded. Defendants' misbranding was achieved through the promulgation of false and misleading

¹⁵⁴ La. Rev. Stat. Ann. § 40:617(A).

¹⁵⁵ La. Rev. Stat. Ann. §40:602.

¹⁵⁶ La. Rev. Stat. Ann. §40:617.

advertising and marketing, *inter alia*, that opioids were unlikely to lead to addiction; that rare incidence of addiction could be easily managed; that opioids were appropriate and first-line treatment for chronic pain; that withdrawal is easily managed; that increased doses of opioids posed no additional risks, and by falsely omitting or minimizing the adverse effects of opioids, in their advertising and marketing efforts.

440. By reason of the defendants' continuing wrongful conduct, as alleged herein, Plaintiff, its members and their families were injured and continue to be injured in that Defendants offered drugs dangerous to health under the use prescribed in their labeling and in that Defendants' labeling contained representations that were not supported by demonstrable scientific facts, or substantial and reliable medical or scientific opinion. Such labeling caused consumers to request, doctors to prescribe, and payors to pay for long-term opioid treatment using opioids manufactured and/or distributed by Defendants that they would not have otherwise paid for were it not for Defendants' misbranding.

441. Defendants' misconduct alleged herein is ongoing and persistent.

442. The Defendants' continuing wrongful conduct as alleged herein, including but not limited to Defendants' misbranding, has foreseeably caused, and continues to cause, damage to Plaintiff, its tribe members and their families, such as but not limited to the following:

- a. Costs associated with past efforts to eliminate the hazards to public health and safety;
- b. Costs associated with permanently eliminating the hazards to public health and safety and abate the public nuisance;
- c. Costs of rehabilitation and medical treatment for substance abuse;
- d. Costs associated with additional care and needs for children within the Tribe born addicted to prescription opioids and other controlled substances;
- e. Costs associated with treatment of members necessary to cope with short and long-

term emotional and physical damage;

- f. Costs associated with long-term opioid abuse treatment;
- g. Costs associated with foster care and/or adoption.
- h. Costs for providing mental-health services, treatment, counseling, rehabilitation services, and social services to victims of the opioid epidemic and their families;
- i. Costs for providing treatment of infants born with opioid-related medical conditions, or born dependent on opioids due to drug use by mother during pregnancy;
- j. Costs associated with providing care for children whose parents suffer from opioid-related disability or incapacitation, including foster care and other social services cost;
- k. Losses caused by diminished property values within Tribe Communities in the form of decreased business investment and tax revenue.
- l. Other increased costs associated with opioid addiction.

**COUNT VIII
UNJUST ENRICHMENT
La. Civil Code Article 2298
(All Defendants)**

443. Plaintiff incorporates by reference all previous allegations within the preceding paragraphs as if fully set forth herein and further alleges as follows:

444. Louisiana Civil Code Art. 2298 provides, "A person who has been enriched without cause at the expense of another person is bound to compensate that person."

445. As an expected and intended result of their conscious wrongdoing as set forth in this Complaint, Defendants have unjustly profited and benefited from the increase in the distribution and purchase of opioids within Plaintiffs' community, including from opioids foreseeably and deliberately diverted within and into Plaintiffs' community. The Defendants' retention of said profits and benefits violates the fundamental principles of justice, equity, and good conscience.

446. By virtue of the acts alleged herein, Defendants knowingly, willfully, and intentionally marketed, promoted and/or distributed opioid medications in a false and deceptive manner and knowingly, willfully, and intentionally and without justification withheld information from persons located in Plaintiff's Community, and Tribal members and their families, their insurers, public health providers, prescribers, medical assistance programs and other government payors regarding the risks associated with long term opioid therapy.

447. By illegally and deceptively promoting opioids to treat chronic pain, directly, and/or through their control of third parties, and/or by acting in concert with third parties, Defendants have unjustly enriched themselves at Plaintiff's expense.

448. The enrichment of Defendants at the expense of Plaintiff was without justification.

449. Defendants' misconduct alleged herein is ongoing and persistent.

450. Because of their ongoing deceptive promotion of opioids, and other deceptive and fraudulent conduct, as alleged herein, Defendants obtained enrichment, to the detriment of Plaintiff its members and their families that they would not otherwise have obtained, such as but not limited to the following:

- a. Costs associated with past efforts to eliminate the hazards to public health and safety;
- b. Costs associated with permanently eliminating the hazards to public health and safety and abate the public nuisance;
- c. Costs of rehabilitation and medical treatment for substance abuse;
- d. Costs associated with additional care and needs for children within the Tribe born addicted to prescription opioids and other controlled substances;
- e. Costs associated with treatment of members necessary to cope with short and long-term emotional and physical damage;
- f. Costs associated with long-term opioid abuse treatment;

- g. Costs associated with foster care and/or adoption.
- h. Costs for providing mental-health services, treatment, counseling, rehabilitation services, and social services to victims of the opioid epidemic and their families;
- i. Costs for providing treatment of infants born with opioid-related medical conditions, or born dependent on opioids due to drug use by mother during pregnancy;
- j. Costs associated with providing care for children whose parents suffer from opioid-related disability or incapacitation, including foster care and other social services cost;
- k. Losses caused by diminished property values within Tribe Communities in the form of decreased business investment and tax revenue.
- l. Other increased costs associated with opioid addiction.

451. Plaintiff demands judgment against each Defendant for restitution and disgorgement of any profits which have been obtained at the expense of Plaintiff.

COUNT IX
RACKETEER INFLUENCED AND CORRUPT ORGANIZATIONS ACT
18 U.S.C. 1961, *et seq.*¹⁵⁷
(Against All Defendants)

452. Plaintiff incorporates by reference all other paragraphs of this Complaint as if fully set forth herein, and further alleges as follows.

453. Plaintiff brings this Count against all defendants, who are referred to in this Count as the “RICO Defendants”.

454. 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.”

455. Section 1962(a) of RICO makes it unlawful “for any person who has received any

¹⁵⁷ For convenience, Sections of the so-called RICO statute are referred to as, for example, “Section 1962 (a) or Section 1962 (b)” and so forth.

income derived, directly or indirectly, from a pattern of racketeering activity ... in which such person has participated as a principal within the meaning of section 2, title 18, United States Code, to use or invest, directly or indirectly, any part of such income, or the proceeds of such income, in acquisition of any interest in, or the establishment or operation of, any enterprise which is engaged in, or the activities of which affect, interstate or foreign commerce.” 18 U.S.C. 1962 (a); *St. Paul Mercury v. Williamson*, 224 F. 3d 425, 441 (5th Cir. 2000).

456. Section 1962(b) of RICO makes it unlawful “for any person through a pattern of racketeering activity or through collection of an unlawful debt to acquire or maintain, directly or indirectly, any interest in or control of any enterprise which is engaged in, or the activities of which affect, interstate or foreign commerce.

457. 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); *St. Paul Mercury v. Williamson*, 224 F. 3d 425, 445 (5th Cir. 2000).

A. THE RICO ENTERPRISE

458. 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. U.S.*, 556 U.S. 938, 944 (2009); *Crow v. Henry*, 43 F.3d 198, 204-205 (5th Cir. 1995). 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.’” *Id. Turkette*, 452 U.S. at 577. The second category is not a more generalized description of the first. *Id.*

459. As set forth herein, the Controlled Substances Act, 21 U.S.C. § 821, *et seq.* (the “CSA”), establishes a “closed” system for “the manufacturing, distributing and dispensing of controlled substances.”¹⁵⁸ The linchpin of this system is the registration with the DEA of all persons who manufacture or distribute controlled substances.¹⁵⁹

460. Central to the closed system created by the CSA was the directive that the DEA determine quotas of each basic class of Schedule I and II controlled substances each year.¹⁶⁰ The quota system was intended to reduce or eliminate diversion from “legitimate channels of trade” by controlling the “quantities of the basic ingredients needed for the manufacture of [controlled substances], and the requirement of order forms for all transfers of these drugs.”¹⁶¹

461. DEA’s quota system for the basic classes of controlled substances consists of three types of quota summarized below: Aggregate Production Quota (APQ), Individual Manufacturing Quota, and Procurement Quota.

- *Aggregate Production Quota:* The Administrator determines the total amount of each basic class of Schedule I and II controlled substance necessary to be manufactured in a calendar year to provide for the estimated medical, scientific, research, and industrial need of the United States, for lawful export requirements, and for the establishment and

¹⁵⁸ *Pharmacy Practice and the Law*, Richard R. Abood, p. 184.

¹⁵⁹ 21 U.S.C. 822(a)(1). Although this statute requires registration with the “Attorney General in accordance with Rules and Regulation promulgated by him,” the Attorney General has delegated his functions under the CSA to the DEA. See 28 C.F.R. 0.100.

¹⁶⁰ 21 U.S.C. 826.

¹⁶¹ 1970 U.S.C.C.A.N. 4566 at 5490; *see also* Testimony of Joseph T. Rannazzisi before the Caucus on International Narcotics Control, United States Senate, May 5, 2015 (available at https://www.drugcaucus.senate.gov/sites/default/files/Rannazzisi%20Testimony_0.pdf).

maintenance of reserve stocks.

- *Individual Manufacturing Quota*: Amount of a basic class allocated to registered bulk manufacturers in order to manufacture the substance by producing, preparing, propagating, compounding, or processing it from another substance.
- *Procurement Quota*: Issued to registered manufacturers who desire to obtain any Schedule I and/or II basic class of controlled substances in order to further manufacture that substance by packaging, repackaging, labeling, relabeling, or producing dosage forms or other substances.¹⁶²

DEA establishes the APQ for approximately 200 Schedule I and II controlled substances annually. Once issued, a quota may be increased or decreased, as appropriate. Any registrant who holds an individual manufacturing quota for a basic class of a Schedule I or II controlled substance may, at any time, request an increase in that quota in order to meet estimated net disposal, inventory, and other requirements during the remainder of the year. In addition, the Administrator may, at any time, reduce an individual manufacturing quota for a basic class of controlled substance in order to prevent the aggregate of the individual manufacturing quotas from exceeding the APQ for that basic class.¹⁶³

462. The DEA considers the following factors in its determination of quotas:

- a. Information provided by the Department of Health and Human Services;
- b. Total net disposal of the basic class by all manufacturers;
- c. Trends in the national rate of net disposal of the basic class;
- d. An applicant's production cycle and current inventory position;
- e. Total actual or estimated inventories of the class and of all substances manufactured from the class and trends in inventory accumulation; and

¹⁶² *Id.*

¹⁶³ *Id.*

- f. Other factors such as: changes in the currently accepted medical use of substances manufactured for a basic class; the economic and physical availability of raw materials; yield and sustainability issues; potential disruptions to production; and unforeseen emergencies.¹⁶⁴

463. For more than a decade, the RICO Defendants aggressively sought to sell their dangerous products, enhance revenues and profits, and increase their share of the prescription painkiller market, by unlawfully and surreptitiously increasing the volume of sales of opioid medications. However, the Defendants are not permitted to engage in a limitless expansion of their market through the unlawful sales of regulated painkillers. As “registrants,” the Defendants operated and continue to operate within the “closed-system” created under the CSA. The CSA restricts the RICO Defendants’ ability to manufacture or distribute Schedule II substances like opioids by requiring them to: (1) register to manufacture or distribute opioids¹⁶⁵; (2) to maintain complete and accurate inventories and records of transactions involving controlled substances¹⁶⁶ (3) maintain effective controls against diversion of the controlled substances that they manufacturer or distribute¹⁶⁷; (4) design and operate a system to identify suspicious orders of controlled substances,¹⁶⁸ halt such unlawful sales, and report them to the DEA; and (5) make sales within a limited quota set by the DEA for the overall production of Schedule II substances like opioids.¹⁶⁹

464. It is unlawful for a registrant to manufacture a controlled substance in Schedule II, such as prescription opioids, that is (1) not expressly authorized by its registration and by a quota

¹⁶⁴ *Id.* See also 21 C.F.R. 1303.11.

¹⁶⁵ 21 U.S.C. 822 (a) (1).

¹⁶⁶ 21 U.S.C. 827(a)(3); 21 CFR §§ 1304.21(a), 1304.22(a) and (b).

¹⁶⁷ 21 U.S.C. 823 (a)(1).

¹⁶⁸ 21 CFR 1301.74 (b).

¹⁶⁹ 21 U.S.C. 826.

assigned to it by DEA, or (2) in excess of a quota assigned to it by the DEA.¹⁷⁰

465. Upon information and belief, the RICO Defendants [i.e. as members of the RICO Enterprise (as defined below)], finding it impossible to legally achieve the level of opioid sales which they desired, systematically and fraudulently violated their statutory and legal duty to maintain effective controls against diversion of their drugs, and/or to design and operate a system to identify suspicious orders of their drugs, and/or to halt unlawful sales of suspicious orders, and/or to notify the DEA of suspicious orders.¹⁷¹ As discussed in detail herein, the RICO Defendants, as members of the RICO Enterprise (sometimes hereinafter “RICO Enterprise” or “Enterprise”) repeatedly engaged in unlawful sales of opioids which, in turn, artificially and illegally increased the annual production quotas for opioids established by the DEA.¹⁷² In doing so, the RICO Defendants worked together to cause hundreds of millions of pills to enter the illicit market, which in turn, allowed them to generate huge profits and which created the opioid epidemic which has damaged Plaintiff.

466. The conduct of the Defendants, and their continuing conduct, has occurred through legitimate and illegitimate means. The Pharmaceutical Defendants and the Distributor Defendants formed an association-in-fact enterprise and, within and among them, individual enterprises which, in turn, joined their larger association-in-fact enterprise. The RICO Defendants were associated with, conducted and participated in, and engaged in decision-making in the Enterprise. The RICO Defendants further derived substantial income from a pattern of racketeering activity and invested all or a part of that income to operate the Enterprise, whose purpose was to engage in the unlawful sales of opioids and deceive the public and federal and state regulators into believing that opioids

¹⁷⁰ 21 U.S.C. 842(b)(1) and (b)(2).

¹⁷¹ 21 U.S.C. § 823(a)(1), (b)(1); 21 C.F.R. § 1301.74(b)-(c).

¹⁷² 21 C.F.R. § 1303.11(b); 21 C.F.R. § 1303.23.

were safe and that the RICO Defendants were fulfilling their statutory obligations. As a direct result of the RICO Defendants' scheme(s), course of conduct, and pattern of racketeering activity, they were able to derive substantial revenue and profits from the American public, including in Plaintiff's Community, while entities like the Plaintiff, as well as its members and their families, experienced injury caused by the reasonably foreseeable consequences of the prescription opioid addiction epidemic. As explained in detail below, the RICO Defendants' misconduct violated Sections 1962(a), 1962(b), and 1962(c) and 1962(d).

467. Alternatively, the RICO Defendants were members of a legal entity enterprise within the meaning of 18 U.S.C. § 1961(4), through which the RICO Defendants conducted their pattern of racketeering activity in this jurisdiction and throughout the United States; to wit, the Healthcare Distribution Alliance (the "HDA").¹⁷³ The HDA is a distinct legal entity that satisfies the definition of a RICO enterprise. The HDA is a non-profit corporation formed under the laws of the District of Columbia. As a non-profit corporation, HDA qualifies as an "enterprise" within the definition set out in 18 U.S.C. § 1961(4) because it is a corporation and a legal entity.

468. Upon information and belief, each of the RICO Defendants is a member, participant, and/or sponsor of the HDA and utilized the HDA to conduct the RICO Enterprise and to engage in the pattern of racketeering activity that gives rise to this Count.

469. Each of the RICO Defendants is a legal entity separate and distinct from the HDA. And, the HDA serves the interests of distributors and manufacturers beyond the RICO Defendants. Therefore, the HDA exists separately from the RICO Enterprise, and each of the RICO Defendants exists separately from the HDA. Therefore, the HDA may serve as a RICO enterprise.

¹⁷³ See HDMA is now the Healthcare Distribution Alliance, Pharmaceutical Commerce, (June 13, 2016, updated July 6, 2016), <http://pharmaceuticalcommerce.com/business-and-finance/hdma-now-healthcare-distribution-alliance/>.

470. The legal and association-in-fact enterprises alleged in the previous and subsequent paragraphs were each used by the RICO Defendants to conduct the RICO Enterprise by engaging in a pattern of racketeering activity. Therefore, the legal and association-in-fact enterprises alleged in the previous and subsequent paragraphs are pled in the alternative and are collectively referred to as the “RICO Enterprise.”

471. At all relevant times, the RICO Enterprise: (a) had an existence separate and distinct from each individual RICO Defendant; (b) was separate and distinct from the pattern of racketeering in which the RICO Defendants engaged; (c) was an ongoing and continuing organization consisting of legal entities and/or an association-in-fact, including each of the RICO Defendants; (d) characterized by interpersonal relationships among the RICO Defendants; (e) had sufficient longevity for the enterprise to pursue its purpose; and (f) functioned as a continuing unit. *Turkette*, 452 U.S. at 580; *Boyle*, 556 U.S. at 944 (2009). Each member of the RICO Enterprise participated in the conduct of the enterprise, including patterns of racketeering activity, and shared in the skyrocketing growth of profits obtained as a result of the RICO Defendants’ scheme.

472. The RICO Enterprise functioned by selling prescription opioids. While there are some legitimate uses and/or needs for prescription opioids, the RICO Defendants, through their illegal enterprise, engaged in a pattern of racketeering activity, that involved a fraudulent scheme to increase revenue by violating State and Federal laws requiring the maintenance of effective controls against diversion of prescription opioids, and the identification, investigation, and reporting of suspicious orders of prescription opioids destined for the illicit drug market. The goal of the RICO Defendants’ scheme was to increase profits from opioid sales. But, the RICO Defendants’ profits were limited by the production quotas set by the DEA, so the RICO Defendants refused to identify, investigate, and/or report suspicious orders of their prescription opioids being diverted into the illicit drug market. The end result of this strategy was to increase and maintain artificially high production

quotas of opioids so that there was a larger pool of opioids for the RICO Defendants to manufacture and distribute for public consumption.

473. The RICO Defendants operated as an association-in-fact; alternatively, a legal entity enterprise, to improperly and illegally increase sales and revenues in order to unlawfully increase quotas set by the DEA and, in turn, to collectively profit from manufacturing and distribution of greater and greater pools of opioids each year. Each member of the RICO Enterprise participated in the conduct of the enterprise including patterns of racketeering activity. Each shared profits generated by the scheme.

474. The RICO Enterprise engaged in, and its activities affected, interstate and foreign commerce because the enterprise involved commercial activities across states lines, such as manufacture, sale, distribution, and shipment of prescription opioids throughout the Plaintiff's Community and this jurisdiction, and the corresponding payment and/or receipt of money from the sale of the same.

475. Within the RICO Enterprise, there were interpersonal relationships and common communication by which the RICO Defendants shared information on a regular basis. These interpersonal relationships also formed the organization of the RICO Enterprise. The RICO Enterprise used their interpersonal relationships and communication network for the purpose of conducting the Enterprise through a pattern of racketeering activity.

476. Each RICO Defendant communicated with the other RICO Defendants and with others in the chain of distribution on a regular basis by participating in joint lobbying efforts, trade industry organizations and contractual relations, sharing of information, observation of activities and behaviors at the market place, and by other means. For example, but not exclusively, the RICO Defendants worked together through Advocacy Groups to spend multimillions **of dollars** in lobbying across the United States. These funds were used to enable and operate the RICO

Enterprise. Defendants and their Advocacy Groups have engaged in extensive lobbying efforts to either defeat legislation restricting opioid prescribing or promote laws encouraging opioid treatment for pain.¹⁷⁴ Another non-exclusive example: upon information and belief, the RICO Defendants, through their Advocacy Groups and/or through the HDA engaged in lobbying efforts to weaken the DEA's enforcement authority.¹⁷⁵ Another non-exclusive example: Upon information and belief, the RICO Defendants were all members of the Pain Care Forum ("PCF"). According to an article¹⁷⁶ published by the Center for Public Integrity and The Associated Press, the PCF has been lobbying on behalf of the Pharmaceutical Defendants and the Distributor Defendants for more than a decade; and from 2006 through 2015 participants in the PCF spent more than \$740 million lobbying "in the nation's capital and in all 50 state houses on an array of issues, including opioid-related measures..."¹⁷⁷ Plaintiff is informed and believes that the RICO Defendants worked together as an ongoing and continuous organization throughout the existence of the Enterprise.

477. The RICO Defendants participated in the operation and management of the RICO Enterprise by directing its affairs, as described herein. The RICO Defendants exerted substantial

¹⁷⁴ See "Fueling an Epidemic Report Two: Exposing the Financial Ties Between Opioid Manufacturers and Third party Advocacy Groups" <https://www.hsgac.senate.gov/.../hsgac-minority-staff-report-fueling-an-epidemic>.

¹⁷⁵ Lenny Bernstein & Scott Higham, *Investigation: The DEA Slowed Enforcement While the Opioid Epidemic Grew Out of Control*, Wash. Post, Oct. 22, 2016, https://www.washingtonpost.com/investigations/the-dea-slowed-enforcement-while-the-opioid-epidemic-grew-out-of-control/2016/10/22/aea2bf8e-7f71-11e6-8d13-d7c704ef9fd9_story.html; Lenny Bernstein & Scott Higham, *Investigation: U.S. Senator Calls for Investigation of DEA Enforcement Slowdown Amid Opioid Crisis*, Wash. Post, Mar. 6, 2017, https://www.washingtonpost.com/investigations/us-senator-calls-for-investigation-of-dea-enforcement-slowdown/2017/03/06/5846ee60-028b-11e7-b1e9-a05d3c21f7cf_story.html; Eric Eyre, *DEA Agent: "We Had no Leadership" in WV Amid Flood of Pain Pills*, Charleston Gazette-Mail, Feb. 18, 2017, https://www.wvgazettemail.com/news/health/dea-agent-we-had-no-leadership-in-wv-amid-flood/article_928e9bcd-e28e-58b1-8e3f-f08288f539fd.html.

¹⁷⁶ Matthew Perrone, *Pro-Painkiller echo chamber shaped policy amid drug epidemic*, The Center for Public Integrity (September 19, 2017, 12:01 a.m.), <https://www.publicintegrity.org/2016/09/19/20201/pro-painkiller-echochamber-shaped-policy-amid-drug-epidemic>; "Politics of Pain: A decade of opioid lobbying", Associated Press, http://data.ap.org/projects/2016/cpi_ap_opioids/indexcpiap.html.

¹⁷⁷ *Id.* See also "Politics of pain: Drugmakers fought state opioid limits amid crisis", <https://www.publicintegrity.org/2016/09/18/20200/politics-pain-drugmakers-fought-state-opioid-limitsamid-crisis>.

control over the RICO Enterprise by their membership in the Pain Care Forum, the HDA, and through their contractual relationships.

B. CONDUCT OF THE RICO ENTERPRISE

478. During the time period alleged in this Complaint, the RICO Defendants exerted control over, conducted and participated in the RICO Enterprise by fraudulently failing to comply with their federal and state obligations to identify, investigate and report suspicious orders of opioids, and to halt such unlawful sales, all for the purpose of increasing production quotas and generating unlawful profits, as follows:

479. As set forth herein, the RICO Defendants disseminated false and misleading statements to the public regarding the safety of opioid use. They also disseminated false and misleading statements assuring their compliance with obligations to protect the public against theft, suspicious orders, diversion, over-prescriptions, mis-prescriptions and false information about opioid medications.

480. As set forth herein, the RICO Defendants paid nearly \$800 million dollars to influence local, state, and federal governments through joint lobbying efforts as part of the PCF. The RICO Defendants were all members of the PCF either directly or indirectly through the HDA. The lobbying efforts of the PCF and its members, included efforts to pass legislation making it more difficult for the DEA to suspend and/or revoke the registrations of drug manufacturers and distributors for failure to report suspicious orders of opioids.

481. As set forth herein, the RICO Defendants failed to comply with their legal duties under the CSA, including refusal and/or failure to identify, investigate or report suspicious activities of the marketplace and failure to identify and report drug diversion rings about which they had actual knowledge. The RICO Defendants worked together to ensure that opioid

production quotas continued to increase, allowing them to generate more and more profits from their illegal Enterprise. For example, but not exclusively, the Pharmaceutical Defendants lobbied the DEA to increase Aggregate Production Quotas, year after year, by submitting “net disposal information” that the Pharmaceutical Defendants knew included sales that were suspicious and involved the diversion of opioids that had not been properly investigated or reported by the RICO Defendants. It is averred that since the DEA was unaware that false and inaccurate “net disposal information” was being submitted, the DEA unwittingly increased the production quotas for prescription opioids.

482. Upon information and belief, the RICO Defendants engaged in an industry-wide practice of paying rebates and chargebacks to incentivize unlawful opioid prescription sales. As set forth hereinabove, a chargeback is a payment made by a manufacturer to a distributor after the distributor sells the manufacturer’s product at a price below a specified rate. After a distributor sells a manufacturer’s product to a pharmacy, for example, the distributor requests a chargeback from the manufacturer and, in exchange for the payment, the distributor identifies to the manufacturer the product, volume and the pharmacy to which it sold the product. Moreover, as a result, the Pharmaceutical Defendants knew – just as the Distributor Defendants knew – the volume, frequency, and pattern of opioid orders being placed and filled. The Pharmaceutical Defendants built receipt of this information into the payment structure for the opioids provided to the Distributor Defendants. The Pharmaceutical Defendants used the chargeback program to acquire detailed, high-level data regarding sales of the opioids they manufactured. And the Pharmaceutical Defendants used this high-level information to direct the Distributor Defendants’ sales efforts to regions where prescription opioids were selling in larger volumes. Thus, like the Distributor Defendants, the Pharmaceutical Defendants had access to and possession of the

information necessary to monitor, report, and prevent suspicious orders and to prevent diversion.¹⁷⁸

483. The RICO Defendants worked together to control the flow of information and influence state and federal governments and political candidates to pass legislation that was pro-opioid. The Pharmaceutical and Distributor Defendants did this in pertinent part through their participation in the PCF and HDA.

484. The RICO Defendants exerted substantial control over the RICO Enterprise by their membership in the organizations set forth herein and through their contractual relationships (such as, but not exclusively, rebate or chargeback agreements).

485. As RICO scheme participants, the RICO Defendants engaged in intentional steps to conceal their scheme. As set forth herein, they used unbranded advertisements, third parties, Advocacy Groups, and other methods to disguise the sources of their fraudulent statements, increase the effectiveness of their misinformation campaign, deceive hospitals, doctors and patients, and sell more and more quantities of opioids.

C. PATTERN OF RACKETEERING ACTIVITY

486. In pertinent part, the term “racketeering activity” is defined as “(A) any act or threat involving ... or dealing in a controlled substance or listed chemical (as defined in section 102 of the Controlled Substances Act), which is chargeable under State law and punishable by imprisonment for more than one year; ... (B) any act which is indictable under any of the following provisions of title 18, United States Code: ... Section 1341 (relating to mail fraud), section 1343 (relating to wire fraud), ... (D) any offense involving fraud connected with a case under title 11 (except a case under section 157 of this title), fraud in the sale of securities, *or the felonious*

¹⁷⁸ Administrative Memorandum of Agreement between the United States Department of Justice, the Drug Enforcement Agency, and Mallinckrodt, plc. and its subsidiary Mallinckrodt, LLC, *Justice.gov*, U.S. Dept. of Justice, July 2017, p. 5. Web. 25 Oct. 2017; <https://www.justice.gov/usao-edmi/press-release/file/986026/download>.

manufacture, importation, receiving, concealment, buying, selling, or otherwise dealing in a controlled substance or listed chemical (as defined in section 102 of the Controlled Substances Act), punishable under any law of the United States, ...” 18 U.S.C. § 1961(1)(A)-(D) (emphasis supplied).

487. The RICO Defendants conducted and participated in the conduct of the RICO Enterprise through a pattern of racketeering activity as defined in 18 U.S.C. § 1961(1)(B), including mail fraud (18 U.S.C. § 1341) and wire fraud (18 U.S.C. § 1343); and 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 section 102 of the Controlled Substance Act), punishable under any law of the United States.

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

489. The RICO Defendants committed, conspired to commit, and/or aided and abetted in the commission of at least two predicate acts of racketeering activity (i.e. violations of 18 U.S.C. §§ 1341 and 1343), the last of which occurred within ten years after the commission of the prior act of racketeering activity. 18 U.S.C. § 1961(5).¹⁷⁹ The multiple acts of racketeering activity that the RICO Defendants committed, or aided and abetted in the commission of, were related to each other, posed a threat of continued racketeering activity, and therefore constitute a “pattern of racketeering activity.” The racketeering activity was made possible by the RICO Defendants’

¹⁷⁹ In fact, upon information and belief, the last incident of racketeering activity occurred within five years of the commission of a prior incident of racketeering.

regular use of the facilities, services, distribution channels, and employees of the RICO Enterprise. The RICO Defendants participated in the scheme to defraud by using mail, telephone and the Internet to transmit mailings and wires in interstate or foreign commerce.

490. 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.

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

- a. Mail Fraud: The RICO Defendants violated 18 U.S.C. § 1341 by sending or receiving, or by causing to be sent and/or received, materials via U.S. mail or commercial interstate carriers for the purpose of executing the unlawful scheme to design, manufacture, market, and sell the prescription opioids by means of false pretenses, misrepresentations, promises, and omissions.
- b. Wire Fraud: The RICO Defendants violated 18 U.S.C. § 1343 by transmitting and/or receiving, or by causing to be transmitted and/or received, materials by wire for the purpose of executing the unlawful scheme to design, manufacture, market, and sell the prescription opioids by means of false pretenses,

492. Each time a participant in the RICO scheme distributed (or distributes) a false statement by mail or wire, or via the Internet, it committed (or commits) a separate act of mail or wire fraud contrary to 18 USC §§ 1341 and 1342 respectively.

493. Each RICO Defendant used (or uses) thousands of pieces of interstate mail and of interstate wire communications and email to accomplish their scheme through virtually uniform misrepresentations, concealments, false and material omissions, and deceptions concerning opioid products, and regarding their compliance with their mandatory reporting requirements. The pattern was (and is) one of racketeering activity intentionally committed and participated in, by each said Defendant, to carry out their unlawful goal of selling prescription opioids without reporting

suspicious orders or the diversion of opioids into the illicit market.

494. The RICO Defendants' use of the mail and wires includes, but is not limited to, the transmission, delivery, or shipment of the following by the Manufacturers, Distributors, or third parties that were foreseeably caused to be sent as a result of the RICO Defendants' illegal scheme, including but not limited to:

- a. The prescription opioids themselves;
- b. Documents and communications that facilitated the manufacture, purchase and unlawful sale of prescription opioids;
- c. Defendants' DEA registrations;
- d. Documents and communications that supported and/or facilitated Defendants' DEA registrations;
- e. Documents and communications that supported and/or facilitated the Defendants' request for higher aggregate production quotas, individual production quotas, and procurement quotas;
- f. Defendants' records and reports that were required to be submitted to the DEA pursuant to 21 U.S.C. § 827;
- g. Documents and communications related to the Defendants' mandatory DEA reports pursuant to 21 U.S.C. § 823 and 21 C.F.R. § 1301.74;
- h. Documents intended to facilitate the manufacture and distribution of Defendants' prescription opioids, including bills of lading, invoices, shipping records, reports and correspondence;
- i. Documents for processing and receiving payment for prescription opioids;
- j. Payments from the Distributors to the Manufacturers;
- k. Rebates and chargebacks from the Manufacturers to the Distributors;
- l. Payments to Defendants' lobbyists through the Pain Care Forum;
- m. Payments to Defendants' trade organizations, like the HDA, for memberships and/or sponsorships;
- n. Deposits of proceeds from Defendants' manufacture and distribution of prescription opioids; and

o. Other documents and things, including electronic communications.

495. Each Defendant was a “registrant,” as alleged herein, and required to comply with the CSA. Each Defendant knowingly and intentionally failed and refused to do so and conspired with the others to conceal their non-compliance and accomplish their scheme.

D. DAMAGES

496. There is a grave and immediate threat of continuing and ongoing wrongful conduct and harm by the RICO Defendants, who have paid massive fines and penalties (some of which are set forth herein), but whose subsequent actions evidence that fines and penalties are merely a cost of doing business in an industry that generates billions of dollars in revenue.

497. Defendants’ misconduct alleged herein is ongoing and persistent.

498. The RICO Defendants’ violations of law and their pattern of racketeering activity foreseeably, directly, and proximately caused, and continues to cause, Plaintiff injury in its business and property because Plaintiff its members and their families have has incurred increased costs associated with the opioid epidemic, as described above in allegations expressly incorporated herein by reference. But for the RICO Defendants’ conduct, Plaintiff, its members and their families would not have suffered the damages alleged herein, such as but not limited to the following:

- a. Costs associated with past efforts to eliminate the hazards to public health and safety;
- b. Costs associated with permanently eliminating the hazards to public health and safety and abate the public nuisance;
- c. Costs of rehabilitation and medical treatment for substance abuse;
- d. Costs associated with additional care and needs for children within the Tribe born addicted to prescription opioids and other controlled substances;
- e. Costs associated with treatment of members necessary to cope with short and long-term emotional and physical damage;

- f. Costs associated with long-term opioid abuse treatment;
- g. Costs associated with foster care and/or adoption.
- h. Costs for providing mental-health services, treatment, counseling, rehabilitation services, and social services to victims of the opioid epidemic and their families;
- i. Costs for providing treatment of infants born with opioid-related medical conditions, or born dependent on opioids due to drug use by mother during pregnancy;
- j. Costs associated with providing care for children whose parents suffer from opioid-related disability or incapacitation, including foster care and other social services cost;
- k. Losses caused by diminished property values within Tribe Communities in the form of decreased business investment and tax revenue.
- l. Other increased costs associated with opioid addiction.

499. Plaintiff is the most directly harmed entity and there is no other Plaintiff better suited to seek a remedy for the economic harms at issue here.

500. Plaintiff seeks all legal and equitable relief as allowed by law, including *inter alia* actual damages, treble damages, equitable relief, forfeiture as deemed proper by the Court, attorney fees and all costs and expenses of suit and pre- and post-judgment interest.

501. Pursuant to 18 USC § 1964 (c) Plaintiff is further entitled to recover treble damages.

COUNT X
LOUISIANA RACKETEERING ACT
La. Rev. Stat. Ann. § 15:1351 *et seq.*
(Against All Defendants)

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

503. Plaintiff has standing to bring this action as a “person who is injured by reason of any violation of the provisions of R.S. 15:1353.” La. Rev. Stat. Ann. § 15:1356(E).

504. The Louisiana Racketeering Act prohibits “committing, attempting to commit, conspiring to commit, or soliciting, coercing, or intimidating another person to commit any crime that is punishable under ... the Uniform Controlled Dangerous Substances Law,” among other enumerated acts. La. Rev. Stat. Ann. § 15:1352(A). Opioids are classified as both Schedule I and Schedule II drugs under Louisiana law. La. Rev. Stat. Ann. § 40:964. The Louisiana Uniform Controlled Dangerous Substances Law explicitly provides that “[p]hysical dependence is an expected result of opioid use.” La. Rev. Stat. Ann. § 40:961(29.1). Unauthorized manufacture, distribution, or dispensing of opioids constitute predicate acts of racketeering activity under the Louisiana Racketeering Act. La. Rev. Stat. Ann. § 15:1352(A)(13) (citing La. Rev. Stat. Ann. § 40:967(A)).

505. The RICO Defendants violated section 15:1353 of the Louisiana Racketeering Act by knowingly, intentionally, and unlawfully aiding and abetting each other to commit violations of the Louisiana Uniform Controlled Dangerous Substances Law.

506. The RICO Defendants also violated section 15:1353 of the Louisiana Racketeering Act by knowingly receiving “proceeds derived, directly or indirectly, from a pattern of racketeering activity to use or invest, whether directly or indirectly, any part of such proceeds, or the proceeds derived from the investment or use thereof, in the acquisition of any title to, or any right, interest, or equity in immovable property or in the establishment or operation of any enterprise.” La. Rev. Stat. Ann. § 15:1353(A).

507. The RICO Defendants conducted the RICO Enterprise, as defined above, through a pattern of racketeering activity in violation of Section 15:1353(C) and have conspired to violate Section 15:1353(C) in violation of Section 15:1353(D). La. Rev. Stat. Ann. § 15:1353.

508. The RICO Defendants violated Section 15:1353(D) by knowingly, intentionally,

and unlawfully aiding and abetting each other and the RICO Enterprise and conspired to conduct and participate, directly and indirectly, in the conduct of the RICO Enterprise, through the pattern of racketeering activity described herein. La. Rev. Stat. Ann. § 15:1353(D).

509. The RICO Defendants' RICO Enterprise existed as an "enterprise" as defined in Section 15:1352(B). The RICO Defendants' RICO Enterprise existed as an association in fact and included unlawful as well as lawful enterprises. La. Rev. Stat. Ann. § 15:1352(B).

510. As described above and as fully incorporated herein, the violations set forth herein, which have been continuous in nature, constitute "racketeering activity" within the meaning of sections 15:1352(C) and 15:1353, with at least two such acts of racketeering activity having occurred within five years of each other.¹⁸⁰

511. The RICO Defendants' violations of law and their pattern of racketeering activity foreseeably, directly, and proximately caused, and continues to cause, Plaintiff injury in its business and property because Plaintiff paid for costs (in excess of the norm) associated with the opioid epidemic, as described above in allegations expressly incorporated herein by reference.

512. Defendants' misconduct alleged herein is ongoing and persistent.

513. The RICO Defendants' violations of law and their pattern of racketeering activity foreseeably, directly, and proximately caused Plaintiff injury in its business and property because Plaintiff, its members, and their families have incurred increased costs associated with the opioid epidemic, as described above in allegations expressly incorporated herein by reference. But for the RICO Defendants' conduct, Plaintiff, its members and their families would not have suffered the damages alleged herein, such as but not limited to the following:

- a. Costs associated with past efforts to eliminate the hazards to public health and safety;

¹⁸⁰ See note 170, *supra*.

- b. Costs associated with permanently eliminating the hazards to public health and safety and abate the public nuisance;
- c. Costs of rehabilitation and medical treatment for substance abuse;
- d. Costs associated with additional care and needs for children within the Tribe born addicted to prescription opioids and other controlled substances;
- e. Costs associated with treatment of members necessary to cope with short and long-term emotional and physical damage;
- f. Costs associated with long-term opioid abuse treatment;
- g. Costs associated with foster care and/or adoption.
- h. Costs for providing mental-health services, treatment, counseling, rehabilitation services, and social services to victims of the opioid epidemic and their families;
- i. Costs for providing treatment of infants born with opioid-related medical conditions, or born dependent on opioids due to drug use by mother during pregnancy;
- j. Costs associated with providing care for children whose parents suffer from opioid-related disability or incapacitation, including foster care and other social services cost;
- k. Losses caused by diminished property values within Tribe Communities in the form of decreased business investment and tax revenue.
- l. Other increased costs associated with opioid addiction.

514. Plaintiff is the most directly harmed entity and there is no other Plaintiff better suited to seek a remedy for the economic harms at issue here.

515. Plaintiff seeks all legal and equitable relief as allowed by law, including *inter alia* actual damages, treble damages, equitable relief, forfeiture as deemed proper by the Court, attorney fees and all costs and expenses of suit and pre- and post-judgment interest. La. Rev. Stat. Ann. § 15:1356(E).

COUNT XI
LANHAM ACT
15 U.S.C.A. 1125 (a)(1)(B)
(Against All Defendants)

516. Plaintiff incorporates by reference all other paragraphs of this Complaint as if fully set forth herein, and further alleges as follows.

517. Each Defendant, as manufacturer or distributor, did, in connection with opioids, their manufacture, testing, distribution and delivery, used in commerce, in connection therewith, words, terms, names, symbols and devices or a combination thereof, as well as false and/or misleading descriptions of fact and/or false and misleading representations of fact. These actions were and are likely to cause confusion or to cause mistake or to deceive as to the approval of their goods or commercial activities by another person. In addition, in commercial advertising or promotion the Defendants misrepresented the nature, characteristics, and/or qualities of the opioids they sold and/or distributed, all in violation of 15 U.S.C. 1125 (a)(1)(B).

518. Defendants' misconduct alleged herein is ongoing and persistent.

519. The aforementioned violations of the Lanham Act foreseeably, directly, and proximately caused, and continues to cause, Plaintiff, its members and their families injury in its business and property because Plaintiff has incurred increased costs associated with the opioid epidemic, as described above in allegations expressly incorporated herein by reference. But for the Defendants' violation of the Lanham Act, Plaintiff its members and their families would not have suffered the damages alleged herein, such as but not limited to the following:

- a. Costs associated with past efforts to eliminate the hazards to public health and safety;
- b. Costs associated with permanently eliminating the hazards to public health and safety and abate the public nuisance;

- c. Costs of rehabilitation and medical treatment for substance abuse;
- d. Costs associated with additional care and needs for children within the Tribe born addicted to prescription opioids and other controlled substances;
- e. Costs associated with treatment of members necessary to cope with short and long-term emotional and physical damage;
- f. Costs associated with long-term opioid abuse treatment;
- g. Costs associated with foster care and/or adoption.
- h. Costs for providing mental-health services, treatment, counseling, rehabilitation services, and social services to victims of the opioid epidemic and their families;
- i. Costs for providing treatment of infants born with opioid-related medical conditions, or born dependent on opioids due to drug use by mother during pregnancy;
- j. Costs associated with providing care for children whose parents suffer from opioid-related disability or incapacitation, including foster care and other social services cost;
- k. Losses caused by diminished property values within Tribe Communities in the form of decreased business investment and tax revenue.
- l. Other increased costs associated with opioid addiction.

520. Plaintiff seeks all legal and equitable relief as allowed by law, including inter alia actual damages, treble damages, equitable relief, forfeiture as deemed proper by the Court, attorney fees and all costs and expenses of suit and pre- and post-judgment interest.

JURY DEMAND

521. Plaintiff hereby demands trial by jury.

RELIEF

WHEREFORE, Plaintiff, Four Winds Tribe - Louisiana Cherokee, prays that the Court:

A. Enter Judgment in favor of the Plaintiff against each of the Defendants jointly, severally and *in solido* for all damages hereinabove alleged and which have been alleged to have been caused by the actions of the Defendants;

B. Enjoin the Defendants and their employees, officers, directors, agents, successors, assignees, merged or acquired predecessors, parent or controlling entities, subsidiaries, and all other persons acting in concert or participation with it, from engaging in unfair or deceptive practices in violation of law and ordering temporary, preliminary or permanent injunction;

C. Award treble damages, penalties and costs pursuant to La. Rev. Stat. Ann. §51:1409(A).

D. Award restitution, disgorgement of profits, actual damages, treble damages, forfeiture as deemed proper by the Court, and attorney fees and all costs and expenses of suit pursuant to Plaintiff's LUTPA claims;

E. Award compensatory damages in favor of the Plaintiff for past and future costs to abate the ongoing public nuisance caused by the opioid epidemic, including restitution;

F. Award attorney fees pursuant to La. Civil Code Art. 1958;

G. 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;

H. 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 Lanham Act claims;

I. Order Defendants to fund an "abatement fund" for the purposes of abating the opioid nuisance;

J. Award the Plaintiff all damages incurred by it and caused by the opioid epidemic, including but not limited to: (1) costs for providing medical care, and other treatments for Tribe members and their families suffering from opioid-related addiction or disease, including overdoses and deaths; (2) costs for providing treatment, counseling, and rehabilitation services; (3) costs for providing treatment of infants born within the Tribe with opioid-related medical conditions; (4) costs for providing care for children whose parents suffer from opioid-related disability or incapacitation and costs for providing treatment of infants born with opioid-related medical conditions, or born dependent on opioids due to drug use by mother during pregnancy; (5) cost of establishing and maintaining such program or programs to provide needed treatment, counselling and/or rehabilitation services to persons for members of the Tribe and their families affected by opioid addiction; and (6) any and all other increased costs associated with opioid addiction.

K. Award the cost of investigation, reasonable attorney fees, and all costs and expenses, pre-judgment and post-judgment interest;

L. Award all such other relief including damages as provided by law and/or as the Court deems appropriate and just.

This 14th day of June, 2019.

Respectfully submitted,

/s/ Ralph R. Alexis, III

Ralph R. Alexis, III, La. Bar No. 02379

Glenn B. Adams, La. Bar No. 02316

Corey D. Moll, La. Bar No. 34245

PORTEOUS, HAINKEL AND JOHNSON, LLP

704 Carondelet Street

New Orleans, LA 70130

Phone: (504) 581-3838

Facsimile: (504) 581-4069

ralexis@phjlaw.com

gadams@phjlaw.com

cmoll@phjlaw.com

Justin L. Winch, La. Bar No. 36323

WINCH LAW FIRM, L.L.C

1713 N. Dorgenois Street

New Orleans, Louisiana 70119

Phone: (504) 214-3400

Facsimile: (831) 295-6497

justin.winch@winchlawfirm.com

*Counsel for Plaintiff, Four Winds Tribe
Louisiana Cherokee*

SERVICE OF PROCESS:

By waiver, pursuant to Rule 4(d) of the F.R.CP.