UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF MICHIGAN

CITY OF FLINT, MICHIGAN, a municipal corporation **Plaintiff,** **v.** **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 PHARMACEUTICALS, INC. n/k/a JANSSEN PHARMACEUTICALS, INC.; JANSSEN PHARMACEUTICA, INC. n/k/a JANSSEN PHARMACEUTICALS, INC.; NORAMCO, INC.; ENDO HEALTH SOLUTIONS, INC.; ENDO PHARMACEUTICALS, INC.; ALLERGAN PLC f/k/a ACTAVIS, PLS; WATSON PHARMACEUTICALS, INC. f/k/a ACTAVIS, INC.; WATSON LABORATORIES, INC.; ACTAVIS, LLC; ACTAVIS PHARMA, INC. f/k/a WATSON PHARMA, INC.; MALLINCKRODT, PLC; MALLINCKRODT LLC; MCKESSON CORPORATION; CARDINAL HEALTH, INC.; AND AMERISOURCEBERGEN DRUG CORPORATION;** **Defendants.**	)	**Civil Action No:** **COMPLAINT FOR (1) PUBLIC NUISANCE; (2) NEGLIGENCE PER SE; (3) NEGLIGENCE; and (4) VIOLATIONS OF RACKETEER INFLUENCED AND CORRUPT ORGANIZATIONS ACT**

COMPLAINT AND DEMAND FOR JURY TRIAL

TAG-ALONG ACTION

Plaintiff, the City of Flint, Michigan ("Plaintiff"), brings this Complaint against Defendants 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 Pharmaceuticals, Inc. n/k/a Janssen Pharmaceuticals, Inc.; Janssen Pharmaceutica Inc. n/k/a Janssen Pharmaceuticals, Inc.; Noramco, Inc.; Endo Health Solutions Inc.; Endo Pharmaceuticals, Inc.; Allergan PLC f/k/a Actavis PLS; Watson Pharmaceuticals, Inc. n/k/a Actavis, Inc.; Watson Laboratories, Inc.; Actavis, LLC; Actavis Pharma, Inc. f/k/a Watson Pharma, Inc.; Mallinckrodt PLC; Mallinckrodt LLC; McKesson Corporation; Cardinal Health, Inc.; and AmerisourceBergen Drug Corporation (collectively "Defendants"). This civil action is a potential tag-along action and, in accordance with 28 U.S.C. §14077, should be transferred to the United States District Court for the Northern District of Ohio to be included in *In re: National Prescription Opiate Litigation*, MDL No. 2804, for purposes of coordinated and consolidated pretrial proceedings (Hon. Dan A. Polster). Plaintiff alleges as follows:

I. INTRODUCTION

1. Plaintiff, by and through undersigned counsel, brings this civil action to eliminate the nuisance caused by the Defendants' conduct which has created a hazard to public health and safety and to recoup monies that have been spent because of Defendants' false, deceptive, and unfair marketing and/or unlawful diversion of prescription opioids. Such economic damages were foreseeable to Defendants and were sustained because of Defendants intentional and/or unlawful actions and omissions.

2. The use of highly addictive narcotic drugs such as oxycodone, hydrocodone, methadone,

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

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

4. The opioid epidemic has been unsparing, and undiscriminating, in the victims it has claimed. Opioids—recklessly sold to treat virtually any ailment—have destroyed the lives of countless men and women who had the misfortune of suffering from back pain, arthritis, workplace injuries and a countless array of other relatively minor and term-limited painful conditions. Opioids have devastated families whose teenaged sons and daughters were killed by accidental overdoses. America's raging opioid epidemic has turbocharged the heroin trade, as people addicted to prescription opioids often end up turning to highly potent street drugs.

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

[1] As used herein, the term "opioid" refers to the entire family of opiate drugs including natural, synthetic, and semi-synthetic opiates.

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

7. The misinformation campaign worked. Across the country, doctors began prescribing highly addictive opioids for ailments ranging from neck pain to headaches. At the same time, in response to the aggressive marketing campaigns, public demand for opioids soared. That demand, in turn, created a cottage industry of "pill mills," where unscrupulous doctors handed out opioid prescriptions for even the most minor (claimed) ailments, without any consideration of the drugs' highly addictive properties.

8. With stunning speed, and as a direct result of drug manufacturers' deceit, America quickly became awash in prescription opioids. Neither the State of Michigan nor the City of Flint was spared from the flood of highly addictive opioids. Indeed, by 2012, there were more opioid prescriptions written in the State of Michigan than the State has residents.[2]

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

10. If corporate actors had only followed federal law, however, the heavy flow of

[2] Ctr. for Disease Control & Prevention Opioid Painkiller Prescribing Infographic, CDC.GOV (July 1, 2014), https://www.cdc.gov/vitalsigns/opioid-prescribing/infographic.html#map.

prescription opioids into American homes, schools, towns and cities might have been slowed to a trickle. Aware that opioids can have devastating effects if diverted to the black market, the U.S. Congress created a system requiring any drug manufacturer, distributor, or retailer to: (1) report suspicious orders of prescription opioids to the Drug Enforcement Administration ("DEA"); and (2) perform required due diligence prior to filling any suspicious orders. *See* 21 U.S.C. § 823(b)(1); 21 C.F.R. § 1301.74(b). Had those requirements been followed, manufacturers, distributors and retailers of opioids could have dramatically reduced opioid use.

11. Instead, manufacturers and distributors opted not to follow federal law.

12. When presented with absurdly large opioid orders—orders which, in Michigan, *exceeded the population of the state*, on aggregate—manufacturers and distributors simply looked the other way.

13. In prioritizing profit over legal duty, the prescription drug industry wreaked havoc on the lives of countless Americans. Along the way, the industry drained the coffers of local governmental entities across the country, forcing municipalities to shoulder increased costs associated with the opioid epidemic.

14. Plaintiff, City of Flint, has been uniquely and disproportionately impacted by the plague of opioid addiction. Flint is the largest city and county seat of Genesee County, Michigan. Flint is being forced to expend city resources combatting the opioid epidemic and its cascading effects. As a direct result of Defendants' corporate malfeasance, the City's medical professionals and first responders must now prioritize combatting drug overdoses, including opioid overdoses. The City's law-enforcement officers are engaged in a pitched battle against the heroin trade, and against criminal enterprises illegally trading in prescription opioids. The City's medical professionals must now spend their time and resources combatting the multifaceted harms that drug addiction imposes on families, children, and infants.

15. As in communities across the country, the adverse effects of opioid addiction radiate across the City of Flint. When workers in the City become addicted, it decreases their productivity and

their earning power, and ultimately harms the local economy. When heads of households fall victim to the opioid epidemic, the children that rely on them fall victim as well— increasing the strain on social-service providers. The opioid epidemic has, perhaps, its most harmful effects in neighborhoods where drugs are sold. The illegal drug trade often invites violence and decimates the quality of life for innocent families living nearby. Many choose to leave. The opioid epidemic has contributed to the destabilization of communities and neighborhoods in Flint and elsewhere, and, in turn, has deprived the City of Flint of tax revenue and increased the costs of delivering city services.

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

II. PARTIES

A. City of Flint

17. Plaintiff, the City of Flint ("Plaintiff", "Flint", "City", or "Flint"), is a chartered municipal corporation with offices located in Flint, Michigan.

18. Under Michigan's Home Rule City Act, "[e]ach organized city shall be a body corporate." *See* Mich. Comp. Laws ("MCL") § 117.1. Under MCL § 600.2051, a corporate body can sue in its corporate name. *Id.*

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

§ 1964(c).

20. Plaintiff directly and foreseeably sustained the economic damages alleged herein.

21. Defendants' conduct has imposed an extraordinary financial burden on Plaintiff, for which Plaintiff seeks relief. Plaintiff has sustained, and continues to sustain, damages including, *inter alia:* (1) municipal costs for providing additional health and mental-health services to employees suffering from opioid-related addiction, opioid-related diseases, and opioid dependence, overdose and death; (2) municipal costs for providing additional law-enforcement services, additional emergency-response services, and additional judicial and public safety services relating to the opioid epidemic; and (3) municipal costs for providing additional treatment and care for minors affected by parents and/or guardians suffering from prescription opioid-related addiction, dependence, overdose and death. These are only a few of the many additional costs the opioid epidemic has imposed on Plaintiff—while Defendants' bottom lines have soared.

22. Plaintiff has suffered, and continues to suffer, damages as a direct and foreseeable result of Defendants' reckless, intentional and unlawful conduct, as well as Defendants' conduct that was, at times, fraudulent.

23. Plaintiff additionally seeks the means to abate the ongoing opioid epidemic—an epidemic that was created by Defendants' reckless, intentional and/or unlawful conduct.

B. Manufacturer Defendants

24. The Manufacturer Defendants are defined below. At all relevant times, the Manufacturer 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 Manufacturer Defendants, at all times, have manufactured and sold prescription opioids without fulfilling their legal duty to prevent diversion and report suspicious orders.

25. 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 is a Delaware corporation with its principal place of business in Stamford, Connecticut (collectively, "Purdue").

26. 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. OxyContin is Purdue's best-selling opioid. 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).

27. Cephalon Inc. is a Delaware corporation with its principal place of business in Frazer, Pennsylvania. Teva Pharmaceutical Industries, Ltd. ("Teva Ltd.") is an Israeli corporation with its principal place of business in Petah Tikva, Israel. In 2011, Teva Ltd. acquired Cephalon, Inc. Teva Pharmaceuticals USA, Inc. ("Teva USA") is a Delaware corporation and is a wholly owned subsidiary of Teva Ltd. in Pennsylvania. Teva USA acquired Cephalon in October 2011.

28. Cephalon, Inc. manufactures, promotes, sells, and distributes opioids such as Actiq and Fentora in the United States. Actiq has been approved by the FDA only for the "management of break through cancer pain inpatients 16 years and older with malignancies who are already receiving and who are tolerant to around-the-clock opioid therapy for the underlying persistent cancer pain."[3] Fentora has been approved by the FD A only for the "management of break through pain in cancer patients 18 years of age and older who are already receiving and who are tolerant to around-the-clock opioid therapy for their underlying persistent cancer pain."[4] 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.[5]

[3] *Highlights of Prescribing Information, ACTIQ® (fentanyl citrate) oral transmucosal lozenge, CII* (2009), https://www.accessdata.fda.gov/drugsatfda_docs/label/2009/020747s030lbl.pdf.
[4] *Highlights of Prescribing Information, FENTORA® (fentanyl citrate) buccal tablet, CII* (2011), https://www.accessdata.fda.gov/drugsatfda_docs/label/2012/021947s015lbl.pdf.
[5] Press Release, U.S. Dep't of Justice, Biopharmaceutical Company, Cephalon, to Pay $425 Million & Enter Plea to

29. Teva Ltd., Teva USA, and Cephalon, Inc. work together closely to market and sell Cephalon products in the United States. Teva Ltd. conducts all sales and marketing activities for Cephalon in the United States through Teva USA and has done so since its October 2011 acquisition of Cephalon. Teva Ltd. and Teva USA hold out Actiq and Fentora as Teva products to the public. Teva USA sells all former Cephalon branded products through its "specialty medicines" division. The FDA-approved prescribing information and medication guide, which is distributed with Cephalon opioids, discloses that Teva USA submitted the guide, and directs physicians to contact Teva USA to report adverse events.

30. All of Cephalon's promotional websites, including those for Actiq and Fentora, display Teva Ltd.'s logo.[6] Teva Ltd.'s financial reports list Cephalon's and Teva USA's sales as its own, and its year-end report for 2012 – the year immediately following the Cephalon acquisition–attributed a 22% increase in its specialty medicine sales to "the inclusion of a full year of Cephalon's specialty sales," including *inter alia* sales of Fentora®.[7] Through interrelated operations like these, Teva Ltd. operates in the United States through its subsidiaries Cephalon and Teva USA. The United States 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 Pharmaceutical Industries, Ltd., Teva Pharmaceuticals USA, Inc., and Cephalon, Inc. are referred to as "Cephalon."

31. 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

Resolve Allegations of Off-Label Marketing (Sept. 29, 2008),

[6] *E.g.*, ACTIQ, http://www.actiq.com/(displaying logo at bottom-left) (last visited Aug. 21,2017).

[7] Teva Ltd., Annual Report (Form 20-F) 62 (Feb. 12, 2013), http://annualreports.com/HostedData/AnnualReportArchive/t/NASDAQ_TEVA_2012.pdf.

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 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 Pharmaceutica, Inc., Noramco, and J&J are referred to as "Janssen."

32. Janssen manufactures, promotes, sells, and distributes drugs in the United States, 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.

33. 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."

34. Endo develops, markets, and sells prescription drugs, including the opioids Opana/Opana ER, Percodan, Percocet, and Zydone, in the United States. 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, by itself and through its subsidiary, Qualitest Pharmaceuticals, Inc.

35. 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 (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. 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."

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

37. Mallinckrodt, PLC is an Irish public limited company headquartered in Staines-upon-Thames, United Kingdom, with its U.S. headquarters in St. Louis, Missouri.

38. 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. Mallinckrodt, PLC and Mallinckrodt, LLC are referred to as "Mallinckrodt."

39. Mallinckrodt manufactures, markets, and sells drugs in the United States including generic oxycodone, of which it is one of the largest manufacturers. In July 2017, Mallinckrodt agreed to pay $35 million to settle allegations brought by the Department of Justice that it failed to detect and notify the DEA of suspicious orders of controlled substances.

C. Distributor Defendants

40. The Distributor Defendants also 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 duty of wholesale drug distributors to detect and warn of diversion of dangerous drugs for non-medical purposes. The Distributor Defendants universally failed to comply with federal and/or state law. The Distributor Defendants are engaged in "wholesale distribution," as defined under state and federal law.

41. Plaintiff alleges the unlawful conduct by the Distributor Defendants is responsible for the volume of prescription opioids plaguing Plaintiff's Community.

42. McKesson Corporation ("McKesson") at all relevant times, operated as a licensed pharmacy wholesaler in Michigan. McKesson is a Delaware corporation. McKesson has its principal place of business located in San Francisco, California.

43. Cardinal Health, Inc. ("Cardinal") at all relevant times, operated as a licensed pharmacy wholesaler in Michigan. Cardinal's principal office located in Dublin, Ohio.

44. AmerisourceBergen Drug Corporation ("AmerisourceBergen") at all relevant times, operated as a licensed pharmacy wholesaler in Michigan.

45. The data which reveals and/or confirms the identity of each wrongful opioid distributor is hidden from public view in the DEA's confidential ARCOS database. *See Madel v. US DOJ*, 784

F.3d 448 (8th Cir.2015). Neither the DEA[8] nor the wholesale distributors[9] will voluntarily disclose the data necessary to identify with specificity the transactions which will form the evidentiary basis for the claims asserted herein.

46. Plaintiff has named the three (3) wholesale distributors (i.e., AmerisourceBergen Drug Corporation, Cardinal Health, Inc., and McKesson Corporation) which dominate 85% of the market share for the distribution of prescription opioids. The "Big 3" are Fortune 500 corporations listed on the New York Stock Exchange whose principal business is the nationwide wholesale distribution of prescription drugs. *See Fed. Trade Comm'n v. Cardinal Health, Inc.*, 12 F. Supp.2d 34 (D.D.C.1998) (describing Cardinal Health, Inc., McKesson Corporation, and AmerisourceBergen Drug Corporation predecessors). Each has been investigated and/or fined by the DEA for the failure to report suspicious orders. Plaintiff has reason to believe each has engaged in unlawful conduct which resulted in the diversion of prescription opioids into our community and that discovery will likely reveal others who likewise engaged in unlawful conduct.

47. Each of the Manufacturer Defendants and Distributor Defendants are collectively referred to herein as the "Defendants."

III. JURISDICTION AND VENUE

48. This Court has subject matter jurisdiction over this action in accordance with 28 U.S.C. § 1332(a). Complete diversity exists between Plaintiff (a citizen of the State of Michigan) and Defendants (citizens of states other than Michigan). The amount in controversy exceeds the sum or value of $75,000, exclusive of interest and costs.

49. This Court also has subject matter jurisdiction under 28 U.S.C. § 1331 based upon the

[8] *See* Declaration of Katherine L. Myrick, Chief, Freedom of Information (FOI)/Privacy Act Unit("SARF"), FOI, Records Management Section ("SAR"), Drug Enforcement Administration (DEA), United States Department of Justice (DOJ), *Madel v. US DOJ*, Case 0:13-cv-02832-PAM-FLN, (Document 23) (filed 02/06/14) (noting that ARCOS data is "kept confidential by the DEA").

[9] *See* Declaration of Tina Lantz, Cardinal Health VP of Sales Operation, *Madel v. US DOJ*, Case 0:13-cv-02832-PAM-FLN, (Document93) (filed 11/02/16) ("Cardinal Health does not customarily release any of the information identified by the DEA notice letter to the public, nor is the information publicly available. Cardinal Health relies on DEA to protect its confidential business information reported to the Agency.").

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

50. Venue is proper within this District pursuant to 28 U.S.C. § 1391, as this District is a judicial district where Defendants are subject to personal jurisdiction in accordance with 28 U.S.C. §§ 1391(a) and (c), as well as Mich. Comp. Laws § 600.705, the Michigan Long-Arm statute.

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

52. Defendants are non-domiciliaries of the State of Michigan and regularly engage in business within the State of Michigan. Defendants have committed tortious acts outside and within the State of Michigan that have caused injury within Michigan to the City of Flint. Defendants expect or should reasonably have expected those acts to have consequences in the State of Michigan. Defendants, moreover, solicited business within the State of Michigan, engaged in persistent courses of conduct in the State of Michigan, and derived substantial revenue from goods used and services rendered in the State of Michigan through interstate commerce.

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

IV. THE INAPPLICABILITY OF MICHIGAN'S REGULATORY IMMUNITY STATUTE

54. Michigan law includes a provision enacted as a portion of Public Act 249 of 1995 which provides immunity from liability for certain "product liability actions" as the term is defined in the statute. *See* Mich. Comp. Laws § 600.2946(5). This limited immunity provision is inapplicable to the claims in the instant case because, *inter alia*, the claims brought in this lawsuit do not fall within the definition of a "product liability action," because the claims brought in this lawsuit are subject to one of more statutory exceptions to Public Act 249, and because the immunity conferred in Public Act 249 does not extend to illegal drug diversionary conduct.

V. GENERAL FACTUAL ALLEGATIONS

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

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

57. Opioids are a class of drugs which contain molecules that bind to naturally occurring opioid receptors in the human brain. When those molecules are in place, they block the brain's pain signaling mechanism. In addition, by blocking the brain's dopamine-regulation mechanism, opioids cause a massive release of dopamine (in turn causing euphoria, drowsiness, and slowed breathing). Over time, a patient's dose must be increased to produce the same pain-relieving effects, and the patient will experience worsening withdrawal symptoms when the drug is not present in the body.

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

poppy plant various opioids including morphine, laudanum, codeine, thebaine, hydrocodone, oxymorphone, and heroin.

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

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

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

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

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

64. Accordingly, prior to the 1990's, doctors used opioid pain relievers sparingly, and only in the short term, for cases of severe injury or illness, or during surgery. Meldrum ML, *Progress in Pain Research and Management*, Vol. 25 Seattle, WA: IASP Press; 2003. Doctors' reluctance to use opioids

for an extended period of time, despite their short-term effectiveness for pain, sprang from the legitimate fear of causing addiction. *Id*.

65. In addition, Congress enacted laws which strictly regulated the marketplace for medical opioids. Pursuant to the Controlled Substances Act of 1970 ("CSA"), the federal Drug Enforcement Agency ("DEA") annually caps the aggregate number of opioids that could be produced in the United States. 21 U.S.C. § 826(a); 28 C.F.R. § 0.100. Under the CSA, moreover, can be sold only through a controlled, highly regulated distribution network that requires manufacturers, wholesale distributors, and retailers to act as substance-abuse watchdogs, and report any suspicious orders of opioids to the DEA. 21 C.F.R. § 1301.74(b).

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

A. Manufacturer Defendants' Misinformation Campaign Regarding Opioids

i. Manufacturer Defendants' Campaign to Promote Widespread Opioid Use

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

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

Manufacturer Defendants successfully rebranded what is essentially morphine and convinced doctors to prescribe it for bad backs, arthritis, and headaches.

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

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

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

72. What the Manufacturer Defendants realized is opioids are a perfect inelastic manufactured good. Patients treated with opioids, once they become addicted, do not have the free will to choose not to purchase the product. Given enough time on opioids, a patient will need higher and higher doses just to stave off the ever-looming and life-threatening effects of opioid withdrawal—for which the only short-term remedy is more of opioids.

73. During the 1980s and 1990s, Manufacturer Defendants introduced new opioid drugs and sought to maximize the market for them. They did so by taking advantage of, and massively taking out of context, a single letter to the editor in the *New England Journal of Medicine*. They then funded

purportedly neutral foundations and organizations to convince doctors and the general public that, contrary to what doctors and the general public had previously been taught, opioids were safe and could be addiction-proof.

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

> Recently, we examined our current files to determine the incidence of narcotic addiction in 39,946 hospitalized medical patients who were monitored consecutively. Although there were 11,882 patients who received at least one narcotic preparation, there were only four cases of reasonably well-documented addiction in patients who had no history of addiction. The addiction was considered major in only one instance. The drugs implicated were meperidine in two patients, Percodan in one, and hydromorphone in one. We conclude that despite widespread use of narcotic drugs in hospitals, the development of addiction is rare in medical patients with no history of addiction.

Addiction rate in patients treated with narcotics, 302(2) New Eng. J. Med. 123 (Jan. 10, 1980).

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

pain: report of 38 cases, 25 Pain 171 (1986). Portenoy's study also cited Hershel Jick's one-paragraph letter to the *New England Journal of Medicine*.

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

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

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

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

Live interview with Dr. Russell Portenoy. Physicians Responsible for Opioid Prescribing. https://www.youtube.com/watch?v=DgyuBWN9D4w. Accessed December 3, 2017 (emphases added).

79. As to the *New England Journal of Medicine* letter, Dr. Jick, in an interview with Sam Quinones decades after the letter was published, stated: "[t]hat particular letter, for me, is very near the bottom of a long list of studies that I've done. It's useful as it stands because there's nothing else like it on hospitalized patients. But if you read it carefully, it does not speak to the level of addiction in outpatients who take these drugs for chronic pain."

80. *The New England Journal of Medicine* itself has since disavowed the letter, stating "[the letter] was heavily and uncritically cited as evidence that addiction was rare with long-term opioid

therapy." 376 *New Eng. J. Med*. 2194, 2194–95 (2017). "We believe," the journal provided, "that this citation pattern contributed to the North American opioid crisis by helping to shape a narrative that allayed prescribers' concerns about the risk of addiction associated with long-term opioid therapy." *Id.*

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

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

83. To expand the markets for those new products, Manufacturer Defendants engaged in a concerted push to convince doctors and the general public that opioids were safe and effective for long-term pain relief. In large part, Manufacturer Defendants turned to Russell Portenoy, the author of the 1986 *Pain* study. Because Portenoy's study dovetailed perfectly with Manufacturer Defendants' marketing strategy, within a decade, Portenoy was financed by "at least a dozen companies, most of which produced prescription opioids." Meier B., *Pain Killer: A Wonder Drug's Trail of Addiction and Death*, New York, NY: St. Martin's Press; 2003.

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

85. Manufacturer Defendants funded these concept peddlers. In turn, these concept peddlers

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

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

87. All of these purportedly neutral, industry-funded organizations took aggressive stances to convince doctors and medical professionals that America was suffering from an epidemic of untreated pain—and that opioids were the solution. For example, the American Pain Foundation, of which Dr. Portenoy was a director, urged tracking of what they called an epidemic of untreated pain. The American Pain Society, of which he was president, campaigned to make pain what it called the "fifth vital sign" that doctors should monitor, alongside blood pressure, temperature, heartbeat and breathing.[10]

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

89. In actuality, the risk of addiction is as high as 56%. Martell BA, O'Connor PG, Kerns RD, Al E., *Systematic review: opioid treatment for chronic back pain: prevalence, efficacy, and*

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

association with addiction, 146 Ann. Intern. Med. 116 (2007).

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

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

92. A key player in Manufacturer Defendants' misinformation campaign, Russell Portenoy, has since admitted that the information Manufacturer Defendants were pushing was false. "I gave innumerable lectures in the late 1980s and '90s about addiction that weren't true," Dr. Portenoy told a fellow doctor in 2010. "It was the wrong thing to do." [11]

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

B. Manufacturer Defendants' Misrepresentations Regarding Their Specific Products

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

[11] Thomas Catan and Evan Perez, *A Pain-Drug Champion Has Second Thoughts*, The Wall Street Journal (Dec. 17, 2012).

drugs.

i. FDA Approval Process

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

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

a) *First*, the sponsoring company must conduct laboratory testing in animals to determine whether the drug will be relatively safe and, to some extent, effective. If animal testing indicates that the drug or compound is relatively safe, the company then submits an investigational new drug ("IND") application to the FDA to gain approval to test the product with human subjects;

b) *Second*, the sponsoring company must conduct "clinical trials" on human subjects. Clinical trials are carried out sequentially in three phases—Phase I, II, and III studies. Each phase increases the number of subjects, and is designed to test for safety and efficacy of the drug for specific uses and patient populations; and

c) *Third*, after the clinical trials are completed, the company compiles the data and analysis into a new drug application ("NDA"). FDA then reviews the NDA, focusing on three major potential concerns: (1) safety and effectiveness in the drug's proposed use; (2) appropriateness of the proposed labeling; and
(3) adequacy of manufacturing methods to assure the drug's strength, quality, and identity. After evaluating the NDA, the FDA will make the decision whether to approve or reject the drug.

97. When a drug is approved by the FDA, it means the drug manufacturer has satisfied the regulatory requirements set forth in the Food Drug and Cosmetic Act ("FDCA"). It does not mean that the drug meets all state law requirements, or that it can be promoted for all uses in all populations.

98. Though the FDA plays an important role in approving drugs for use, its role is limited by the fact that it does not conduct its own clinical trials. The FDA must therefore rely heavily on the

representations and reports made by the sponsoring company. For example, in the context of efficacy, the FDA can deny an application only if it finds the *application* lacks "substantial evidence that the drug will have the effect it purports or is represented to have[.]" *See* 21 U.S.C. § 355(d)(5).

99. The FDA's role is similarly circumscribed with respect to drug labeling. The FDA does not draft drug labels. Instead, the drug manufacturer submits proposed labeling and, unless the FDA finds, under FDCA standards, that the label is misleading, it must approve it. 21 U.S.C. § 355(d).

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

101. Towards that end, sections 502(a) and 201(n) of the FDCA (21 U.S.C. §§ 352(a), 321(n)) impose on drug manufacturers an ongoing duty to fully and accurately disclose information in their possession relating to the efficacy of a drug—as well as information relating to adverse events associated with that drug's use. These disclosures must appear in the drug's package insert, other labeling, and promotional materials.

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

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

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

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

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

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

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

ii. Each Manufacturer Defendant Flouted This Process For its Particular Product(s)

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

109. Manufacturer Defendants did so by sponsoring pro-opioid front groups who published misleading prescription guidelines, articles and Continuing Medical Education sessions ("CMEs"), and paid physicians thousands of dollars every year to publicly opine on the safety, efficacy, and non-addictive nature of opioids for a wide variety of uses.

a. Purdue

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

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

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

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

114. Despite this, Purdue continued to claim that OxyContin's delayed release mechanism rendered it less addictive, less subject to abuse and to diversion into illegal channels, and less likely to build opioid tolerance and cause withdrawal symptoms than predecessor drugs.

115. Initially, OxyContin was available in 10 mg, 20 mg, 40mg, and 60 mg tablets. 80 mg and

[12] Harriet Ryan, *et al., "You Want A Descripton of Hell?" OxyContin's 12-Hour Problem*, The Los Angeles Times (May 5, 2016).

160 mg tablets were introduced in 1997 and 2001, respectively.

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

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

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

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

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

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

122. Upon information and belief, Purdue was incentivized to cling to its 12-hour claim of pain relief in order to protect its revenue stream because many available generic competitors successfully treated pain for less than 12-hour intervals. Without the 12-hour of pain relief claim,

OxyContin did not stand out from its competitors, which obviated the need for doctors to continue prescribing OxyContin over available less-expensive alternatives.

123. Upon information and belief, when Purdue began receiving reports from physicians, sales representatives, and independent researchers that OxyContin did not last 12 hours, it nevertheless clung to its 12-hour of pain relief claim. Instead of reconsidering its claims, Purdue instead recommended that doctors prescribe higher doses of OxyContin rather than more frequent doses. Upon information and belief, Purdue deployed a team of hundreds of sales representatives to refocus physicians on 12-hour dosing, with company executives noting in internal documents that any consideration of more frequent dosing "needs to be nipped in the bud. NOW!"

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

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

126. From 1996 to 2001, Purdue conducted more than 40 national pain-management and speaker training conferences at lavish resorts in Florida, Arizona, and California. More than 5000 physicians, pharmacists, and nurses attended these all-expenses-paid symposia, where they were recruited and trained for Purdue's national speaker bureau with the intent of influencing prescribing patterns towards prescribing opioids more liberally for non-cancer related chronic pain.

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

128. One of the cornerstones of Purdue's marketing plan was the use of sophisticated marketing data to influence physicians' prescribing patterns towards prescribing opioids more liberally

for non-cancer related chronic pain.

129. Purdue (in an innovation that, on information and belief, was copied by other Manufacturer Defendants) compiled prescriber profiles on individual physicians detailing their prescribing patterns, to influence doctors' prescribing patterns towards prescribing opioids more liberally for non-cancer related chronic pain.

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

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

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

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

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

135. From 1996 to 2000, Purdue increased its internal sales force from 318 sales representatives to 671, and its total physician call list from approximately 33,400 to 44,500 to approximately 70,500 to 94,000 physicians. Through its sales representatives, Purdue used a patient starter coupon program for OxyContin, providing patients with a free limited-time prescription for a 7-day to 30-day supply. When the program was discontinued, approximately 34,000 coupons had been redeemed national.

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

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

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

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

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

141. While Purdue did withdraw the offensive promotional materials, rather than distributing a “Dear Healthcare Professional” (DHP) letter correcting the misinformation or altering the labeling for OxyContin, Purdue doubled down and instructed their sales force to "refocus" physicians if and when they learn that physician was misinformed regarding the addictive qualities of their products.

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

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

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

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

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

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

148. Purdue also funded "Responsible Opioid Prescribing," a guide sponsored by the Federation of State Medical Boards ("FSMB") and authored by Dr. Scott Fishman, and former chairman

and president of the now defunct APF in 2007. The guide was ultimately disseminated to 700,000 practicing doctors, with doctors in Michigan alone receiving 42,366 copies. A June 8, 2012 letter submitted by FSMB to the Senate Finance Committee disclosed that Purdue paid $40,000 to fund the production of the guide. Purdue also paid the FSMB at least $822,400 from 1997-2012.

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

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

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

152. In 2009 the American Pain Society ("APS") and AAPM jointly issued guidelines ("APS/AAPM Guidelines") recommending the use of opioids to treat chronic pain. The APS/AAPM guidelines promoted the use of opioids for the treatment of chronic pain and concluded that the risk of opioid addiction was manageable in patients regardless of previous histories of abuse. At least fourteen of the twenty-one panel members who drafted the APS/AAPM Guidelines received funding from Purdue.

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

b. Cephalon, Inc.

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

155. Cephalon also:

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

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

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

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

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

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

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

157. Cephalon was also required to:

a) send letters to doctors about the settlement agreement to enable doctors to report questionable sales representative conduct; and

b) post information about payments the manufacturer made to doctors on its website.

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

159. The FDA found that the sponsored links omitted the most serious and frequently occurring risks associated with the Fentora, misleadingly suggesting Fentora is safer than demonstrated.

160. The FDA also found that the sponsored link for Fentora made incomplete and misleading statements about what the drug is indicated for, suggesting that Fentora is useful in a broader range of conditions or patients than had been demonstrated.

161. The FDA noted that the marketing material provided only a brief statement about what Fentora is indicated for, which was incomplete and misleading. Specifically, the marketing material suggested that Fentora is useful in a broader range of conditions or patients than is supported was by substantial evidence in clinical experience. The advertisement implied that Fentora was indicated for breakthrough pain in any patient with cancer, rather than only those who are already receiving, and already tolerant to, around-the-clock opioid therapy.

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

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

by the FDA.

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

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

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

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

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

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

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

c. Janssen Pharmaceuticals, Inc.

171. On December 9, 1999, the FDA sent Janssen a letter indicating that it had reviewed

several "homemade" marketing pieces that had been used by Janssen sales representatives for its fentanyl-based synthetic opioid, Duagesic. The FDA found those marketing pieces to be false or misleading because they contained misrepresentations regarding safety information, broadened Duragesic's indication for use, contained unsubstantiated claims, and lacked fair balance.

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

a) "Significantly LESS constipation!", which suggested Duragesic had been demonstrated to be associated with less constipation than other available opioids, thus, minimizing the risk of constipation; and
b) "Low abuse potential!", which suggested that Duragesic had less potential for abuse than other available opioids and minimized and contradicted fentanyl's status as a Schedule II controlled substance.

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

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

a) "Preferred regimen: 2 x per week versus 2 x per day!";
b) "Easy for Patient compliance."; and
c) "And the #1 reason to convert your patients to the Duragesic patch: QUALITY OF LIFE," and "… without pain, patient's [sic] sleep better, increase daily."

175. Janssen received further warning by way of a September 2, 2004 warning letter. That letter was in relation to Janssen's Duragesic patch. FDA found that a file card used by Janssen in

connection with that patch contained false and misleading claims about the abuse potential of Duragesic, as well as unsubstantiated claims of the effectiveness of Duragesic. The FDA noted Janssen's representations could encourage the unsafe use of the drug, potentially resulting in serious or life-threatening hypoventilation, or even death.

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

177. Janssen's promotional materials in question included:

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

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

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

d) "86% of patients experienced overall benefit in a clinical study based on: pain control, disability in ADLs, quality of sleep", "all patients who experienced overall benefit from Duragesic would recommend it to others with chronic low back pain", "significantly reduced nighttime awakenings" and "significant improvement in disability scores as measured by the Oswestry Disability Questionnaire and Pain Disability Index" which were again based on an open-

label, single arm trial with no control group—which is inadequate to support such claims;

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

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

178. The FDA stated they were not aware of any substantial evidence or clinical experience to support these comparative claims.

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

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

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

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

183. The statements were made on December 8, 2010 at the 2010 American Society of Health-

System Pharmacists ("ASHP") Midyear Clinical Meeting and Exhibition in Anaheim, CA.

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

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

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

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

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

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

d. Endo International PLC

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

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

190. Endo claimed to have reformulated Opana ER to be resistant for patients who crush and snort prescription opioid pills. Instead, the route of abuse significant shifted from insufflation (crushing and snorting) to intravenous injection.

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

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

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

194. A June 8, 2012 letter submitted by FSMB to the Senate Finance Committee disclosed that Endo paid $50,000 respectively to fund the production of the "Responsible Opioid Prescribing," a

guide authored by Dr. Scott Fishman, former chairman and president of the now defunct American Pain Foundation in 2007. The guide was ultimately disseminated to 700,000 practicing doctors, with Michigan alone receiving 42,366 copies. Since that time, Endo has paid the FSMB at least $371,620.

e. Actavis

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

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

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

198. The brochure also failed to present risk information with a prominence and readability that is reasonably comparable to the presentation of benefit information.

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

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

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

b) "Better pain control …";

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

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

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

f) "Less pain. More options."

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

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

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

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

f. Mallinckrodt

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

206. The letter also stated that its unapproved morphine formulation was misbranded under 21 U.S.C. § 352(f)(1) because the conditions it was intended to treat were not amenable to self-diagnosis

and treatment. Adequate directions for such use, therefore, could not be written. As a result, introduction or delivery for introduction into interstate commerce of its unapproved morphine formulation violated 21 U.S.C. §§ 331(a) and (d).

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

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

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

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

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

211. The opioid supply chain begins with manufacturers (including Manufacturer Defendants), who manufacture and package the pill. Manufacturer Defendants then transfer the opioids to wholesale distributors (including Distributor Defendants).[13] Wholesale Distributors then dispense the opioids to hospitals and pharmacies.

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

[13] Collectively, Distributor Defendants account for over 90% of all drugs distributed within the United States.

on such drugs.

213. *First*, the DEA sets limits on the quantity of schedule II controlled substances—such as opioids—that may be produced in the United States in any given year. *See* 21 U.S.C. § 826(a). 28 C.F.R. § 0.100. DEA determines these quotas based on a variety of data including sales, production, inventories, and exports. The DEA can and does lower quotas as a means of addressing abuse and diversion.

214. *Second*, Congress anticipated that highly addictive prescription drugs like opioids could be abused and diverted to the black market. The CSA thus sought to combat diversion of prescription narcotics by providing for a closed system of drug distribution in which every actor in the opioid supply chain—*i.e.*, manufacturers and distributors—must register with the DEA. Every registrant, in turn, is charged with being be vigilant in deciding whether a customer, whether a pharmacy, wholesaler, or end customer, can be trusted to deliver or use controlled prescription narcotics only for lawful purposes. 21 U.S.C. 823(e). Specifically, every registrant—manufacturers and distributors—is required to "maintain effective control against diversion of particular controlled substances into other than legitimate medical, scientific, and industrial channels." 21 U.S.C. § 823(b)(1)

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

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

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

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

219. "Congress," the Court has explained, "was particularly concerned with the diversion of drugs from legitimate channels. It was aware that registrants, who have the greatest access to controlled substances and therefore the greatest opportunity for diversion, were responsible for a large part of the illegal drug traffic." *United States v. Moore*, 423 U.S. 122, 135 (1975).

220. Manufacturers and distributors must therefore be vigilant in deciding whether a prospective customer can be trusted to deliver controlled substances only for lawful purposes. This responsibility is critical, as Congress has expressly declared that the illegal distribution of controlled substances has a substantial and detrimental effect on the health and general welfare of the American people.

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

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

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

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

d) Ordering the same controlled substance from multiple distributors.

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

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

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

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

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

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

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

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

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

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

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

223. In 2007, the DEA sent letters to every registered manufacturer or distributor of controlled

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

224. In the letter, the DEA expressly warned that the regulation "requires that the registrant inform the local DEA Division Office of suspicious orders when discovered by the registrant." The DEA also warned that "[r]egistrants are reminded that their responsibility does not end merely with the filing of a suspicious order report. Registrants must conduct an independent analysis of suspicious orders prior to completing a sale to determine whether the controlled substances are likely to be diverted from legitimate channels. Reporting an order as suspicious will not absolve the registrant of responsibility if the registrant knew, or should have known, that the controlled substances were being diverted."

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

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

227. Federal law imposes a duty upon Defendants to comply with applicable State and local law. *See* 21 U.S.C.A. § 823(b)(2), incorporated into Michigan law by Mich. Admin. Code R. §

338.493c(i).

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

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

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

i. Failure of the Manufacturer Defendants

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

232. Manufacturers manage the actual distribution of drugs from manufacturing facilities to drug wholesalers, and in some cases, directly to retail pharmacy chains, mail-order and specialty pharmacies, hospital chains, and some health plans. Manufacturers may also distribute products directly

to government purchasers, such as the Veterans Administration.

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

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

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

236. Instead, they utilized the data to understand which regions, and which doctors, to target through their sales force.

237. Manufacturer Defendants failed to report each instance of diversion to the DEA while rolling out marketing campaigns to churn its prescription opioid sales.

238. Indeed, upon information and belief, Manufacturer Defendants withheld from the DEA information about suspicious orders—and induced Distributor Defendants to do the same—to obfuscate the extent of the opioid epidemic. Upon information and belief, Manufacturing Defendants knew that if they or the other defendants disclosed suspicious orders, the DEA would become aware that many opioids were being diverted to illegal channels and would refuse to increase the production quotas for opioids.

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

ii. Failure of the Distributor Defendants

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

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

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

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

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

245. The ARCOS database does not alert the DEA to the suspicious nature of a particular order. The DEA investigators regard the database as unwieldy because it encompassed dozens of drugs

sold by more than a thousand companies and is frequently six months out of date.

246. Distributors are a crucial link in the closed system envisioned by Congress in enacting the CSA. Wholesale distributors are the closest link to pharmacies in the pharmaceutical supply chain, as such, they are best situated to determine whether a pharmacy is facilitating the diversion of prescription opioid pills.

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

248. Distributor Defendants are a key link in the pharmaceutical supply chain, as they that have the power to determine that an order is not being diverted before filling suspicious orders— thereby preventing diversion before it can even occur.

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

250. Once the DEA started to enforce suspensions of registrations to distribute controlled substances, rather than comply, manufacturers and defendants spent at least $102 million to undermine the DEA's ability to do so.

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

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

iii. The Defendants Failed to Track and Report Suspicious Sales as Required by Michigan and Federal Law

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

1) McKesson

254. McKesson is a significant distributor of opioids in the United States and was under investigation by former Michigan Attorney General Bill Schuette and that investigation is continuing by current Michigan Attorney General Dana Nessel.

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

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

257. Despite the CSMP, a DEA investigation revealed that between 2008 and 2013,

McKesson continued to fail to inform the DEA about a plethora of suspicious orders of prescription opioids. In that time period, a single warehouse in Aurora, Co filled 1.6 million prescription orders and reported only 16 as suspicious.

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

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

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

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

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

263. Upon information and belief, Distributor Defendants had a policy of not reporting suspicious orders until the DEA was already aware of wrongdoing. In this way the Distributor Defendants believed they could protect themselves from liability, while obfuscating the true extent of opioid diversion to keep DEA quota on opioids high.

264. Prior to Jeffrey Clawson's indictment, McKesson did not report, as suspicious, that a

small pharmacy in rural Colorado needed the more prescription opioids than a medical center in the city of Denver. Nor did it report a more than fourteen-fold increase in prescription opioids deliveries to Platte Valley Pharmacy over only three years was out of place.

265. The DEA's Denver field division rightly realized that if McKesson had been so bold in Colorado, it likely was ignoring suspicious orders elsewhere. What surprised the DEA most was that McKesson would be so reckless despite its violations in 2007 and the implementation of the CSMP program.

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

267. What they found was striking. McKesson hadn't just been ignoring suspicious orders. Rather, McKesson was acutely aware of the situation at Platte Valley Pharmacy. Worse, McKesson warehouses in Livonia, and in Washington Court House, Ohio were supplying pharmacies that sold to criminal drug rings. In all, 12 McKesson distribution centers, including a Livonia, Michigan location, failed to report suspicious orders involving millions of opioids across the country. The DEA even pushed to completely revoke McKesson's Livonia location's registration to distribute controlled substances.

268. The DEA investigative finding revealed that McKesson systematically:

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

b) Ignored blatant diversion;

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

d) Failed to review orders for suspicious activity; and

e) Ignored own procedures designed to prevent diversion.

269. David Schiller of the DEA's Denver field division, which first recognized McKesson's bad acts, asserted that "This is the best case we've ever had against a major distributor in the history of the Drug Enforcement Administration." Individuals at the DEA believed that a fine of more than $1

billion would be appropriate, and one unnamed source asserted that "[the DEA] could have fined them out of existence, or indicted the company and put [McKesson, the 5th largest Corporation in the United States] out of business.

270. It was only after the DEA visited the Aurora, Colorado location on March 2013 that McKesson started to comply, enhancing its monitoring program that resulted in report of 2,447 suspicious orders between June and November of that year.

271. On January 17, 2017, McKesson agreed to pay a record $150 million in fines and suspend sales of controlled substances from distribution centers in four states (Colorado, Ohio, Michigan and Florida) to settle allegations that the company violated federal law As part of the agreement, McKesson acknowledged that: "at various times during the Covered Time Period, it did not identify or report to DEA certain orders placed by certain pharmacies, which should have been detected by McKesson as suspicious, in a manner fully consistent with the requirements set forth in the 2008 MOA." The company promised to institute significant changes to its program designed to flag suspicious orders, the same promise it made and broke in 2008.

272. McKesson was fined the equivalent of less than two year's salary of its board chairman and chief executive, John Hammergren.

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

2) Cardinal Health

274. Cardinal Health is a significant distributor of opioids in the United and was under investigation by former Michigan Attorney General Bill Schuette and that investigation is continuing by current Michigan Attorney General Dana Nessel.

275. Cardinal fully acknowledged that from January 1, 2009 to May 14, 2012 it did fail to comply with regulations that required reports of any suspicious orders from pharmacies. Cardinal

Health's chief legal and compliance officer, Craig Morford, also noted that going forward it would work "with all participants in addressing the epidemic of prescription drug abuse." In a press release from Cardinal Health on January 9, 2017, Cardinal Health notes that it is continuously improving a "sophisticated anti-diversion program that includes advanced analytics, technology, and the deployment of teams of anti-diversion specialists and investigators embedded within its supply chain," to address suspicious orders that are likely meant for illegitimate use.

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

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

a) "timely identify suspicious orders of controlled substances and inform the DEA of those orders, as required by 21 C.F.R. §1301.74(b)";

b) "maintain effective controls against diversion of particular controlled substances into other than legitimate medical, scientific, and industrial channels, as required by 21 C.F.R. §1301.74, including the failure to make records and reports required by the CSA or DEA's regulations for which a penalty may be imposed under 21 U.S.C. §842(a)(5)"; and

c) "execute, fill, cancel, correct, file with the DEA, and otherwise handle DEA 'Form 222' order forms and their electronic equivalent for Schedule II controlled substances, as required by 21 U.S.C. § 828 and 21 C.F.R. Part 1305."

278. In the press release announcing the settlement agreement, U.S Attorney for the District of Maryland, Rod Rosenstein, stated: "Pharmaceutical suppliers violate the law when they fill unusually large or frequent orders for controlled substances without notifying the DEA… Abuse of pharmaceutical drugs is one of the top federal law enforcement priorities. Cases such as this one, as well

as our $8 million settlement with CVS in February 2016, reflect the federal commitment to prevent the diversion of pharmaceutical drugs for illegal purposes."

279. In the press release, DEA's Washington Division Special Agent-in-Charge, Karl Colder, clarified that the settlement specifically concerned oxycodone: "[The] DEA is responsible for ensuring that all controlled substance transactions take place within DEA's regulatory closed system. All legitimate handlers of controlled substances must maintain strict accounting for all distributions and Cardinal failed to adhere to this policy … Oxycodone is a very addictive drug and failure to report suspicious orders of oxycodone is a serious matter. The civil penalty levied against Cardinal should send a strong message that all handlers of controlled substances must perform due diligence to ensure the public safety …"

3) AmerisourceBergen

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

281. AmerisourceBergen is a significant distributor of opioids in the United States and was under investigation by former Michigan Attorney General Bill Schuette and that investigation is continuing by current Michigan Attorney General Dana Nessel.

282. In 2012, West Virginia sued AmerisourceBergen and Cardinal Health, as well as several smaller wholesalers, for numerous causes of action, including violations of the CSA, consumer credit and protection, and antitrust laws and the creation of a public nuisance. Unsealed court records from that case demonstrate that AmerisourceBergen, along with McKesson and Cardinal Health, together shipped 423 million pain pills to West Virginia between 2007 and 2012. AmerisourceBergen itself shipped 80.3 million hydrocodone pills and 38.4 oxycodone pills during that time period. Moreover, public documents also demonstrate that that the average dose of each tablet distributed grew

substantially during that time period. The Distributor Defendants, including AmerisourceBergen, shipped large quantities of oxycodone and hydrocodone tablets to the state. In 2016, AmerisourceBergen agreed to settle the West Virginia lawsuit by paying $16 million to the state, with the funds set aside to fund drug treatment programs in order to respond to the opioid addiction crisis.

4) Mallinckrodt PLC

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

284. The July 2017 agreement by Mallinckrodt PLC also settled charges by the DOJ stemming from Mallinckrodt PLC's failure to utilize chargeback data received from distributors to identify suspicious orders of customers further down in the supply chain, such as order from pharmacies or pain clinics from distributors, which Mallinckrodt required distributors provide it with in order to obtain chargeback discounts.

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

D. Examples of Unreported Suspicious Prescribing Habits in Michigan

286. Defendants' gross inadequacies in the performance of their due diligence obligations is underscored by the following examples of illegal prescribing and diversion activities. Upon information and belief, none of the following doctors, who were apprehended and convicted as a result of a DEA

investigation, were prosecuted at the initial prompting by reports of an opioid manufacturer, wholesale distributor, or retail distributor.

287. Mukunda Dev Mukherjee, M.D. (“Mukherjee”), was sentenced to 328 years in prison after he was found guilty of 44 counts of illegal distribution of controlled substances in the United States District Court for the Eastern District of Michigan. Records indicate that between January 1, 2003 and April 30, 2004, Mukherjee issued prescriptions for 56,414 dosage units of OxyContin, 166,516 dosage units of hydrocodone pain killers, and 6,200 codeine cough suppressant prescriptions. These numbers far exceeded any other medical practice in the area and are far higher than are expected from a legitimate medical practice of this size. In fact, Mukherjee issued more 80 mg OxyContin prescriptions than any other physician or hospital in the state of Michigan during the period of January 1, 2003, through June 30, 2004. The trial judge described Mukherjee's office as "effectively a prescription mill."

288. Salahuddin S. Ahmad, M.D. (“Ahmad”), of Ferndale, Michigan, pleaded guilty in the United States District Court for the Eastern District of Michigan to one count of Conspiracy to Possess with Intent to Distribute Oxycodone. According to court documents, on May 13, 2008, Ahmad, outside the scope of his legitimate practice of medicine, planned to sell (and possessed with the intent to sell) over 2,400 OxyContin tablets. At one point the defendant claimed he could get 1,500 80mg OxyContin tablets in a “few weeks.”

289. Stuart W. Bilyeu, D.O. (“Bilyeu”), of Southfield, Michigan, pleaded guilty in the United States District Court for the Eastern District of Michigan to the unlawful distribution of hydrocodone, a Schedule III controlled substance. According to court documents, Bilyeu admitted that he prescribed without medical necessity or justification quantities of controlled substances to patients. For example, in October 2004, Bilyeu wrote a prescription for 120 Vicodin to an individual, without any good faith attempt to determine the legitimate medical needs of the patient. From January 2003 until May 10, 2005, Bilyeu prescribed without medical necessity or justification 100 dosage units of oxycodone 80mg; 100 dosage units of Dilaudid, 20,000 Schedule III drugs, and 40,000 Schedule IV drugs.

290. Philip Lafata, M.D. ("Lafata"), of Pigeon, Michigan, pleaded guilty in the U.S. District Court for the Eastern District of Michigan to one count of Use of a Communication Facility to Facilitate Distribution of Hydromorphone. According to court documents, between July 2007 and June 2008, Lafata intentionally wrote a person prescriptions for 2050 vials of Hydromorphone—a Schedule II pharmaceutical—without performing any examination of that person. During the time Lafata wrote these prescriptions, Lafata knew this person was addicted to hydromorphone and that the person was not suffering from any disease, accident, or illness that would justify those prescriptions.

291. Fanny Dela Cruz, M.D. ("Dela Cruz"), of Livonia, Michigan, was sentenced to 96 months in federal prison for participating in a conspiracy to illegally distribute prescription pills, and to defraud Medicare. During her plea, she admitted she would write pre-signed prescriptions for controlled substances and non-controlled maintenance medication. When pre-signing the prescriptions for controlled substances, Dela Cruz would write the name, milligram and quantity of the controlled substance on the prescription and affix her signature. Dela Cruz would not write in the patient name. The patient name was affixed to the prescription later, by other individuals. These patients were not examined by Dela Cruz prior to her issuing the controlled substance prescriptions. Dela Cruz was compensated in cash by other individuals for issuing these prescriptions. In a 13-month period, Dela Cruz issued the following controlled substances: approximately 577,707 dosage units Oxycodone HCl, 333,394 dosage units of Oxymorphone, 35,185 dosage units of Alprazolam and 663,778 milliliters of Promethazine with Codeine. Dela Cruz was the number one prescriber of Oxycodone and Oxymorphone in the State of Michigan in 2015. Law enforcement officials were never notified of Dela Cruz's malfeasance by the opioid manufacturers, wholesale distributors, or retail distributors. Rather, the investigation was predicated on information provided by a former employee of Dela Cruz.

292. Chiropractor Boris Zigmond, D.C. ("Zigmond"), of Oak Park, Michigan—as well as a number of his co-conspirators—pleaded guilty in the United States District Court for the Eastern District of Michigan to writing prescriptions for oxycodone without medical justification. From January 2013

through May 2015, Zigmond was the leader of a large-scale prescription drug trafficking organization whose purpose was to secure written prescriptions from medical doctors for controlled substances (primarily Roxicodone and its generic equivalent Oxycodone) which could be filled at various pharmacies. According to a superseding indictment filed in the United States District Court for the Eastern District of Michigan, Zigmond's organization distributed approximately 1.1 million pills or more than 30 kilograms of Roxicodone. Every week, Zigmond prescribed a staggering 12,000 dosages of brand name and generic 30 mg Roxicodone. Zigmond's last charged coconspirator, Dr. Jennifer Franklin, pleaded guilty before Judge George Caram Steeh of the Eastern District of Michigan in August of 2017.

293. Dr. Oscar Linares, M.D. ("Linares"), of Monroe, Michigan, was sentenced by the United States District Court for the Eastern District of Michigan to 57 months in prison for unlawful distribution of prescription drugs. According to court records, between April 1, 2008 and March of 2011, Linares unlawfully prescribed millions of dosage units of Schedule II, III and IV narcotics, including opioids such as OxyContin and Opana. Court records further showed that Linares prescribed controlled substances for as many as 250 patients per day.

294. Doctors. Hussein Awada, M.D. ("Awada"), of Royal Oak, Michigan, and Luis Collazo, M.D. ("Collazo"), of Farmington Hill, Michigan, pleaded guilty in the United States District Court for the Eastern District of Michigan to charges of drug conspiracy and health-care fraud. From December 2010 through 2012, Awada and Collazo distributed controlled substances, including the highly addictive drugs Oxycodone, Roxicodone, and Opana ER, outside the course of usual medical practice and for no legitimate purpose. According to court documents, Awada for sixteen months ran a "pill mill." Awada prescribed a total of more than 400,000 oxycodone pills during the relevant time period. Awada was sentenced to seven years in prison for his crimes, whereas Collazo, as a result of his plea, received a non-jail sentence.

E. Examples of Unreported Suspicious Orders from Pharmacies in Michigan

295. Upon information and belief, none of the following pill mill conspiracies were uncovered as a result of a DEA investigation prompted by reports from an opioid manufacturer, wholesale distributor, or retail distributor.

296. Sohrab Shafinia, D.O. ("Shafinia"), of Farmington Hills, Michigan, pleaded guilty in U.S. District Court, Eastern District of Michigan, to one count of Conspiracy to Possess with Intent to Distribute Controlled Substances. According to court documents, beginning in or about October 2005 and continuing up to and including May 2007, Shafinia maintained medical practices at various locations in West Bloomfield, Michigan, Southfield, Michigan, and Farmington Hills, Michigan. During that period of time, Shafinia conspired with several other persons to write prescriptions for individuals who were not patients and on whom he did not conduct any physical examinations. Shafinia was paid between $100 and $300 for each prescription that he wrote. Shafinia typically provided in his prescriptions the same combination of Oxycodone, Hydrocodone, and Xanax. Shafinia referred the individuals who received his prescriptions to SafeScript Pharmacy in Farmington Hills, where one of his co-conspirators worked as the pharmacist. After receiving the drugs Shafinia prescribed, these individuals turned the pills over to other members of the conspiracy for subsequent distribution. SafeScript Pharmacy, which prior to the conspiracy had not been among the top 100 pharmacies in Michigan for Oxycodone prescriptions filled, shot to the number one spot for Oxycodone prescriptions in 2006 with over 368,000 dosage units filled. During the conspiracy, Shafinia prescribed approximately 300,000 dosage units of Oxycodone, 340,000 dosage units of Hydrocodone, and 231,000 dosage units of Xanax. This trio of drugs prescribed by Shafinia became known at SafeScript Pharmacy as the "Shafinia Cocktail."

297. In *United States of America v. Mason et al* (No. 2:11-cr-20551) (E.D. Mich.) 44 individuals, including doctors and pharmacists, were charged, in the United States District Court for the Eastern District of Michigan, with conspiracy to distribute controlled substances. According to the

indictment, Sardar Ashrafkhan, Deepak Kumar, John Check, and David Vezzossi—owners of home health agencies—would provide kickbacks, bribes, and other illegal benefits to physicians to induce them to write opioid prescriptions for patients with Medicare, Medicaid, and private insurance. Patients were recruited into the scheme by patient recruiters or "marketers," who would pay kickbacks and bribes to patients in exchange for the patients' permitting the pharmacies and physicians to bill their insurance for medications and services that were medically unnecessary and/or never provided. During this conspiracy, prescriptions were presented to the Sav-Max (pharmacist Ahab Elmadhoun), Sav-Mart (pharmacist Waleed Yaghmour), Atrium (pharmacist Krina Patel and manager Sanjay Patel), or Caremax (pharmacist Jayshriben Gandhi and manager Guarang Gandhi) pharmacies for filling. The five doctors named in the indictment prescribed a combined total of more than 500,000 dosage units of OxyContin 80 mg and 2 million dosage units of Vicodin. A cooperating pharmacy, Sav-Max, ordered over 700,000 dosage units of OxyContin 80 mg in a 21-month period. The devastation of the broader community is well documented in this case—as unleashing $10 million to $20 million of opioids onto the street market had predictably disastrous effects.

298. According to an FBI press release dated March 19, 2013, Babubhai Patel, a pharmacist, was the owner and controller of some 26 pharmacies in and around Detroit from approximately 2006 through 2011. The indictment alleges that Babubhai Patel would (1) offer and pay kickbacks, bribes, and other inducements to physicians in order to induce physicians to write opioid prescriptions for patients with Medicare, Medicaid, and private insurance, and (2) direct that those prescriptions be presented to one of his pharmacies for billing. In exchange for their kickbacks and inducements, the medical professionals wrote prescriptions for the patients, and billed the relevant insurers for services supposedly provided to the patients, without regard to the medical necessity of those prescriptions and services. Patients were recruited into the scheme by patient recruiters, who would pay kickbacks and bribes to patients in exchange for the patients' permitting the Patel Pharmacies (and the physicians associated with Patel) to bill their insurance for medications and services that were medically

unnecessary and/or never provided. The indictment further alleges that since January of 2009, the Patel Pharmacies have dispensed not less than 250,000 doses of OxyContin, not less than 4.6 million doses of Vicodin, not less than 1.5 million doses of Xanax, and not less than 6,100-pint bottles of codeine cough syrup. Notably, the Patel conspiracy was not uncovered by federal authorities. Rather, the impetus for the investigation came from observations by the Dearborn Police Department at one of the Patel Pharmacy locations.

299. The DEA was never alerted by either opioid manufacturers or wholesale distributors of any of the foregoing "pill mill" conspiracies. Instead—and despite their awareness of the suspicious nature of the foregoing enterprises—manufacturers and wholesale distributors continued to supply them with prescription opioids.

F. The Opioid Epidemic's Devastating Effects

300. As a result of: (1) Manufacturer Defendants' misinformation campaigns, and (2) Defendants' failure to abide by their obligations under the CSA, opioid addiction in the United States has skyrocketed. Defendants' actions created an opioid ecosystem in which prescriptions for highly addictive drugs could be easily obtained, and easily filled. Overprescribing, in turn, drove opioid-related addiction, overdose, and infections, and it sustained nonmedical use of prescription opioids.[14][15]

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

G. Deaths from Prescription Opioid Overdoses

302. Weighted National Survey on Drug Use and Health ("NSDUH") estimates suggested

[14] L. Manchikanti et al., *Opioid Epidemic in the United States*. 15 PAIN PHYSICIAN ES9–38 (supplemental material) (2012).
[15] AM Arria & WM Compton, *Complexities In Understanding and Addressing the Serious Public Health Issues Related to the Nonmedical Use of Prescription Drugs*, 65 ADDICT BEHAV. 215–17 (2017).

that, in 2016, 91.8 million people—more than one-third the population of civilian, noninstitutionalized U.S. adults—used prescription opioids. For many of those people, opioid use will prove fatal.

303. Since 1999, two hundred thousand Americans have died as a result of overdoses from OxyContin and other prescription opioids.

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

305. Over the next decade, the number of prescription opioid-related deaths is expected to exceed 650,000, outpacing the estimated number of deaths caused by breast and prostate cancers combined during the same period. To put this figure in context, that figure exceeds the approximately 620,000 Americans who lost their lives in the line of duty during the entire American Civil War.

306. Opioids could kill nearly as many Americans in a decade as HIV/AIDS has killed since that epidemic began in the early 1980s.

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

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

309. Mortality rates from opioid overdose have climbed dramatically. Since 1999, overdose deaths due to prescription opioids have continued to rise. And in 2002, unintentional overdose deaths from prescription opioids surpassed those from heroin and cocaine nationwide.

310. The crisis in opioid overdose deaths has reached epidemic proportions in the United States (33,091 in 2015), and currently exceeds all other drug-related deaths or traffic fatalities.

311. Thus far in 2017, 175 Americans have died every day as a result of the opioid epidemic.

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

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

their communities.

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

314. A recent Brookings Institution study examining the implications of the opioid crisis on the labor force suggests that the increase in opioid prescriptions could account for much of the decline in the labor force participation of "prime age men" (ages 25-54).[16]

315. On any given day, 31% of prime age men not in the labor force report taking prescription pain medication, most likely opioid based. In fact, the true percentage is likely far higher than this self-reported number, due to the stigma and legal risk associated with narcotics.[17]

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

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

318. The number of children experiencing neonatal abstinence syndrome ("NAS"), a group of problems that occur in newborns exposed to opioids in utero, increased 383% during the period 2000-2012 (1.2 cases per 1000 hospital births in 2000 to 5.8 cases per hospital births in 2012).[18]

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

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[16] Alan B. Krueger, Princeton University, *Where Have All the Workers Gone? An Inquiry into the Decline of the U.S. Labor Force Participation Rate*. BROOKINGS PAPERS ON ECONOMIC ACTIVITY: BPEA CONFERENCE DRAFTS (2017), https://www.brookings.edu/wp-content/uploads/2017/09/1_krueger.pdf.

[17] *Id.*

[18] Ctr. for Disease Control & Prevention, *Morbidity and Mortality Weekly Report – Incidence of Neonatal Abstinence Syndrome–28 States, 1999–2013*, CDC.GOV (Aug. 12, 2016), https://www.cdc.gov/mmwr/volumes/65/wr/mm6531a2.htm.

320. In Flint, as in communities across the country, the number of children who have entered foster care due to parental drug use has increased in recent years. As a result, child welfare agencies have seen a dramatic increase in their caseloads. Such welfare agencies, however, are often severely underfunded. Child welfare agencies thus frequently lack enough resources to support drug treatment or parenting classes, or to fund community-based support for children of addicted parents.

321. The adverse effects of the opioid epidemic are not confined to addicted individuals or their families.

322. To the contrary, the costs of the opioid epidemic radiate outward, and are borne by society at large.

323. The monetary costs of prescription opioid overdose, abuse, and dependence are staggering. The White House Council of Economic Advisers recently reported that, in 2015, "the economic cost of the opioid crisis was $504.0 billion, or 2.8 percent of the GDP that year."[19]

324. The total cost of the opioid crisis is so high, the White House Council of Economic Advisers emphasized, because of the multifaceted harms caused by prescription opioids. Among other things, the opioid epidemic has imposed significant costs on the healthcare system, and on the criminal justice system. It has also significantly reduced worker productivity, both as a result of addiction and incarceration.[20]

325. As staggering as a $504 billion annual cost might be, however, the actual current economic cost of the opioid epidemic is probably even higher. As one commentator noted, the White House's 2015 "estimate is probably low for 2016, given that drug and opioid overdose deaths spiked last year compared to 2015."[21]

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[19] COUNCIL ECON. ADVISERS, THE UNDERESTIMATED COST OF THE OPIOID CRISIS 1 (2017), https://www.whitehouse.gov/sites/whitehouse.gov/files/images/The%20Underestimated%20Cost%20of%20the%20Opioid%20Crisis.pdf.

[20] *Id.*

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

I. The Rising Tide of the Heroin Epidemic

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

327. Heroin use in the United States increased dramatically the period in which the country witnessed a rise in prescription opioid misuse. Data from the 2001-2002 and 2012-2013 National Epidemiologic Survey on Alcohol and Related Conditions-I and–III ("NESARC") showed prevalence of heroin use increased five-fold in the United States during the period between the two surveys.[22]

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

329. Scientific studies indicate that the prescription opioid epidemic is, far and away, the key driver of new heroin users. People who report previous nonmedical prescription pain- reliever use are 19 times more likely to begin using heroin than the general population.[23] What is more, prescription opioid abuse, not heroin, is now the main pathway into opioid addiction. Fifty years ago, 80% of people who abused opioids initiated that abuse through heroin. By the 2000s, however, number had flipped on

[22] SS Martins et al., *Changes In Lifetime Heroin Use And Heroin Use Disorder: Prevalence From The 2001–2002 to 2012-2013 National Epidemiologic Survey on Alcohol and Related Conditions.* 74 JAMA PSYCHIATRY 445–55 (2017).
[23] Pradip K. Muhuri et al., *Associations of Nonmedical Pain Reliever Use and Initiation of Heroin Use in the United States*, SAMHSA CTR. FOR BEHAVIORAL STATS. & QUALITY (August 2013), https://www.samhsa.gov/data/sites/default/files/DR006/DR006/nonmedical-pain-reliever-use-2013.htm.

its head: 75% of people who began abusing opioids in the 2000s started through prescription opioids.[24]

330. Highlighting the link between prescription opioid use and heroin use, Washington University St. Louis Professor Theodore Cicero and his colleagues reported—in a letter to the *New England Journal of Medicine*—that after Purdue introduced a reformulated, purportedly "abuse resistant" strand of OxyContin, heroin use nearly doubled among previous opioid users. The authors noted that there was no evidence that OxyContin-addicted individuals ceased their drug use as a result of the abuse deterrent formulation. Rather, addicted individuals simply shifted to a new opioid: in many instances, heroin.[25]

331. That shift from prescription opioids to heroin is often a deadly one. Heroin deaths escalated 4-fold in the five-year period comprising 2010-2015 alone.

332. Flint is at the epicenter of the heroin epidemic. Of all United States Census regions, heroin use in the Midwest—the region that includes Michigan—increased the most drastically from 2000 to 2013. The Midwest experienced 2,791 heroin-related deaths in 2013, compared to 285 heroin-related deaths in 2002, a near ten-fold increase.[26]

333. Opioids users' shift to heroin in Michigan did more than just exacerbate a public health crisis—it also exacerbated a law-enforcement crisis. By 2010, law enforcement officers concluded that heroin trafficking in Michigan counties was being fueled, at least in part, by oxycodone users substituting heroin for prescription opioids.[27]

334. According to a 2009 Drug Market Analysis of the Michigan High Intensity Drug Trafficking ("HIDTA") region of Detroit, law enforcement officials report that some OxyContin abusers eventually switch to heroin because it is less expensive.

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[24]TJ Cicero et al., *The Changing Face of Heroin Use in the United States: A Retrospective Analysis of the Past 50 Years*, 71 JAMA PSYCHIATRY 81(2014).
[25] TJ Cicero et al., *Effect of Abuse-Deterrent Formulation of OxyContin*, 367 N. ENG. J. MED.187–89 (2012).
[26] Holly Hedegaard, M.D., Ctrs. for Disease Control & Prevention, *Drug-Poisoning Involving Heroin: United States, 2000–2013*, CDC.GOV (March 2015), https://www.cdc.gov/nchs/data/databriefs/db190_table.pdf#5
[27] MSP Headquarters, Michigan Intelligence Operations Center, interview by NDIC IA, January 26, 2011; BAYANET, interview by NDIC IA, January 26, 2011; Kalamazoo Public Safety, KVET, response to NDIC RFI, February 8, 2011; DEA, Detroit Division, Strategic Intelligence Group, interview by NDIC IA, January 25, 2011.

335. The number of publicly funded treatment admissions in the region in which heroin was indicated as the primary substance of abuse was higher than for any other drug and increased more than 20 percent from fiscal year (FY) 2005 (8,439) to FY2009 (10,358).

336. By 2010, the high level of heroin trafficking in Michigan HIDTA counties has been fueled, at least in part, by oxycodone users substituting heroin for prescription opioids.[28]

VI. SPECIFIC FACTUAL ALLEGATIONS

337. The City of Flint has been largely impacted by the opioid epidemic. The City participates in the Genesee County Community Wide Strategy to Address the Opioid Epidemic. The goal is to engage children, seniors, and the community's residents most impacted by the opioid crisis through a collaborative, multi-sector effort that builds and strengthens current workforce capacity, utilizes upstream prevention strategies, and creates an innovative, integrated model that coordinates care, services, and community resources to improve the treatment for and prevention of opioid misuse.

338. The Michigan Health Endowment Fund has awarded the Greater Flint Health Coalition (GFHC) a two-year $499,950 grant to implement a Community-Wide Strategy to Address the Opioid Epidemic.

339. The City of Flint began conducting various types of training for identifying and responding to opioid overdoses in the City in 2017.

340. In July 2018, the City of Flint experience 12 heroin overdoses in a span of a few hours.[29]

341. Within the State of Michigan, Genesee County has the 18th highest rate of opioid deaths and has seen a steady increase 2013. In 2015, there were 54 deaths from opioid/heroin overdose. Genesee County residents had 14,820 prescriptions per 10,000 residents, an average of 1.5 opioid prescriptions for every county resident in 2015, a 46% increase compared to 2009.

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[28] MSP Headquarters, Michigan Intelligence Operations Center, interview by NDIC IA, January 26, 2011; BAYANET, interview by NDIC IA, January 26, 2011; Kalamazoo Public Safety, KVET, response to NDIC RFI, February 8, 2011; DEA, Detroit Division, Strategic Intelligence Group, interview by NDIC IA, January 25, 2011.

[29] Bad batch of heroin leads to 12 overdoses in 3 hours, https://fox17online.com/2018/07/27/police-warn-against-using-heroin-after-bad-batch-leads-to-12-overdoses-in-3-hours/

342. Diverted opioids are widely abused in the Michigan High Intensity Drug Trafficking Area ("HIDTA").

343. Publicly funded treatment admissions show that the abuse of opioids increased from 2003 to 2007 including those for opiates/synthetics by 98 percent.

344. By 2009, the HIDTA Drug Market Analysis for the Michigan region reported that Diverted opioids are commonly available and abused in Michigan.

345. By 2011, the ability of users to acquire controlled prescription drugs ("CPDs") in the Michigan HIDTA region has driven CPD addiction to its highest level in 5 years.

346. According to the National Drug Threat Survey ("NDTS") data, 38 of the 49 respondents in the Michigan region reported high controlled prescription drug availability in their areas.

347. Opioid prescriptions in Michigan increased 41% between 2009 and 2015. In 2016, there were 11 million prescriptions written for opioids, about 1.1 prescriptions for every Michigan residents, about the same as 2015, according to the state's drug monitoring system.

348. Michigan health-care providers wrote 11 million prescriptions for opioid drugs in 2015 and another 11 million in 2016 -- enough to provide every Michigan resident with his or her own bottle of narcotics, according to state data.

349. The 2016 prescriptions accounted for 835 units of opioids -- enough to give every Michigan resident about 84 opioid pills, patches or other types of doses of opioid drugs.

350. The number of Michigan deaths from an overdose of opioids, including heroin, exceeded deaths from traffic crashes or gun fatalities in 2015, according to data from the Michigan Department of Health and Human Services.

351. In total, 1,275 people in Michigan died from opioid overdoses in 2015, compared to 1,164-gun deaths and 840 traffic fatalities.

352. Deaths from other drugs have stayed about the same over the past decade while opioid/heroin deaths have spiked.

353. In 1999, opioids and heroin accounted for 22% of Michigan's overdose deaths. By 2015, it was 67%.

354. Prescription opioids account for more than twice as many overdose deaths as heroin, although many addicts get their prescription painkillers illegally.

355. Michigan saw an increase in inpatient hospital stays related to opioid use between 2009 and 2014, according to a federal survey.

356. In 2015, Michigan had an age-adjusted drug overdose death rate of 20.4 per 100,000 people, the 15th highest rate in the country.

VII. TOLLING OF STATUTE OF LIMITATIONS AS TO THE CLAIMS AGAINST THE MANUFACTURER DEFENDANTS AND THE DISTRIBUTOR DEFENDANTS

357. In Michigan, if a person who is or may be liable for any claim fraudulently conceals the existence of the claim or the identity of any person who is liable for the claim from the knowledge of the person entitled to sue on the claim, the action may be commenced at any time within two years after the person who is entitled to bring the action discovers, or should have discovered, the existence of the claim or the identity of the person who is liable for the claim, although the action would otherwise be barred by the period of limitations. M.C.L. § 600.5855.

358. The running of any statute of limitation has been tolled because the Manufacturer Defendants fraudulently concealed from Plaintiff the existence of Plaintiff's claims by manipulating and distorting public information, knowledge, and facts; negligently and recklessly failing to make public or otherwise produce nonpublic information, over which the Manufacturer Defendants had exclusive possession, dominion, and control, that would have revealed the truth; and by deliberately and fraudulently concealing the truth.

359. Specifically, the Manufacturer Defendants concealed from Plaintiff the existence of Plaintiff's claims by manipulating and distorting public information, knowledge, and facts when the Manufacturer Defendants engaged in a public disinformation campaign which knowingly and

maliciously misrepresented that opioids, when used correctly, as directed, and for approved indications, were, *inter alia*, non-addictive, abuse proof or deterrent, safe, and effective for daily, long-term treatment of pain.

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

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

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

363. Specifically, the Distributor Defendants fraudulently concealed the existence of Plaintiff's claims by affirmatively seeking to convince the public that their legal duties had been satisfied through public assurances that they were working to curb the opioid epidemic. For example, Cardinal Health, through an executive, claimed that it used "advanced analytics" to monitor the supply chain and falsely represented that it was being "as effective and efficient as possible in constantly monitoring, identifying, and eliminating any outside criminal activity." McKesson stated that it has a "best-in-class controlled substance monitoring program to help identify suspicious orders" and claims that it is "deeply passionate about curbing the opioid epidemic in our country." Given each Distributor Defendants' sales volumes and history of violations, these false statements were made intentionally and fraudulently or recklessly without regard to the truth and as a positive assertion.

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

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

366. As set forth in the foregoing paragraphs of this Complaint, the Manufacturer Defendants made material misrepresentations about opioids, such as that they are non-addictive; the Manufacturer Defendants were aware that they were false because they had possession, dominion, and control over information indicating that opioids were far more addictive that the Manufacturer Defendants misled the public to believe; the Manufacturer Defendants intended that consumers, including Plaintiff, would act upon those misrepresentations (or Plaintiff reasonably believed that the Manufacturer Defendants so intended) as demonstrated by the existence of extensive marketing campaigns that asserted these misrepresentations; Plaintiff recommended that its employees' insurance carriers cover, and that its workers' compensation system reimburse, treatment with opioids because Plaintiff was unaware of the underlying truth about the Manufacturer Defendants' opioids; and Plaintiff reasonably or justifiably relied on those misrepresentations to its detriment because Plaintiff's reliance on the Manufacturer Defendants was reasonable considering that the Manufacturer Defendants possessed and controlled more information about their opioids than any other party and such reliance was harmful to Plaintiff as set forth in the damages section of this Complaint.

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

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

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

370. Also, the economics of this fraud should be considered. During the relevant time period, the Defendants all derived record profits as a result of their sales and distribution of prescription opioids. The Defendants had the ability to and did spend enormous amounts of money in furtherance of their purpose of marketing and promoting a profitable drug, notwithstanding the known or reasonably known risks. Plaintiff could not have afforded, and due to a lack of the requisite expertise could not have possibly conducted, studies to determine the nature, extent and identity of related health risks. As a result, the public and members thereof, including Plaintiff, were forced to rely on Defendant's untrue and fraudulent representations.

371. Much of the reckless distribution of opioids that were distributed through retail pharmacies in Michigan came from McKesson's Livonia distribution center. McKesson minimized and misrepresented the extent of the violations at the Livonia distribution center, which were hidden by McKesson and recently disclosed in a 60 Minutes episode that aired on December 17, 2017.

372. David Schiller, the Assistant Special Agent in Charge of the Denver Field Division of the Drug Enforcement Agency, spoke in the 60 Minutes episode regarding McKesson's distribution practices to Michigan pharmacies that were recklessly distributing opioids in Michigan, stating:

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

VIII. CAUSES OF ACTION

COUNT I

Public Nuisance
As Against All Defendants

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

374. Defendants' conduct has unreasonably interfered with the health, safety, peace, comfort, and convenience of the general public in the City of Flint.

375. Defendants, individually and acting through their employees and agents, have unreasonably interfered with a right common to the general public of the City of Flint, including by: (a) interfering significantly with the public health, safety, peace, comfort and convenience of the general community; (b) engaging in conduct proscribed by statute, ordinance or administrative regulation; and (c) engaging in conduct of a continuing nature that Defendants knew or should have known produced and continues to produce permanent and long-lasting significant effect of these rights common to the general public.

376. Each of the Manufacturer Defendants unreasonably interfered with rights common to the general public of the City of Flint-including by interfering with the public health, safety, peace and comfort-by, among other things, misleading federal regulators as to the addictive nature of their drugs, promoting and marketing the use of opioids for uses not federally approved, circulating false and misleading information concerning opioids' safety and efficacy, and downplaying or failing to disclose the risk of addiction arising from their use. In so doing, the Manufacturer Defendants acted unreasonably, reckless and with actual malice.

377. Each of the Defendants unreasonably interfered with rights common to the general public of the City of Flint—including by interfering with the public health, safety, peace and comfort—by failing to design and operate a system that would disclose the existence of suspicious orders of controlled

substances and/or by failing to report suspicious orders of opioids as required by the CSA, 21 C.F.R. §1301.74(b), and by Mich. Admin. Code R. 338.493c(i). In so doing, Defendants acted unreasonably, reckless and with actual malice.

378. Defendants' conduct contributing to the opioid epidemic has impinged the rights of the general public to use the streets and public ways without fear, apprehension and injury.

379. In light of Defendants' failures to disclose suspicious orders of opioids, and in light of Manufacturer Defendants' aggressive misinformation campaign regarding opioids, the City of Flint was unaware of, and could not reasonably know or have learned through reasonable diligence, that it had been exposed to the risks alleged herein. Information pertaining to the suspicious orders of opioids Defendants were required to disclose—but did not—was nonpublic information over which the Defendants had and continue to have exclusive control, and which Defendants knew was unavailable to the City of Flint.

380. At all times relevant to this Complaint, Defendants were in complete control over the instrumentalities constituting the public nuisance.

381. The City of Flint had neither knowledge nor reason to suspect that the Defendants were engaged in the wrongdoing alleged herein. Because of the fraudulent acts of concealment of wrongdoing by the Defendants, the City of Flint could not have reasonably discovered the wrongdoing in time to stem the opioid epidemic in the City of Flint.

382. As detailed herein, Defendants' conduct has interfered with and continues to interfere with rights common to the general public of the City of Flint, and has caused City of Flint to sustain damages special and particular in kind, including, without limitation, increased law enforcement and overtime pay for police officer patrols, judicial expenditures, increased prison and public works expenditures, increased substance abuse treatment and diversion plan expenditures, increased emergency and medical care services, increased medical examiner expenditures, and lost economic opportunity.

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

COUNT II

Negligence Per Se
As Against All Defendants

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

384. Each of the Defendants owed the City of Flint statutory duties, including the duty to report suspicious orders of opioids (and the appurtenant duty to investigate any such orders before filling them), the duty to abide by any government agreements entered regarding the same, and the duty to comply with the federal CSA, 21 C.F.R. § 1301.74(b), as incorporated by Mich. Admin. Code R. § 338.493c(i), which required the design and operation of a system to detect and disclose suspicious orders of controlled substances.

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

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

387. Each of the Manufacturer Defendants breached those duties by, among other things,

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

388. Each of the Defendants owed the City of Flint statutory duties, including the duty to "provide effective controls and procedures to guard against theft and diversion of controlled substances." *See* 21 C.F.R. § 1301.71(a).

389. The City of Flint suffered both injuries and pecuniary losses proximately caused by Defendants' breaches of their duties set forth in this Count. Among other things, the City's residents are suffering through an unprecedented epidemic of opioid addiction and overdose. This epidemic has forced the City of Flint to shoulder tremendous costs relating, among other things, to health services, emergency services, social services, and law enforcement. The City of Flint has also suffered a loss of productivity in its workforce, as well as lost tax revenue stemming from the cascading effects of the opioid epidemic.

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

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

COUNT III

Negligence
As Against All Defendants

391. The City of Flint incorporates by reference, as if fully set forth herein, each and every

preceding paragraph.

392. Separate and apart from the Defendants' statutory duties, each of the Defendants owed the City of Flint common-law duties, including the duty to report to investigate and report plainly suspicious orders of highly addictive opioids. Each of the Defendants breached these duties by failing to report such suspicious orders to the appropriate regulators, by failing adequately to investigate suspicious orders before filling them, and/or by failing to design and operate a system that would disclose the existence of suspicious orders of controlled substances. In so doing, Defendants acted unreasonably, reckless and with actual malice.

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

394. It was reasonably foreseeable that Defendants' breaches of the duties set forth in this Count would cause harm to the City of Flint.

395. The City of Flint suffered both injuries and pecuniary losses proximately caused by Defendants' breaches of their duties set forth in this Count. Among other things, the City's residents are suffering through an unprecedented epidemic of opioid addiction and overdose. This epidemic has forced the City of Flint to shoulder tremendous costs relating, among other things, to health services, emergency services, social services, and law enforcement. The City has also suffered a loss of productivity in its City of Flint's workforce, as well as lost tax revenue stemming from the cascading

effects of the opioid epidemic.

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

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

COUNT IV

Violations of Racketeer Influenced And Corrupt Organizations Act 18 U.S.C. 1961, *et seq.* As Against Manufacturer Defendants and Distributor Defendants

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

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

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

400. Plaintiff, the City of Flint, is a person under the RICO Act because it is a legal entity capable of holding a legal or beneficial interest in property. Plaintiff is a municipal corporation, and it is capable of holding a legal or beneficial interest in property as demonstrated by its ownership of substantial real estate and other personal property.

401. Plaintiff, the City of Flint, sustained a concrete injury to a proprietary interest in its business or property. Under Michigan law, money constitutes property in which the owner has a proprietary interest. Therefore, purely economic losses are considered "damage to property," and the economic loss rule does not apply in Michigan to prevent recovery of solely pecuniary damages when

a plaintiff had neither the bargaining power, nor the opportunity to otherwise bargain to protect its interests.

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

a) Expenditures to provide health services, mental-health services, and social services to victims of the opioid epidemic and their families in connection with the provision of services well beyond those required during the period predating the opioid epidemic;

b) Expenditures relating to law-enforcement attempts to stem the flow of opioids and heroin into local communities, to arrest and prosecute street-level dealers, to otherwise prevent the current opioid epidemic from spreading and worsening, and to deal with increased levels of other crimes, such as minor and major violence, burglary, robbery, etc., which has directly resulted from an uptick in the size of the homeless and drug-addicted population;

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

d) Losses caused by decreased productivity of City employees at work who are plagued with issues caused by opioid use and abuse;

e) Losses caused diminished property values in neighborhoods where the opioid epidemic, and the heroin trade, have taken root;

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

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

h) Expenditures associated with judicial operations;

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

j) Costs incurred by the Fire Department in connection with emergency responses to opioid overdoses; and

k) Expenses incurred by the various departments of the City of Flint caused by the opioid epidemic.

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

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

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

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

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

408. The RICO Defendants conducted and continue to conduct their business through legitimate and illegitimate means in the form of an association-in-fact enterprise and/or a legal entity enterprise. 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."

409. Section 1962(c) of RICO makes it unlawful "for any person employed by or associated

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

410. 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). In other words, an enterprise is any company (regardless of form or legal organization), person, or group of persons (regardless of how the members are associated, regardless of whether any member is aware of his membership, regardless of whether they intend to comprise a union or group, and regardless of whether wish or do not wish to be part of such group or union, provided that, in fact, that they are somehow associated).

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

DIVERSION ENTERPRISE

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

413. These legal associations and/or associations in fact include, at a minimum, a Manufacturer Defendant and a Distributor Defendant (or a pharmacy not named as a defendant in the instant case). These legal associations and/or associations in fact are, for purposes of the RICO Act, an

enterprise (hereinafter, for purpose of this count, an "Enterprise," a "Diversion Enterprise," or collectively, the "Enterprises").

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

415. To illustrate of the concept of an Enterprise, consider the following example. A Manufacturer Defendant manufactures opioids. The Manufacturer Defendant then sells the same opioids to a Distributor Defendant. The Distributor Defendant then distributes, or sells, the same opioids to a retailer. Finally, the retailer sells the same opioids to its customers who have been provided a prescription for the opioids.

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

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

418. The purpose the Diversion Enterprises, which are schemes organized to maximize the

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

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

a) Register to manufacture or distribute opioids;

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

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

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

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

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

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

423. Members of the Enterprises systematically violated their statutory duty to maintain effective controls against diversion of their drugs, to design and operate a system to identify suspicious orders of their drugs, to halt unlawful sales of suspicious orders, and to notify the DEA of suspicious orders. Consequently, the RICO Defendants allowed hundreds of millions of pills to enter the illicit market, which allowed the RICO Defendants to derive and be unjustly enriched by obscene profits.

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

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

unlawfully increasing revenues, profits, and market share.

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

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

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

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

430. The RICO Defendants committed crimes that are punishable as felonies under the laws of Michigan. Specifically, MCL 333.7407 makes it unlawful for any person to knowingly or intentionally furnish false information in, or omit any material information from, any application, report, record or other document required to be made, kept or filed under Article 7 of the Public Health Code of Michigan. A violation of MCL 333.7407 is punishable by up to four years in jail, making it a felony.

MCL 333.7407(1)(d). In turn, Article 7 of the Public Health Code provides that a person licensed to manufacture, distribute, prescribe, or dispense controlled substances shall keep records in conformance with the record-keeping and inventory requirements of federal law including the statutory requirements of the CSA. MCL § 333.7321.

431. The regulations promulgated under the CSA include a requirement that a person licensed to manufacture, distribute, prescribe, or dispense controlled substances design and operate a system to detect and report "suspicious orders" for controlled substances, as that term is defined in the regulation. *See* 21 C.F.R. §1301.74(b). The provision requiring the reporting of suspicious orders in the federal CSA has been incorporated, via regulation, into Michigan law. Mich. Admin. Code R. § 338.493c(i). Much like Michigan's Public Health Code, a violation of reporting requirements under the CSA is punishable up to 4 years in jail, making it a felony. 21 U.S.C. § 842(a)(4)(A) and (d)(1).

432. Each of the RICO Defendants qualifies as registrants under the CSA and Michigan's Public Health Code. Their status as registrants under the CSA and Michigan law requires that they maintain effective controls against diversion of controlled substances in schedule I or II, design and operate a system to disclose to the registrant suspicious orders of controlled substances and inform the DEA of suspicious orders when discovered by the registrant. 21 U.S.C. § 823; 21 C.F.R. § 1301.74(b). Mich. Admin. Code R. § 338.493c(i). Failure to abide by those requirements is a felony.

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

434. Members of each Enterprise participate in the Enterprise's affairs:

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

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

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

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

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

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

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

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

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

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

b) are otherwise interrelated by distinguishing characteristics, which include, without limitation:

i. commission in the same manner using the same means, such as:

1. intentionally failing to comply with CSA obligations to flag and report

orders of controlled substances as suspicious when they meet certain criteria;

2. using aggressive marketing campaigns that encourage overprescribing medications for unapproved uses;

3. claiming that the drugs were far safer, less addictive, and more effective than alternatives, each of which claim is false and misleading; and

4. providing such strong incentives for prescribing that such practices would be better described as bribery or coercion, (and which, in fact, in some cases, resulted in criminal convictions for violations of federal anti- kickback laws).

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

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

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

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

b) would and did represent that Defendants would comply with their duty to (1) design and operate a system to disclose to the registrant suspicious orders of controlled substances, and (2) disclose the results of such a program to resolve concerns about over prescription and diversion of opioids; and

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

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

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

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

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

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

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

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

445. Many of the precise dates of the RICO Defendants' criminal actions are not known and cannot be alleged without access to Defendants' books and records. Indeed, an essential part of the successful operation of the unified scheme alleged herein depended upon secrecy—and, towards that end, RICO Defendants took deliberate steps to conceal their wrongdoing. However, given the massive scope of the illegal and scheme, RICO Defendants likely committed thousands, if not millions, of predicate acts of racketeering activity.

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

447. It was foreseeable to Defendants that refusing to report and halt suspicious orders, as required by the CSA, the Code of Federal Regulations, and Michigan's Public Health Code would harm the City of Flint by allowing the flow of prescriptions opioids from appropriate medical channels into the illicit drug market.

448. The RICO Defendants knowingly and intentionally furnished false information in their reports to the DEA about suspicious orders, and/or omitted material information from reports, records

and other document required to be filed with the DEA—including the Manufacturer Defendants' applications for production quotas. Specifically, the RICO Defendants were aware of suspicious orders of prescription opioids and the diversion of their prescription opioids into the illicit market and failed to report this information to the DEA in their mandatory reports and their applications for production quotas.

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

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

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

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

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

against diversion of hydrocodone.

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

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

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

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

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

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

450. These actions against the Distributor Defendants confirm that the Distributors knew they had a duty to maintain effective controls against diversion, design and operate a system to disclose suspicious orders, and to report suspicious orders to the DEA. These actions also demonstrate, on information and belief, that the Manufacturer Defendants were aware of the enforcement against their Distributors and the diversion of the prescription opioids. Manufacturer Defendants had a corresponding duty to report these suspicious orders.

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

MARKETING ENTERPRISE

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

453. The formation, existence, and actions of the Marketing Enterprise were essential to the

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

454. At all relevant times, the Marketing Enterprise has existed separate and apart from defendants' racketeering acts and their conspiracy to commit such acts. The Marketing Enterprise has an ascertainable structure and purpose beyond the scope and commission of defendants' predicate acts. It has a consensual decision-making structure that is used to coordinate strategy, manipulate scientific data, suppress the truth about the addictive qualities of opioids, and otherwise further the Manufacturer Defendants' fraudulent unified scheme.

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

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

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

458. Patients relied on Manufacturer Defendants' misrepresentations regarding opioids safety

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

459. The Marketing Enterprise functioned as an ongoing organization and continuing unit. The Marketing Enterprise was created and/or used as tools to effectuate a pattern of racketeering activity. Each of the Marketing Enterprise participants, including Defendants, is a "person" distinct from the Marketing Enterprise.

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

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

462. In order to further the conspiracy, and as part of an Enterprise that was engaged in a pattern of racketeering activity, Defendants formed multiple front groups or infiltrated existing third-party organizations to avoid regulation from the FDA.

a) The American Pain Foundation ("APF"), founded in 1997, described itself as

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

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

c) In 2009, the American Pain Society ("APS") and AAPM jointly issued guidelines ("APS/AAPM Guidelines") recommending the use of opioids to

treat chronic pain. The APS/AAPM guidelines promoted the use of opioids for the treatment of chronic pain and concluded that the risk of opioid addiction was manageable in patients regardless of previous histories of abuse. At least fourteen of the twenty-one panel members who drafted the APS/AAPM Guidelines received funding from manufacturer defendants Purdue, Endo, Cephalon or Janssen;

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

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

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

and distributor defendants McKesson, Cardinal Health, and AmerisourceBergen.

463. The Marketing Enterprise used three principle stratagems to facilitate their goal of misleading doctors and the public about the dangers of opioids. *First*, using the shadow groups discussed above, the Marketing Enterprise created a marketing structure that appeared independent from Manufacturer Defendants. In so doing, Manufacturer Defendants sought to avoid federal regulations concerning off-label promotion. *Second*, Manufacturer Defendants generated and published favorable articles that appeared to emanate from independent physicians. *Third*, in order to widely disseminate the message that opioids were practically non- addictive, Defendants' marketing enterprise developed misleading labeling. That labeling was widely disseminated across the country to physicians and prescribers. These three stratagems were complementary and mutually reinforcing. The production of favorable publications and the peer-to-peer marketing and promotion allowed aggressive sales pitches to continue with the appearance of legitimacy.

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

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

466. These systematic linkages between physicians, marketing participants, physician participants, Manufacturer Defendants and all the Enterprise participants were established for a common purpose: to aid in marketing and selling opioids for ubiquitous use to treat all levels of pain. Many of the Enterprise participants received substantial revenue from the scheme to promote opioids. Such

revenue was exponentially greater than it would have been if opioids been marketed appropriately.

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

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

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

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

a) Mail Fraud: The Manufacturer Defendants violated 18 U.S.C. § 1341 by sending and receiving, and by causing to be sent and/or received, materials via U.S. Mail or commercial interstate carriers for the purpose of executing the unlawful scheme to deceptively market, and sell the opioids by means of false pretenses, misrepresentations, promises and omissions; and

b) Wire Fraud: The Manufacturer Defendants violated 18 U.S.C. § 1343 by transmitting and/or receiving, and by causing to be transmitted and/or received, materials by wire for the purpose of executing the unlawful scheme to defraud and obtain money on false pretenses, misrepresentations, promises and omissions.

471. The Manufacturer Defendants' use of the mails and wires include, but are not limited to,

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

a) false or misleading communications to the public and to regulators;

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

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

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

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

was manageable in patients regardless of previous histories of abuse.

f) Distribution of "Responsible Opioid Prescribing," a guide authored by Dr. Scott Fishman in 2007. The guide was ultimately disseminated to 700,000 practicing doctors, with doctors in Michigan alone receiving 42,366 copies. The "Responsible Opioid Prescribing" guide promoted the use of opioid pain relievers for both acute and chronic pain and severely minimized the risk of addiction—even claiming that opioids could be used safely in patient assessed to have a risk of substance abuse. The guide promoted the widespread use of opioids, stating that "[p]atients should not be denied opioid medications except in light of clear evidence that such medications are harmful to the patient."

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

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

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

475. The City of Flint has been injured in their property by reason of these violations in that the City has paid and will pay millions of dollars to abate the public nuisance that is the opioid epidemic

in Flint, Michigan.

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

477. The Enterprise, and the members thereof, acted and participated to further the purpose of the Enterprise willfully and/or with actual knowledge of the illegal acts of the enterprise, as evidenced by their aggressive marketing campaigns and even recent activities abroad, which includes companies owned and controlled by Purdue running training seminars where doctors are urged to overcome "opiophobia" and prescribe painkillers.[30]

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

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

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

481. As described herein, the RICO Defendants engaged in a pattern of related and continuous

[30] Harriet Ryan, Lisa Girion & Scott Glober, *OxyContin goes Global – "We're only just getting started"*, LOS ANGELES TIMES (Dec. 18, 2016), http://www.latimes.com/projects/la-me-oxycontin-part3/.

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

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

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

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

485. All the RICO Defendants conducted and participated in the conduct of the affairs of the Marketing Enterprise or the Diversion Enterprise through a pattern of racketeering activity as defined in 18 U.S.C. § 1961(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. Furthermore, in so doing the acts alleged herein, the members of the Enterprises (the "Co-Conspirators") conspired to violate § 1962(c) of the RICO Act, and they thereby violated § 1962(d) of the RICO Act.

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

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

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

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

490. The City of Flint's damages are not remote. Nor are the City's damages derivative of harm visited upon third party persons or entities not named in this action.

491. By virtue of the foregoing violations of the RICO Act, including 18 U.S.C. § 1962(c), Manufacturer Defendant is liable to the City of Flint for three times the damages sustained, plus the costs of this suit, including reasonable attorney's fees.

EXEMPLARY DAMAGES

492. Plaintiff re-alleges all paragraphs of this Complaint as if set forth fully herein.

493. By engaging in the above-described intentional and/or unlawful acts or practices, Defendants acted willfully with actual malice, wantonly, and oppressively. Defendants acted with conscious disregard to the rights of others and/or in a reckless, wanton, willful, or grossly negligent manner. Defendants acted with a prolonged indifference to the adverse consequences of their actions and/or omissions. Defendants acted with a conscious disregard for the rights and safety of others in a manner that had a great probability of causing substantial harm. Defendants acted toward the Plaintiff with fraud, oppression, and/or malice, and/or were grossly negligent in failing to perform the duties and obligations imposed upon them under applicable federal and state statutes, and common law.

494. Defendants were selling and/or manufacturing dangerous drugs statutorily categorized as posing a high potential for abuse and severe dependence. Thus, Defendants knowingly traded in drugs that presented a high degree of danger if prescribed incorrectly or diverted to other than legitimate medical, scientific, or industrial channels. Because of the severe level of danger posed by, and indeed visited upon the City of Flint by, these dangerous drugs, Defendants owed a high duty of care to ensure that these drugs were only used for proper medical purposes. Defendants chose profit over prudence, and the safety of the community, and an award of punitive damages is appropriate, as punishment and deterrence.

495. By engaging in the above-described wrongful conduct, Defendants also engaged in willful misconduct and gross negligence, and exhibited an entire want of care that would raise the presumption of a conscious indifference to consequences.

PRAYER FOR RELIEF

WHEREFORE, Plaintiff, acting on behalf of themselves and on behalf of their inhabitants, prays that the Court grant the following relief:

A. Enjoin Defendants from failing to report suspicious orders as required by the federal CSA, as incorporated by Mich. Admin. Code R. § 338.493c(i);

B. Awarding Plaintiff, the City of Flint, damages caused by the opioid epidemic, including (1) costs for providing medical care, additional therapeutic and prescription drug purchases, and other treatments for patients 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 with opioid-related medical conditions; (4) costs for providing care for children whose parents suffer from opioid-related disability or incapacitation; and (5) costs associated with law enforcement and public safety relating to the opioid epidemic;

C. Order that Defendants compensate Plaintiff for past and future costs to abate the ongoing public nuisance caused by the opioid epidemic;

D. Order Defendants to fund an “abatement fund” for the purposes of implementing programs necessary to abate the opioid nuisance;

E. Award actual damages, treble damages, injunctive and equitable relief, forfeiture as deemed proper by the Court, and attorney fees and all costs and expenses of suit pursuant to Plaintiffs' racketeering claims;

F. Awarding judgment against the Defendants requiring Defendants to pay punitive damages;

G. The cost of investigation, reasonable attorneys' fees, and all costs and expenses;

H. Pre-judgment and post-judgment interest; and

I. Grant any such further relief as this Court deems appropriate.

Dated: February 18, 2019

Respectfully submitted,

/s/ Angela Wheeler
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