IN THE COURT OF COMMON PLEAS OF ALLEGHENY COUNTY, PENNSYLVANIA

CIVIL DIVISION

CITY OF PITTSBURGH,

Plaintiff,

vs.

PURDUE PHARMA, L.P.; PURDUE PHARMA INC.; THE PURDUE FREDERICK COMPANY, INC.; ENDO PHARMACEUTICALS INC.; ENDO HEALTH SOLUTIONS 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.; TEVA PHARMACEUTICALS USA, INC.; MALLINCKRODT, PLC; MALLINCKRODT LLC; CARDINAL HEALTH, INC.; MCKESSON CORPORATION; AMERISOURCEBERGEN DRUG CORPORATION,

Defendants.

G.D. No. ________________

Code: ___________________

COMPLAINT IN CIVIL ACTION

JURY TRIAL DEMANDED

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CITY OF PITTSBURGH

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JURY TRIAL DEMANDED

NOTICE

You have been sued in court. If you wish to defend against the claims set forth in the following pages, you must take action within twenty (20) days after this complaint and notice are served, by entering a written appearance personally or by attorney and filing in writing with the court your defenses or objections to the claims set forth against you. You are warned that if you fail to do so the case may proceed without and a judgment may be entered against you by the court without further notice for any money claimed in the complaint or for any claim or relief requested by the plaintiff. You may lose money or property or other rights important to you.

IF YOU CANNOT AFFORD TO HIRE A LAWYER, THIS OFFICE MAY BE ABLE TO PROVIDE YOU WITH INFORMATION ON AGENCIES THAT MAY OFFER LEGAL SERVICES TO ELIGIBLE PERSONS AT A REDUCED FEE OR NO FEE.

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COMPLAINT IN CIVIL ACTION

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I. PRELIMINARY STATEMENT

1. "The opioid overdose epidemic is the worst public health crisis in Pennsylvania, and the nation, in almost a generation," [1]—the worst drug crisis in American history, according to Attorney General Jeff Sessions. Plaintiff the City of Pittsburgh, Pennsylvania ("the City"), is being hit especially hard, with opioid overdose rates multiple times higher than in Pennsylvania as a whole, which already is higher than in the United States generally. Most alarmingly, opioid overdose deaths in the City increased from 64 in 2010 to 231 in 2017, for an eight-year total of 1,021 City residents who lost their lives to opioids.

2. Unlike the crack cocaine and crystal methamphetamine epidemics that preceded it, this drug crisis began with a white-collar corporate business plan. It started with a decision by Purdue Pharma L.P., and its corporate family (collectively, "Purdue"), to promote opioids deceptively and illegally in order to significantly increase sales and generate billions of dollars in revenue for Purdue and its private owners, the Sackler family. Unfortunately, Purdue's strategies were quickly joined by Endo Pharmaceuticals Inc., Endo Health Solutions Inc., Johnson & Johnson, Janssen Pharmaceuticals, Inc. Orto-McNeil-Janssen Pharmaceuticals, Inc. N/K/A Janssen Pharmaceuticals, Inc., Janssen Pharmaceutica, Inc. N/K/A Janssen Pharmaceuticals, Inc. Teva Pharmaceuticals USA, Inc, and Mallinckrodt LLC (collectively with Purdue, "the Manufacturing Defendants"), which all used misrepresentations regarding the risks and benefits of opioids to enable the widespread prescribing of opioids for common, chronic pain conditions

[1] Pennsylvania Opioid Data Dashboard, Commonwealth of Pennsylvania, https://data.pa.gov/stories/s/9q45-nckt/.

like low back pain, arthritis, and headaches.[2] As a direct consequence, the rampant use, overuse, and abuse of opioids is devastating much of the country, including the City and its residents.

3. Distributor Defendants McKesson Corporation d/b/a McKesson Drug Company, AmerisourceBergen Drug Corporation, and Cardinal Health, Inc. distribute opioid medications, including the medications listed above, to pharmacies, pain clinics and other dispensaries across the country and, upon information and belief, in the City.

4. Prescription opioids are narcotics regulated as controlled substances. They are derived from opium and possess properties similar to heroin. While opioids can work to dampen the perception of pain, they also can create an addictive, euphoric high. At higher doses, they can slow the user's breathing, causing potentially fatal respiratory depression. Most patients receiving more than a few weeks of opioid therapy will experience prolonged withdrawal symptoms—including severe anxiety, nausea, headaches, tremors, delirium, and pain—if opioid use is delayed or discontinued. When using opioids continuously, patients grow tolerant to their analgesic effects, requiring progressively higher doses and increasing the risks of withdrawal, addiction, and overdose.

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

6. As Purdue developed OxyContin in the mid-1990s, it knew that to expand its market and profits, it needed to change the perception of opioids to permit and encourage the use

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

of opioids as a first-line, long-term treatment for widespread chronic conditions like back pain, migraines, and arthritis. Purdue, along with the other Manufacturing Defendants, helped cultivate a narrative that pain was undertreated and pain treatment should be a higher priority for health care providers. This paved the way for increased prescribing of opioids for first-line treatment for chronic pain. Manufacturing Defendants' promotional efforts dovetailed with this narrative, as Manufacturing Defendants began to promote opioids generally, and their own opioids in particular, as safe, effective, and appropriate for first-line, long-term use for routine pain conditions. As part of this strategy, Manufacturing Defendants misrepresented the risk of addiction for pain patients as modest, manageable, and outweighed by the benefits of opioid use.

7. Between the 1990s and 2011, opioid prescriptions increased some 31% from approximately 1.6 million to approximately 2.2 million. According to a U.S. Department of Health and Human Services Fact Sheet, "[i]n 2014, more than 240 million prescriptions were written for prescription opioids, which is more than enough to give every American adult their own bottle of pills."

8. Manufacturing Defendants' deceptive marketing efforts continued over the next several years, eventually coming under investigation by a number of state and federal entities. In 2007, Purdue and three of its executives pled guilty to federal criminal charges for deceptively marketing opioids and reached civil settlements with 26 states, including Pennsylvania. As laid out in its plea agreement, Purdue systematically misrepresented the risk of addiction, including promising that opioid addiction occurred in less than 1% of patients and that opioids were not addictive when legitimately prescribed. However, rather than reforming its opioid marketing to comply with the law, Purdue continued to mislead and obfuscate, as did the other Manufacturing

Defendants. Similarly, in 2008, Cephalon pled guilty to a criminal violation of the Federal Food, Drug and Cosmetic Act and agreed to pay $425 million in civil fines.

9. To this day, Manufacturing Defendants have failed to correct their earlier misrepresentations, and, in many respects, persist in the same types of misconduct. In the decade that followed Purdue's guilty plea, the Manufacturing Defendants sustained a multi-billion dollar pain franchise through the same pattern of deceptive marketing. Specifically:

> Manufacturing Defendants informed and instructed doctors that patients receiving opioid prescriptions for pain generally would not become addicted, and that doctors could use screening tools to exclude patients who might.
>
> Manufacturing Defendants informed and instructed doctors that patients who did appear addicted were not; they were instead "pseudoaddicted" and needed more opioids.
>
> Manufacturing Defendants informed and instructed doctors that opioids relieved pain when used long-term, without any studies to support this claim and without disclosing the lack of evidence that opioids were safe or effective long-term or the other risks from long-term use of opioids.
>
> Manufacturing Defendants informed and instructed doctors that opioids could be taken in higher and higher doses without disclosing the increased risk to patients.
>
> Purdue informed and instructed doctors that OxyContin provided 12 hours of relief when Purdue knew that, for many patients, it did not.
>
> Manufacturing Defendants promised that opioids would improve patients' function and quality of life while trivializing or omitting the many adverse effects of opioids that diminish patients' function and quality of life.

10. Manufacturing Defendants knew that their representations regarding the risks and benefits of opioids were not supported by, or were directly contrary to, the scientific evidence. Indeed, rather than helping patients, the explosion in opioid use has come at the expense of many chronic pain patients. In 2016, after reviewing the existing research, the U.S. Centers for Disease Control ("CDC") concluded that "for the vast majority of [chronic pain] patients, the known, serious, and too-often-fatal risks [of opioids] far outweigh the unproven and transient

benefits." As the then CDC director concluded: "We know of no other medication routinely used for a nonfatal condition that kills patients so frequently."

11. When faced with a rising tide of opioid addiction, overdose, and death – precisely the risks that they denied for years – Purdue and Endo falsely promoted their abuse-deterrent opioids as preventing abuse and diversion and as "safe." Both Defendants knew, and evidence showed, that the "abuse-deterrent" features of their opioids could be easily defeated, did nothing to decrease oral abuse, which is the most common means of abuse, and increased conversion to heroin. Purdue's and Endo's marketing was intended to, and did, reassure prescribers who became concerned about addiction that they not only could continue to prescribe opioids, but in fact, needed to switch to their brands of abuse-deterrent opioids, thus preserving and expanding these Defendants' market-share.

12. In the same vein, Purdue also misrepresented its efforts to rein in the diversion and abuse of opioids, while privately failing to report suspicious prescribing. Upon information and belief, all Manufacturing Defendants paid reimbursements known as "chargebacks" to wholesale distributors, and thereby obtained information about where their drugs were going as they progressed from wholesalers to retailers and down the supply chain. Also upon information and belief, Manufacturing Defendants also had access to detailed prescribing data, which they monitored regularly to target and monitor their marketing efforts. Upon information and belief, Manufacturing Defendants failed to report suspicious orders or prescription patterns that information available to them should have revealed.

13. Manufacturing Defendants' scheme was resoundingly successful. Manufacturing Defendants' deceptive marketing caused prescribing not only of their opioids, but of opioids as a class, to skyrocket. Opioids are now among the most prescribed classes of drugs. According to

the CDC, opioid prescriptions, as measured by number of prescriptions and morphine milligram equivalent ("MME") per person, tripled from 1999 to 2015. In 2015, on an average day, more than 650,000 opioid prescriptions were dispensed in the U.S. While previously a small minority of opioid sales, today between 80% and 90% of opioids (measured by weight) are used for chronic pain. Approximately 20% of the population between the ages of 30 and 44, and nearly 30% of the population over 45, have used opioids. Opioids are the most common treatment for chronic pain, and 20% of office visits now include the prescription of an opioid.

14. While opioids have been diverted through illicit prescribing and sales, it is the regular, legitimate prescribing of opioids that created and fueled this crisis. A study of 254 accidental opioid overdose deaths in Utah found that 92% had been receiving prescriptions from health care providers for chronic pain.

15. Once Manufacturing Defendants created a mass market for prescription opioids, Distributor Defendants flooded it. Distributor Defendants are responsible for delivering opioids made and marketed by the Manufacturing Defendants to pharmacies throughout the country. Distributor Defendants have a duty to report any suspicious orders of controlled substances including orders of opioids that exceed reasonable volume or frequency, into the City. Yet, on information and belief, Distributor Defendants have supplied opioids to pharmacies within the City in quantities that they knew, or should have known, exceed any legitimate market for opioids without reporting such suspicious orders to the Drug Enforcement Administration.

16. As a direct result of the Manufacturing Defendants' dangerously false marketing and the Distributor Defendants' overzealous desire to fill even suspicious orders, the nation is now swept up in what the CDC called a "public health epidemic" and what President Trump deemed a "public health emergency." The increased volume of opioid prescribing correlates

directly to skyrocketing addiction, overdose, and death; black markets for diverted prescription opioids; and a concomitant rise in heroin and fentanyl abuse by individuals who could no longer legally acquire—or simply could not afford—prescription opioids.

17. Every day, 91 people die across the country from an opioid-related overdose and over 1,000 patients are given emergency treatment for misusing them. Many others are swept into a cycle of addiction and abuse with which they will struggle their entire lives. As many as 1 in 4 patients who receive prescription opioids long-term for chronic pain in primary care settings struggle with addiction. In 2014, almost 2 million Americans were addicted to prescription opioids and another 600,000 to heroin. From 1999 to 2015, more than 194,000 people died in the U.S. from overdoses related to prescription opioids—more than the number of Americans who died in the Vietnam War.

18. The situation in Pennsylvania, including in the City, is equally catastrophic—and getting worse. In the seven-year period between 2008-2014, there were 481 opiate-related overdose deaths in the City. In just three years, the three-year period between 2015-2017, there were 587 opioid overdose deaths.

19. Defendants' conduct has violated, and continues to violate, the Pennsylvania Unfair Trade Practices and Consumer Protection Law, 73 P.S. §§ 201-1 through 201-9.3. Additionally, Defendants' conduct constitutes a common law public nuisance, negligence, gross negligence, and fraudulent misrepresentation, and resulted in their unjust enrichment.

20. Accordingly, the City brings this action to hold Defendants accountable for their conduct; and seeks disgorgement, restitution, abatement, damages, and any other injunctive and equitable relief within this Court's powers to redress and halt these unfair, deceptive, and unlawful practices.

II. JURISDICTION AND VENUE

21. The venue for this claim is proper in the Court of Common Pleas of Allegheny County, Fifth Judicial District of Pennsylvania, pursuant to 42 Pa. C.S.A. § 931(c) and Pa. R. Civ. P. 1006(b) & 2179(a). Venue as to each Defendant is proper in this court because each of the Defendants carries on regular business in Allegheny County, and because each cause of action herein arose in Allegheny County or Allegheny County was the location of a transaction or occurrence that took place out of which the cause of action arose.

22. This Court has jurisdiction pursuant to Pa. Const. Art. V, § 4 and 42 Pa. C.S.A. § 761; 42 Pa. C.S.A. § 931(a); 42 Pa. C.S.A. § 5322; and 16 P.S. § 202. Each Defendant transacts business in the Commonwealth of Pennsylvania, contracts to supply goods in the Commonwealth of Pennsylvania, carries on a continuous and systematic part of their general businesses within Pennsylvania, have transacted substantial business with Pennsylvania entities and residents, and have caused grave harm in Pennsylvania as a result.

23. This action is not removable to federal court. Among other things, there is no diversity jurisdiction. Defendants Teva USA, Cephalon, Endo Health Solutions Inc., Endo Pharmaceuticals Inc., and AmerisourceBergen all have their principal places of business within the Commonwealth of Pennsylvania; and Defendants Janssen Pharmaceuticals, Inc. and Orto-McNeil-Janssen Pharmaceuticals, Inc. are Pennsylvania corporations. In addition, the claims alleged in the Complaint do not permit federal question jurisdiction to be exercised because the case does not arise directly or indirectly under the Constitution, laws or treaties of the United States.

III. PARTIES

A. Plaintiff

24. Plaintiff, the City of Pittsburgh, Pennsylvania, is a political subdivision of the Commonwealth of Pennsylvania. It is the county seat of Allegheny County. As of the 2017, the population of the City was 305,704, making Pittsburgh the second-most populous city in Pennsylvania. Plaintiff provides a wide range of services to its residents, including police, fire and emergency medical services ("EMS"). Plaintiff also offers health insurance coverage for its employees and their dependents, and a workers' compensation program, both of which are self-funded. Accordingly, the City brings this action on its own behalf and as *parens patriae* in the public interest.

B. Defendants

25. Purdue Pharma, L.P. is a limited partnership organized under the laws of Delaware, with its principal place of business in Stamford, Connecticut. Purdue Pharma, Inc. is a New York corporation with its principal place of business in Stamford, Connecticut. The Purdue Frederick Company Inc. is a subsidiary of Pharmaceutical Research Associates, Inc., and is a Delaware corporation with its principal place of business in Stamford, Connecticut. These Defendants are collectively referred to herein as "Purdue." Purdue develops, manufactures, promotes, and sells opioids products such as MS Contin, Dilaudid, Dilaudid-HP, Butrans, Hysingla ER, and OxyContin.[3] Purdue has conducted promotional activities in the City; and has sold its products to distributors that have distributed its products to pharmacists in the City.

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[3] OxyContin is Purdue's best-selling opioid. Since 2009, Purdue's annual sales of OxyContin have fluctuated between $2 billion and $3 billion. Nationwide, OxyContin constitutes roughly 25% of the entire market, by spending, for prescription opioids. Since its launch in 1996, OxyContin alone has generated $35 billion in sales for Purdue.

Prescribers in the City have written prescriptions for Purdue's products, City residents have filled those prescriptions at pharmacies in the City, and have used Purdue's products in the City. Purdue is, or should be, aware that its products have been distributed, prescribed to consumers, and used in the City.

26. Teva Pharmaceuticals USA, Inc. ("Teva USA") is a Delaware corporation with its principal place of business in North Wales, Pennsylvania. Teva USA acquired Cephalon in October 2011.[4] Cephalon, Inc. ("Cephalon") is a Delaware corporation with its principal place of business in Frazer, Pennsylvania. Teva USA and Cephalon work together closely to market and sell Cephalon products. Teva USA also sells generic opioids, including generic opioids previously sold by Allergan plc, whose generics business was acquired by Teva USA's parent company, Teva Pharmaceutical Industries Ltd. Teva USA and Cephalon are collectively referred to herein as "Teva." Teva develops, manufactures, promotes, and sells opioids such as Actiq, a fentanyl lollipop, and Fentora, a dissolving pill. Actiq and Fentora have been approved by the Food and Drug Administration ("FDA") only for the "management of breakthrough cancer pain in patients 16 years of age and older who are already receiving and who are tolerant to opioid therapy for their underlying persistent cancer pain." Teva has conducted promotional activities in the City and has sold its products to distributors that have distributed its products to pharmacists in the City, Prescribers in the City have written prescriptions for Teva's products, and City residents have filled those prescriptions at pharmacies in the City and used Teva's products in the City. Teva is, or should be, aware that its products have been distributed, prescribed to consumers, and used in the City.

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[4] In 2008, Cephalon pled guilty to a criminal violation of the Federal Food, Drug and Cosmetic Act and agreed to pay $425 million for its misleading promotion of Actiq and two other drugs.

27. Janssen Pharmaceuticals, Inc. is a Pennsylvania corporation with its principal place of business in Titusville, New Jersey, and is a wholly owned subsidiary of Johnson & Johnson (J&J), a New Jersey corporation with its principal place of business in New Brunswick, New Jersey. 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 Pharmaceutical 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 it 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. These Defendants are collectively referred to herein as "Janssen." Janssen develops, manufactures, promotes, and sells drugs, including the opioid Duragesic. Before 2009, Duragesic accounted for at least $1 billion in annual sales. Until January 2015, Janssen developed, marketed, and sold the opioids Nucynta and Nucynta ER. Together, Nucynta and Nucynta ER accounted for $172 million in sales in 2014. Janssen has conducted promotional activities in the City, and has sold its products to distributors that have distributed Janssen's products to pharmacists in the City. Prescribers in the City have written prescriptions for Janssen's products, and City residents have filled those prescriptions at pharmacies in the City and have used Janssen's products in the City. Janssen is, or should be, aware that its products have been distributed, prescribed to consumers, and used in the City.

28. 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. These Defendants are collectively referred to herein as "Endo." Endo develops, manufactures, promotes, and sells prescription drugs, including the opioids Opana/Opana ER, Percodan, Percocet, and Zydone. 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 to 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, by itself and through its subsidiary, Qualitest Pharmaceuticals, Inc. On July 6, 2017, in response to an FDA request that Endo voluntarily withdraw the product from the market, the company announced that it would stop marketing and selling a reformulated version of Opana ER that it had marketed as abuse-deterrent. Endo has conducted promotional activities in the City, and has sold its products to distributors that have distributed Endo's products to pharmacists in the City. Prescribers in the City have written prescriptions for Endo's products, and City residents have filled those prescriptions at pharmacies in the City and have used Endo's products in the City. Endo is, or should be, aware that its products have been distributed, prescribed to consumers, and used in the City.

29. Mallinckrodt, plc is an Irish public limited company headquartered in Staines-upon-Thames, United Kingdom, with its U.S. headquarters in St. Louis, Missouri. Mallinckrodt LLC is a limited liability company licensed to do business in Pennsylvania, organized and existing under the laws of the State of Delaware, and with its principal place of business in Missouri. Since June 28, 2013, Mallinckrodt LLC has been a wholly owned subsidiary of Mallinckrodt, plc. Prior to June 28, 2013 Mallinckrodt LLC was a wholly-owned subsidiary of Covidien pllc. Mallinckrodt, plc and Mallinckrodt LLC are referred to herein collectively as "Mallinckrodt." Mallinckrodt develops, manufactures, promotes, distributes, and sells drugs,

including generic oxycodone, of which it is one of the largest manufacturers. Mallinckrodt has conducted promotional activities in the City and has sold its products to distributors that have distributed Mallinckrodt's products to pharmacists in the City and/or has itself distributed its products to pharmacies in the City. Prescribers in the City have written prescriptions for Mallinckrodt's products, and City residents have filled those prescriptions at pharmacies in the City, and have used Mallinckrodt's products in the City. Mallinckrodt is, or should be, aware that its products have been distributed, prescribed to consumers, and used in the City.[5]

30. Cardinal Health, Inc. ("Cardinal") describes itself as a "global, integrated health care services and products company," and is the fifteenth largest company by revenue in the United States, with annual revenue of $121 billion in 2016. Cardinal distributes pharmaceutical drugs, including opioids, throughout the country, including in the City. Cardinal is an Ohio corporation and is headquartered in Dublin, Ohio. Cardinal operates two distribution centers near Pennsylvania—one in Wheeling, West Virginia and one in Swedesboro, New Jersey. Based on Defendant Cardinal's own estimates, one of every six pharmaceutical products dispensed to U.S. patients travels through the Cardinal Health network.

31. McKesson Corporation ("McKesson") is fifth on the list of Fortune 500 companies, ranking immediately after Apple and ExxonMobil, with annual revenue of $191 billion in 2016. McKesson is a wholesaler of pharmaceutical drugs that distributes opioids throughout the country, including in the City. McKesson is incorporated in Delaware and its principal place of business is in San Francisco, California. McKesson operates a distribution center in New Castle, Pennsylvania. In January 2017, McKesson paid a record $150 million to

[5] 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.

resolve an investigation by the U.S. Department of Justice ("DOJ") for failing to report suspicious orders of certain drugs, including opioids, and for failing to maintain effective controls against diversion at its distribution centers.

32. AmerisourceBergen Drug Corporation ("AmerisourceBergen") is a wholesaler of pharmaceutical drugs that distributes opioids throughout the country, including in the City. AmerisourceBergen's principal place of business is located in Chesterbrook, Pennsylvania and it is incorporated in Delaware. AmerisourceBergen operates a distribution center in Bethlehem, Pennsylvania.

33. The Distributor Defendants together distribute 85% to 90% of the prescription drugs in the United States. They are known as the "big three" and dominate the wholesale distribution market, including in the City.

IV. ALLEGATIONS COMMON TO ALL COUNTS

34. Until the mid-1990s, opioids were widely thought to be too addictive for use for chronic pain conditions, which would require long-term use of the drugs at increasingly higher doses. For these conditions, the risks of addiction and other side effects outweighed any benefit from the drugs. For the last two decades, Manufacturing Defendants have sought—and succeeded—to turn that sensible consensus on its head, primarily by covering up the risk of addiction and overstating the benefits of using opioids long-term.

35. Through marketing that was as pervasive as it was deceptive, Manufacturing Defendants convinced health care providers both that the risks of long-term opioid use were overblown and that the benefits, in reduced pain and improved function and quality of life, were proven. The result was that by the mid-2000s, the medical community had abandoned its prior caution, and opioids were entrenched as an appropriate—and often the first—treatment for chronic pain conditions. Manufacturing Defendants not only marketed opioids for chronic pain,

but targeted primary care physicians (along with nurse practitioners and physician assistants), who were most likely to see patients with chronic pain and least likely to have the training and experience to evaluate both Defendants' marketing and patients' pain conditions.

36. Thus, Defendants' deceptive marketing created a cadre of doctors who looked for pain and treated it with opioids, which created an even broader cohort of patients who expected and required opioids. This laid the groundwork for today's epidemic of opioid addiction, injury, and death.

A. Manufacturing Defendants Falsely Trivialized, Mischaracterized, And Failed To Disclose The Known, Serious Risks Of Addiction.

37. Manufacturing Defendants rely heavily on their sales representatives to convey their marketing messages and materials to prescribers in targeted, in-person settings. Not surprisingly, all of the Manufacturing Defendants' sales representatives visited prescribers in the City. Sales representatives from Purdue were the most frequent visitors to prescribers in the City with more than 1,660 visits between the third quarter of 2013 and the end of 2016. These visits frequently coincided with payments to the prescriber for "promotional speaking," "food and beverage," "consulting," "travel and lodging," "honoraria," and "education." The Manufacturing Defendants each visited prescribers in the City and collectively paid prescribers in the City over $14,420 during this 2013 – 2016 time period.

38. The U.S. Senate Homeland Security & Governmental Affairs Committee recently issued a Staff Report noting the link between drug maker payments to prescribers and physician prescribing practices. It found that "a clear link exists between even minimal manufacturer payments and physician prescribing practices." The Report quotes ProPublica findings that "doctors who received industry payments were two to three times as likely to prescribe brand-name drugs at exceptionally high rates as others in their specialty."

39. To ensure that sales representatives delivered the desired messages to prescribers, Defendants Purdue, Teva, Janssen, and Endo directed and monitored their respective sales representatives through detailed action plans, trainings, tests, scripts, role-plays, supervisor tag-alongs, and review of representatives' "call notes" from each visit. These Defendants likewise required their sales representatives to use sales aids reviewed, approved, and supplied by the companies and forbade them to use promotional materials not approved by the company's marketing and compliance departments. They further ensured marketing consistency nationwide through national and regional sales representative training. Thus, upon information and belief,[6] their sales forces in the City carried out national marketing strategies, delivering centrally scripted messages and materials that were consistent across the country.

40. Manufacturing Defendants were aware of the strength of their in-person marketing. The effects of sales calls on prescribers' behavior is well-documented in the literature, including a 2009 study correlating the nearly ten-fold increase in OxyContin prescriptions between 1997 and 2002 to Purdue's doubling of its sales force and trebling its sales calls. A 2017 study found that physicians ordered fewer promoted brand-name medications and prescribed more cost-effective generic versions if they worked in hospitals that instituted rules about when and how pharmaceutical sales representatives were allowed to detail prescribers. The changes in prescribing behavior appeared strongest at hospitals that implemented the strictest detailing policies and included enforcement measures. Another study involved the research of four different practices that included visits by sales representatives, medical journal advertisements, direct-to-consumer advertising, and pricing, and found that sales representatives

[6] Unless otherwise noted, allegations based on "information and belief" are based on the uniformity of Defendants' nationwide strategy and practices, which would reasonably be expected to apply in the City in the same manner as elsewhere.

have the strongest effect on driving drug utilization. An additional study found that doctor meetings with sales representatives are related to changes in doctor prescribing practices and requests by physicians to add the drugs to hospitals' formularies.

41. Manufacturing Defendants also used "key opinion leaders" ("KOLs")—experts in the field who were especially influential because of their reputations and seeming objectivity—to deliver paid talks and continuing medical education programs (or "CMEs") that provided information about treating pain and the risks, benefits, and use of opioids. These KOLs received substantial funding and research grants from the Manufacturing Defendants, and the CMEs were often sponsored by these Defendants—giving them considerable influence over the messenger, the message, and the distribution of the program. Only doctors supportive of the use and safety of opioids for chronic pain received these funding and speaking opportunities, which were not only lucrative, but helped doctors build their reputations and bodies of work. One leading KOL, Dr. Russell Portenoy, subsequently acknowledged that he gave lectures on opioids that reflected "misinformation" and were "clearly the wrong thing to do."

42. In addition to talks and CMEs, these KOLs served on the boards of patient advocacy groups and professional associations, such as the American Pain Foundation and the American Pain Society, which also took money directly from Manufacturing Defendants in an organized effort to exert greater influence because of their seeming independence. According to a report issued by the U.S. Senate Homeland Security & Governmental Affairs Committee, Ranking Member's Office, "many patient advocacy organizations and professional societies focusing on opioids policy have promoted messages and policies favorable to opioid use while receiving millions of dollars in payments from opioid manufacturers. Through criticism of government prescribing guidelines, minimization of opioid addiction risk, and other efforts,

ostensibly neutral advocacy organizations have often supported industry interests at the expense of their own constituencies." These "front groups" for the opioid industry put out patient education materials and treatment guidelines that supported the use of opioids for chronic pain, overstated their benefits, and understated their risks. In many instances, Manufacturing Defendants distributed these publications to prescribers or posted them on their websites. The Senate Committee report referenced above concludes: "[O]rganizations receiving substantial funding from manufacturers have, in fact, amplified and reinforced messages favoring increased opioid use. By aligning medical culture with industry goals in this way, many of the groups described above may have played a significant role in creating the necessary conditions for the U.S. opioids epidemic."

43. The FDA does not regulate all of the Manufacturing Defendants' conduct or review all of its marketing materials. Neither the third-party unbranded materials, nor the marketing messages or scripts used by Manufacturing Defendants' sales representatives, were reviewed or approved by the FDA. For example, Purdue's approved labels do not identify any specific conditions like lower back pain, headaches, or fibromyalgia as appropriate conditions for treatment with opioids, nor do the labels approve of the concept of pseudoaddiction or the technique of suggesting that abuse deterrent formulations are safer.

1. Minimizing or mischaracterizing the risk of addiction.

44. To convince prescribers and patients that opioids are safe, Manufacturing Defendants deceptively represented that the risk of abuse and addiction is modest and manageable and limited to illegitimate users, not patients with genuine pain. This created the dangerously misleading impressions that: (1) patients receiving opioid prescriptions for chronic pain would not become addicted, (2) people at the greatest risk of addiction could be identified,

(3) all other patients could safely be prescribed opioids, and (4) even high risk patients could be prescribed opioids if closely managed.

45. Upon information and belief, sales representatives from Purdue, Teva, Janssen, and Endo regularly omitted from their sales conversations with prescribers in the City any discussion of the risk of addiction from long-term use of opioids. These omissions rendered other arguably truthful statements about opioids false and misleading, and they both reinforced and failed to correct their prior misrepresentations regarding the risk of addiction.

46. Manufacturing Defendants, through sales representatives or other marketing materials, also deceptively undermined evidence that opioids are addictive by suggesting or stating that the risk of addiction is limited to specific, high-risk patients. According to these Defendants, doctors can screen patients to identify those who are likely to become addicted, and therefore could safely prescribe to everyone else. These Defendants discounted general concerns or warnings regarding addiction by reassuring doctors that their patients would not become addicted. One former Purdue sales representative in another region confirmed Purdue's message that opioids were appropriate and safely prescribed to legitimate patients with actual pain, and upon information and belief based on the uniformity of Purdue's practices, the same message was delivered to prescribers in the City. These assurances were false and unsafe, as prescribers cannot accurately predict which patients are at higher risk of addiction. In addition, upon information and belief, sales representatives from Purdue, Teva, Janssen, and Endo also failed to disclose to prescribers in the City the difficulty of withdrawing from opioids. Discontinuing or delaying opioids can cause intense physical and psychological effects, including anxiety, nausea, headaches, and delirium, among others. This difficulty in terminating use is a material risk,

which can leave many patients unwilling or unable to give up opioids and heightens the risk of addiction.

47. Manufacturing Defendants falsely portrayed "true" addiction in its narrowest form. *Providing Relief, Preventing Abuse*, a pamphlet published by Purdue in various editions from 2008-2011 for prescribers and law enforcement, shows pictures of the signs of injecting or snorting opioids—skin popping, track marks, and perforated nasal septa—under the heading "Indications of Possible Drug Abuse." Purdue knew that opioid addicts who resort to these extremes are uncommon; they far more typically become dependent and addicted through oral use. According to briefing materials Purdue submitted to the FDA in October 2010, OxyContin was used non-medically by injection as little as 4% of the time. *Providing Relief, Preventing Abuse* also promoted the concept of pseudoaddiction, further portraying "true" addiction in its narrowest form.

48. These depictions misleadingly reassured doctors that, in the absence of those extreme signs, they need not worry that their patients are abusing or addicted to opioids. Purdue made Providing Relief, Preventing Abuse available to sales representatives to show to or leave with prescribers, including, on information and belief, prescribers in the City.

49. Purdue also disseminated misleading information about opioids and addiction through the American Pain Foundation ("APF"). Purdue was APF's second-biggest donor. Purdue grant letters informed APF that Purdue's contributions reflected the company's effort to "strategically align its investments in nonprofit organizations that share [its] business interests." Purdue also engaged APF as a paid consultant on various initiatives and deployed APF to lobby for its interests on Capitol Hill.

50. *A Policymaker's Guide to Understanding Pain & Its Management*, a 2011 APF publication that Purdue sponsored, claimed that pain generally had been "undertreated" due to "[m]isconceptions about opioid addiction." This guide also asserted, without basis, that "less than 1% of children treated with opioids become addicted" and perpetuated the concept of pseudoaddiction. Purdue provided substantial funding in the form of a $26,000 grant to APF and closely collaborated with APF in creating *A Policymaker's Guide*. On information and belief, based on Purdue's close relationship with APF and the periodic reports APF provided to Purdue about the project, Purdue had editorial input into *A Policymaker's Guide*.

51. Purdue published a "Training Guide for Healthcare Providers" in 2010 that claimed: "[b]ehaviors that suggest drug abuse exist on a continuum, and pain-relief seeking behavior can be mistaken for drug-seeking behavior." This publication also claimed that patients who were physically dependent on opioids, but who had not developed an "addiction disorder" "[c]an generally discontinue their medicine with mild to no withdrawal syndrome once their symptoms are gone by gradually tapering the dosage according to their doctor's orders."

52. Purdue also maintained a website from 2008 to 2015, *In the Face of Pain* that downplayed the risks of chronic opioid therapy. Purdue deactivated this website in October 2015 following an investigation by the New York Attorney General. Although it included the Purdue copyright at the bottom of each page, the site did not refer to any specific Purdue products and cultivated the "impression that it [was] neutral and unbiased."

53. *In the Face of Pain* asserted that policies limiting access to opioids are "at odds with best medical practices" and encouraged patients to be "persistent" in finding doctors who will treat their pain. While a document linked from the website briefly mentioned opioid abuse, the site itself never mentioned the risk of addiction. At the same time, the website contained

testimonials from several dozen physician "advocates" speaking positively about opioids. Eleven of these advocates received a total of $231,000 in payments from Purdue from 2008 to 2013—a fact notably omitted from the site.

54. Purdue and Endo sponsored APF's *Exit Wounds* (2009), a book aimed at veterans. This book sought to reassure veterans about addiction by explaining that although they may become physically dependent on opioids, they will not become addicted:

> Physical dependence means that a person will develop symptoms and signs of withdrawal (e.g., sweating, rapid heart rate, nausea, diarrhea, goose bumps, or anxiety) if a drug medication is suddenly stopped or the dose is lowered too quickly . . . Physical dependence is normal. This does not mean you are addicted. Opioid medications can, however, be abused or used as recreational drugs, and some people who use drugs in this way will become addicted. Addiction is a disease state in which people can no longer control their use of a drug that is causing them harm.
> (Emphasis in original).

55. Endo sponsored a website, *Painknowledge.com*, which claimed in 2009 that "[p]eople who take opioids as prescribed usually do not become addicted." Another Endo website, PainAction.com, stated: "Did you know? Most chronic pain patients do not become addicted to the opioid medications that are prescribed for them."

56. Endo distributed a pamphlet with the Endo logo entitled *Living with Someone with Chronic Pain*, which stated that: "Most health care providers who treat people with pain agree that most people do not develop an addiction problem." A similar statement appeared on the Endo website www.opana.com.

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

58. A Janssen unbranded website, *Prescriberesponsibly.com*, states that concerns about opioid addiction are "overestimated" and that "true addiction occurs only in a small percentage of patients."

59. Until at least June 2007, Mallinckrodt gave education grants to pain-topics.org, a now defunct website that proclaimed to be an organization "dedicated to offering contents that are evidence-based, unbiased, non-commercial, and comply with the highest standards and principles of accrediting and other oversight organizations."

Will you become dependent on or addicted to oxycodone?

- After awhile, oxycodone causes *physical dependence*. That is, if you suddenly stop the medication you may experience uncomfortable withdrawal symptoms, such as diarrhea, body aches, weakness, restlessness, anxiety, loss of appetite, and other ill feelings. These may take several days to develop.
- This is not the same as *addiction*, a disease involving craving for the drug, loss of control over taking it or compulsive use, and using it despite harm. Addiction to oxycodone in persons without a recent history of alcohol or drug problems is rare.

60. Among its content, the website contained a handout titled *Oxycodone Safety for Patients,* which advised doctors that "[p]atients' fears of opioid addiction should be expelled." The handout stated the following misleading information regarding the risk of addiction:

This handout is still available to prescribers and patients today.

61. In 2010, according to a Mallinckrodt Policy Statement, Mallinckrodt launched the C.A.R.E.S. (Collaborating and Acting Responsibly to Ensure Safety) Alliance, which it describes as "a coalition of national patient safety, provider and drug diversion organizations that are focused on reducing opioid pain medication abuse and increasing responsible prescribing habits." Mallinckrodt further states: "Through the C.A.R.E.S. Alliance website, prescribers and pharmacists can access tools and resources to assist them in managing the risks of opioid pain medications, and patients can find information designed to help them better manage their pain

and understand the responsible use of the medications they take." By 2012, the C.A.R.E.S. Alliance and Mallinckrodt were promoting a book titled *Defeat Chronic Pain Now!* This book is still available online in the City and elsewhere. The false claims and misrepresentations in this book include the following statements:

a. "Only rarely does opioid medication cause a true addiction when prescribed appropriately to a chronic pain patient who does not have a prior history of addiction."

b. "[O]pioid medication may also significantly relieve many patients' chronic pain. Over the past decade, lots of good scientific studies have shown that long-acting opioids can reduce the pain in some patients with low back pain, neuropathic pain, and arthritis pain."

c. "It is currently recommended that every chronic pain patient suffering from moderate to severe pain be viewed as a potential candidate for opioid therapy."

d. "[P]hysical dependence . . . is a normal bodily reaction that happens with lots of different types of medications, including medications not used for pain, and is easily remedied."

e. "When chronic pain patients take opioids to treat their pain, they rarely develop a true addiction and drug craving."

f. "[I]n our experience, the issue of tolerance is overblown."

"Only a minority of chronic pain patients who are taking long-term opioids develop tolerance."

"**The bottom line:** Only rarely does opioid medication cause a true addiction when prescribed appropriately to a chronic pain patient who does not have a prior history of addiction."

"Here are the facts. It is very uncommon for a person with chronic pain to become 'addicted' to narcotics IF (1) he doesn't have a prior history of any addiction and (2) he only takes the medication to treat pain."

"Studies have shown that many chronic pain patients can experience significant pain relief with tolerable side effects from opioid narcotic medication when taken daily and no addiction."

62. Manufacturing Defendants' efforts to trivialize the risk of addiction were, and remain, at odds with the scientific evidence. Studies have shown that at least 8-12%, and as many as 30-40% of long-term users of opioids experience problems with addiction. In

September 2013, the FDA emphasized the "serious risks of using ER/LA [extended release / long-acting] opioids" including "addiction, abuse and misuse, even at recommended doses[.]"." In 2016, after a "systematic review of the best available evidence" by a panel excluding experts with conflicts of interest, the CDC published the CDC Guideline for prescribing opioids for chronic pain. The CDC Guideline noted that "[o]pioid pain medication use presents serious risks, including overdose and opioid use disorder" (a diagnostic term for addiction). The CDC also emphasized that "continuing opioid therapy for 3 months substantially increases risk for opioid use disorder." An additional study showed that nearly 60% of patients who used opioids for 90 days continued to use opioids five years later.

B. Manufacturing Defendants Falsely Described Addiction as Pseudoaddiction and Dangerously Encouraged Doctors to Respond by Prescribing More Opioids.

63. Manufacturing Defendants deceptively advised doctors to ignore signs of addiction as the product of an unfounded condition they called pseudoaddiction. Pseudoaddiction was a concept invented to foster the misconception that signs of addiction, including shopping for doctors willing to newly write or refill prescriptions for opioids or seeking early refills, actually reflected undertreated pain that should be addressed with more opioids—the medical equivalent of fighting fire with gasoline.

64. Purdue, through its unbranded imprint *Partners Against Pain*,[7] promoted pseudoaddiction through at least 2013 on its website.

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[7] *Partners Against Pain* consists of both a website, styled as an "advocacy community" for better pain care, and medical education resources distributed to prescribers by the sales force. It has existed since at least the early 2000s and has been a vehicle for Purdue to downplay the risks of addiction from long-term opioid use. One early pamphlet, for example, answered concerns about OxyContin's addictiveness by claiming: "Drug addiction means using a drug to get 'high' rather than to relieve pain. You are taking opioid pain medication for medical purposes. The medical purposes are clear and the effects are beneficial, not harmful."

65. The Federation of State Medical Boards ("FSMB") finances opioid- and pain-specific programs through grants from Manufacturing Defendants. A 2004 version of the FSMB *Model Guidelines for the Use of Controlled Substances for the Treatment of Pain* ("FSMB Guidelines"), and the 2007 book adapted from them, Responsible Opioid Prescribing, advanced the concept of "pseudoaddiction."

66. *Responsible Opioid Prescribing* was sponsored by Manufacturing Defendants. The FSMB website described the book as the "leading continuing medical education (CME) activity for prescribers of opioid medications." In all, more than 163,000 copies of Responsible Opioid Prescribing were distributed nationally, including, upon information and belief, in the City.

67. Janssen sponsored, funded, and edited the *Let's Talk Pain* website, which in 2009 stated: "pseudoaddiction . . . refers to patient behaviors that may occur when pain is under-treated . . . . Pseudoaddiction is different from true addiction because such behaviors can be resolved with effective pain management." This website was accessible online until May 2012.

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

69. Mallinckrodt promoted the book *Defeat Chronic Pain Now!* that includes a discussion of pseudoaddiction. In this discussion, the book states: "Pseudoaddiction happens when a patient's opioid medication is not being prescribed in doses strong enough to provide good pain relief, or the drug is not being prescribed often enough throughout the day." "When a

pseudoaddicted patient is prescribed the proper amount of opioid medication, he or she doesn't take any extra pills, because his or her pain is relieved."

70. Manufacturing Defendants also promoted the concept of pseudoaddiction through Dr. Russell Portenoy, a leading KOL for the Manufacturing Defendants. In doing so, he popularized the concept and falsely claimed that pseudoaddiction is substantiated by scientific evidence.

71. The FAQ section of *Pain-Topics.org*, a website to which Defendant Mallinckrodt provided funding, also contained misleading information about psuedoaddiction. Specfically, the website described psuedoaddiction as behavior that occurs in patients when pain is "undertreated" and includes patients becoming "very focused on obtaining opioid medications, and may be erroneously perceived as 'drug seeking.'"

72. The CDC Guideline rejects the concept of pseudoaddiction. The CDC Guideline nowhere recommends that opioid doses be increased if a patient exhibits signs of addiction. Nor does the CDC Guideline recommend increasing opioid doses if the patient is not experiencing pain relief. To the contrary, the CDC Guideline explains that "[p]atients who do not experience clinically meaningful pain relief early in treatment . . . are unlikely to experience pain relief with longer-term use," and recommends "reassessment of pain and function within 1 month" in order to decide whether to "minimize risks of long-term opioid use by discontinuing opioids" because the patient is "not receiving a clear benefit."

1. Overstating the efficacy of screening tools.

73. Manufacturing Defendants falsely instructed prescribers and patients that addiction risk screening tools, patient contracts, urine drug screens, and similar strategies allow health care providers to safely prescribe opioids to patients, including patients predisposed to addiction, and failed to disclose the lack of evidence that these strategies will mitigate addiction

risk. By using screening tools, these Defendants advised that doctors could identify those who are likely to become addicted and could safely prescribe to everyone else. Thus, Manufacturing Defendants undermined general concerns or warnings regarding addiction by reassuring doctors that, despite the general warnings about addiction, their patients would not become addicted.

74. Such misrepresentations regarding safe opioid prescribing made health care providers more comfortable prescribing opioids to their patients, and patients more comfortable starting chronic opioid therapy. These misrepresentations were especially insidious because Manufacturing Defendants aimed them at general practitioners and family doctors who lack the time and expertise to closely manage higher-risk patients on opioids. Moreover, these misrepresentations reassured doctors that opioid addiction was the result of other prescribers failing to rigorously manage and weed out problem patients.

75. Upon information and belief, Manufacturing Defendants conveyed these safe prescribing messages through their in-person sales calls to doctors in the City. In addition, on information and belief based on their use elsewhere, Purdue sales representatives in the City also shared the Partners Against Pain "Pain Management Kit," which contained several "drug abuse screening tools." These included the "Opioid Risk Tool," which is a five question, one-minute screening tool that relies on patient self-reporting to identify whether there is a personal history of substance abuse, sexual abuse, or "psychological disease," ignoring the sensitivity of the topic and the nature of addiction, which make it unlikely that many patients can be counted on to share this information.

76. Manufacturing Defendants also promoted screening tools as a reliable means to manage addiction risk in CME programs and scientific conferences, which likely were attended by and were available to prescribers in the City.

77. For example, Purdue sponsored a 2011 CME program titled Managing Patients' Opioid Use: Balancing the Need and Risk. This presentation deceptively instructed prescribers that screening tools, patient agreements, and urine tests prevented "overuse of prescriptions" and "overdose deaths."

78. Purdue also funded a 2012 CME program called Chronic Pain Management and Opioid Use: Easing Fears, Managing Risks, and Improving Outcomes. The presentation deceptively instructed doctors that, through the use of screening tools, more frequent refills, and other techniques, high-risk patients showing signs of addictive behavior could be treated with opioids.

79. Purdue used its involvement in the College on the Problems of Drug Dependence ("CPDD"), which promotes scientific research and professional development to support addiction prevention professionals, to promote the idea that addiction risk can be managed. A Purdue employee served on the CPDD board of directors. Purdue presented an outsized number of talks—with very different messages from non-Purdue talks—at each CPDD conference. One of Purdue's consistent themes is that "bad apple" patients, not opioids, are the source of the addiction crisis, and that once those patients are identified doctors can safely prescribe opioids without addicting patients. Hundreds of addiction treatment specialists from across the country and, upon information and belief, prescribers from the City attended these conferences.

80. Endo paid for a 2007 supplement in the Journal of Family Practice written by a doctor who became a member of Endo's speakers' bureau in 2010. The supplement, entitled Pain Management Dilemmas in Primary Care: Use of Opioids, emphasized the effectiveness of screening tools, claiming that patients at high risk of addiction could safely receive chronic

opioid therapy using a "maximally structured approach" involving toxicology screens and pill counts.

81. A 2011 non-credit educational program sponsored by Endo, entitled Persistent Pain in the Older Adult, claimed that withdrawal symptoms, which make it difficult for patients to stop using opioids, can be avoided by tapering a patient's opioid dose by 10%-20% for 10 days.

82. Manufacturing Defendants' efforts to convince doctors that they could confidently prescribe to pain patients who did not intend to abuse the drugs were misleading. As Defendants knew or should have known, sales to patients who doctor-shop (or visit multiple doctors to hide illicit use or overuse) constitute approximately only 1% of opioid volume.

83. Further, the CDC Guideline confirms the falsity of Manufacturing Defendants' claims about the utility of patient screening and managing addiction risk. The CDC Guideline notes that there are no studies assessing the effectiveness of risk mitigation strategies, such as screening tools or patient contracts, "for improving outcomes related to overdose, addiction, abuse, or misuse." The CDC Guideline recognizes that available risk screening tools "show insufficient accuracy for classification of patients as at low or high risk for [opioid] abuse or misuse" and counsels that doctors "should not overestimate the ability of these tools to rule out risks from long-term opioid therapy."

C. Manufacturing Defendants Overstated the Benefits of Chronic Opioid Therapy While Failing to Disclose the Lack of Evidence Supporting Long-Term Use.

1. Mischaracterizing the benefits and evidence for long-term use.

84. To convince prescribers and patients that opioids should be used to treat chronic pain, Manufacturing Defendants had to persuade them of a significant upside to long-term opioid use. Assessing existing evidence, the CDC Guideline found that there is "insufficient evidence

to determine the long-term benefits of opioid therapy for chronic pain." In fact, the CDC found that "[n]o evidence shows a long-term benefit of opioids in pain and function versus no opioids for chronic pain with outcomes examined at least 1 year later (with most placebo-controlled randomized trials ≤ 6 weeks in duration)" and that other treatments were more or equally beneficial and less harmful than long-term opioid use. The FDA, too, has recognized the lack of evidence to support long-term opioid use. In 2013, the FDA stated that it was "not aware of adequate and well-controlled studies of opioid use longer than 12 weeks." The FDA also determined that opioid use disorder and overdose risk are present when opioids are taken as prescribed. As a result, the CDC recommends that opioids be used not in the first instance and only after prescribers have exhausted alternative treatments.

85. Indeed, a recent study found that "the use opioid vs. nonopioid medication therapy did not result in significant better pain-related function over 12 months." These results did "not support initiation of opioid therapy for moderate to serve chronic back pain or hip or knee osteoarthritis pain.

86. Manufacturing Defendants touted the purported benefits of long-term opioid use, while falsely and misleadingly suggesting that these benefits were supported by scientific evidence.

87. Two prominent professional medical membership organizations, the *American Pain Society* ("APS") and the *American Academy of Pain Medicine* ("AAPM"), each received substantial funding from Manufacturing Defendants. According to a letter from U.S. Senate Committee on Finance Ranking Member Ron Wyden to Secretary Thomas Price of the U.S. Department of Health & Human Services, as recently as May 2017, the Corporate Council of AAPM included Endo, Janssen, Mallinckrodt, Purdue and Teva, along with several other

pharmaceutical drug companies. Upon information and belief, Manufacturing Defendants exercised considerable influence over their work on opioids. Both organizations issued a consensus statement in 1997, *The Use of Opioids for the Treatment of Chronic Pain*, which endorsed opioids to treat chronic pain and claimed that the risk that patients would become addicted to opioids was low. The co-author of the statement, Dr. David Haddox, was at the time a paid speaker for Purdue and later became a senior executive for the company. KOL Dr. Portenoy was the sole consultant. The consensus statement remained on AAPM's website until 2011. The statement was taken down from AAPM's website only after a doctor complained.

88. AAPM and APS issued treatment guidelines in 2009 ("AAPM/APS Guidelines") which continued to recommend the use of opioids to treat chronic pain. Treatment guidelines, like the AAPM/APS Guidelines, were particularly important to Manufacturing Defendants in securing acceptance for chronic opioid therapy. They are relied upon by doctors, especially general practitioners and family doctors who have no specific training in treating chronic pain. Six of the twenty-one panel members who drafted the AAPM/APS Guidelines received support from Purdue, eight from Teva, nine from Janssen, and ten from Endo.

89. The AAPM/APS Guidelines promote opioids as "safe and effective" for treating chronic pain. The panel made "strong recommendations" despite "low quality of evidence" and concluded that the risk of addiction is manageable for patients, even with a prior history of drug abuse. One panel member, Dr. Joel Saper, Clinical Professor of Neurology at Michigan State University and founder of the Michigan Headache & Neurological Institute, resigned from the panel because of his concerns that the Guidelines were influenced by contributions that drug companies, including Purdue, Endo, Janssen, and Teva made to the sponsoring organizations and committee members.

90. Dr. Gilbert Fanciullo, a retired professor at Dartmouth College's Geisel School of Medicine who served on the AAPM/APS Guidelines panel, has since described them as "skewed" by drug companies and "biased in many important respects," including its high presumptive maximum dose, lack of suggested mandatory urine toxicology testing, and claims of a low risk of addiction.

91. The AAPM/APS Guidelines are still available online, were reprinted in the Journal of Pain, and have influenced not only treating physicians, but also the body of scientific evidence on opioids. According to Google Scholar, they have now been cited at least 1,647 times in academic literature.

92. Manufacturing Defendants also published misleading studies to enhance the perception that opioids are effective long-term for chronic pain conditions. One study asserts that OxyContin is safe and effective for the chronic pain condition osteoarthritis. The study, sponsored by Purdue, involved providing oxycodone for 30 days, and then randomizing participants and providing a placebo, IR oxycodone with acetaminophen (like Percocet), or OxyContin. Only 107 of the 167 patients went on to the second phase of the study, and most who withdrew left because of adverse events (nausea, vomiting, drowsiness, dizziness, or headache) or ineffective treatment. Despite relating to a chronic condition, opioids were provided only short-term. The authors even acknowledge that the "results… should be confirmed in trials of longer duration to confirm the role of opioids in a chronic condition such as OA [osteoarthritis]." Yet, the authors conclude that "[t]his clinical experience shows that opioids were well tolerated with only rare incidence of addiction and that tolerance to the analgesic effects was not a clinically significant problem when managing patients with opioids long-term." This statement is not supported by the data—a substantial number of patients dropped out

because of adverse effects, there was no reported data regarding addiction, and the study was not long-term.

93. Teva deceptively marketed its opioids Actiq and Fentora for chronic pain even though the FDA has expressly limited their use to the treatment of cancer pain in opioid-tolerant individuals.

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

95. Despite this, Teva conducted and continues to conduct a well-funded campaign to promote Actiq and Fentora for chronic pain and other non-cancer conditions for which it was not approved, appropriate, or safe. As part of this campaign, Teva used CMEs, speaker programs, KOLs, journal supplements, and detailing[8] by its sales representatives to give doctors the false impression that Actiq and Fentora are safe and effective for treating non-cancer pain, without disclosing the lack of evidence or the FDA's rejection of their use for chronic pain.

96. For example: Teva paid to have a CME it sponsored, *Opioid-Based Management of Persistent and Breakthrough Pain*, published in a supplement of Pain Medicine News in

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[8] Pharmaceutical detailing is a one-on-one marketing technique utilized by pharmaceutical companies to educate a physician about a vendor's products in hopes that the physician will prescribe the company's products more often.

2009. The CME instructed doctors that "clinically, broad classification of pain syndromes as either cancer- or noncancer-related has limited utility" and recommended Actiq and Fentora for patients with chronic pain. The CME is still available online.

97. Teva's sales representatives set up hundreds of speaker programs for doctors, including many non-oncologists, which promoted Actiq and Fentora for the treatment of non-cancer pain.

98. In December 2011, Teva widely disseminated a journal supplement entitled "Special Report: An Integrated Risk Evaluation and Mitigation Strategy for Fentanyl Buccal Tablet (FENTORA) and Oral Transmucosal Fentanyl Citrate (ACTIQ)" to Anesthesiology News, Clinical Oncology News, and Pain Medicine News – three publications that are sent to thousands of anesthesiologists and other medical professionals. The Special Report openly promotes Fentora for "multiple causes of pain," and not just cancer pain.

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

100. In December 28, 2011, the FDA mandated a Risk Evaluation and Mitigation Strategy (REMS) for the class of products for which Teva's Actiq and Fentora belong, Transmucosal Immediate Release Fentanyl (TIRF). The TIRF REMS programs include mandatory patient and prescriber enrollment forms, as well as certification requirements for prescribers. The forms are not totally comprehensive and do not, for instance, disclose that addiction can develop when prescribed as directed, nor do they disclose that risks are greatest at higher doses—and patients must already be taking high doses of opioids to be prescribed Actiq and Fentora.

2. Overstating opioids' effect on patients' function and quality of life.

101. Manufacturing Defendants also claimed—without evidence—that long-term opioid use would help patients resume their lives and jobs. Representatives who visited prescribers in the City promoted opioids as improving patients' function and quality of life, especially for elderly patients with conditions such as chronic arthritis.

102. Manufacturing Defendants and Defendant-sponsored materials that, upon information and belief, were distributed or made available in the City reinforced this message. The 2011 publication *A Policymaker's Guide* falsely claimed that "multiple clinical studies have shown that opioids are effective in improving daily function and quality of life for chronic pain patients." A series of medical journal advertisements for OxyContin in 2012 presented "Pain Vignettes"—case studies featuring patients with pain conditions persisting over several months—that implied functional improvement. For example, one advertisement described a "writer with osteoarthritis of the hands" and implied that OxyContin would help him work more effectively. Similarly, since at least May 21, 2011, Endo has distributed and made available on its website opana.com a pamphlet promoting Opana ER with photographs depicting patients with physically demanding jobs like construction worker and chef, misleadingly implying that the drug would provide long-term pain-relief and functional improvement. Additional illustrative examples are described below:

a. Janssen sponsored and edited a patient education guide entitled *Finding Relief: Pain Management for Older Adults* (2009) – which states as "a fact" that "opioids may make it easier for people to live normally." The guide lists expected functional improvements from opioid use, including sleeping through the night, returning to work, recreation, sex, walking, and climbing stairs and states that "[u]sed properly, opioid medications can make it possible for people with chronic pain to 'return to normal.'"

b. Purdue ran a series of advertisements for OxyContin in 2012 in medical journals entitled "Pain vignettes," which were case studies featuring patients with pain conditions persisting over several months and recommending OxyContin for them.

The ads implied that OxyContin improves patients' function.

c. *Responsible Opioid Prescribing* (2007), sponsored and distributed by Teva, Endo and Purdue, taught that relief of pain by opioids, by itself, improved patients' function. The book remains for sale online.

d. Purdue and Teva sponsored APF's Treatment Options: *A Guide for People Living with Pain* (2007), which counseled patients that opioids "give [pain patients] a quality of life we deserve." The guide was available online until APF shut its doors in May 2012.

e. Endo's NIPC website painknowledge.com claimed in 2009 that with opioids, "your level of function should improve; you may find you are now able to participate in activities of daily living, such as work and hobbies, that you were not able to enjoy when your pain was worse." Elsewhere, the website touted improved quality of life (as well as "improved function") as benefits of opioid therapy. The grant request that Endo approved for this project specifically indicated NIPC's intent to make misleading claims about function, and Endo closely tracked visits to the site.

f. Endo was the sole sponsor, through NIPC, of a series of CMEs titled *Persistent Pain in the Older Patient*, which claimed that chronic opioid therapy has been "shown to reduce pain and improve depressive symptoms and cognitive functioning." The CME was disseminated via webcast.

g. Defendant Mallinckrodt's website, in a section called "responsible use" of opioids, claims that "the effect of pain management offered by our medicines help enable patients to stay in the workplace, enjoy interactions with family and friends, and remain an active member of society."

103. Likewise, Manufacturing Defendants' claims that long-term use of opioids improves patient function and quality of life are unsupported by clinical evidence. As noted above, there are no controlled studies of the use of opioids beyond 16 weeks, and there is no evidence that opioids improve patients' pain and function long-term. On the contrary, the available evidence indicates opioids are not effective to treat chronic pain, and may worsen patients' health and pain. Increasing the duration of opioid use is strongly associated with an increasing prevalence of mental health conditions (depression, anxiety, post-traumatic stress disorder, and substance abuse), increased psychological distress, and greater health care utilization.

104. One pain specialist observed, "opioids may work acceptably well for a while, but over the long term, function generally declines, as does general health, mental health, and social functioning. Over time, even high doses of potent opioids often fail to control pain, and these patients are unable to function normally." Studies of patients with lower back pain and migraine headaches, for example, have consistently shown that patients experienced deteriorating function over time, as measured by ability to return to work, physical activity, pain relief, rates of depression, and subjective quality-of-life measures. Analyses of workers' compensation claims have found that workers who take opioids are almost four times more likely to reach costs over $100,000, stemming from greater side effects and slower returns to work. According to these studies, receiving an opioid for more than seven days also increased patients' risk of being on work disability one year later.

105. The CDC Guideline notes that "there is no good evidence that opioids improve pain or function with long-term use." The FDA and other federal agencies have made this clear for years.[9] The CDC also noted that the risks of addiction and death "can cause distress and inability to fulfill major role obligations." The CDC Guideline concluded that "[w]hile benefits for pain relief, function and quality of life with long-term opioid use for chronic pain are uncertain, risks associated with long-term opioid use are clearer and significant." According to

[9] The FDA has warned other drug makers that claims of improved function and quality of life were misleading. *See,* Warning Letter from Thomas Abrams, Dir., FDA Div. of Mktg., Adver., & Commc'ns, to Doug Boothe, CEO, Actavis Elizabeth LLC (Feb. 18, 2010), (rejecting claims that Actavis' opioid, Kadian, had an "overall positive impact on a patient's work, physical and mental functioning, daily activities, or enjoyment of life."); Warning Letter from Thomas Abrams, Dir., FDA Div. of Mktg., Adver., & Commc'ns, to Brian A. Markison, Chairman, President and Chief Executive Officer, King Pharmaceuticals, Inc. (March 24, 2008), (finding the claim that "patients who are treated with [Avinza (morphine sulfate ER)] experience an improvement in their overall function, social function, and ability to perform daily activities . . . has not been demonstrated by substantial evidence or substantial clinical experience."). The FDA's warning letters were available to Manufacturing Defendants on the FDA website.

the CDC, "for the vast majority of patients, the known, serious, and too-often-fatal risks far outweigh the unproven and transient benefits [of opioids for chronic pain]."

106. In materials Manufacturing Defendants produced, sponsored, or controlled, Manufacturing Defendants omitted known risks of chronic opioid therapy and emphasized or exaggerated risks of competing products so that prescribers and patients would be more likely to choose opioids and would favor opioids over other therapies such as over-the-counter acetaminophen or nonsteroidal anti-inflammatory drugs (or NSAIDs, like ibuprofen). None of these claims were corroborated by scientific evidence.

3. Omitting or mischaracterizing adverse effects of opioids.

107. In addition to failing to disclose in promotional materials the risks of addiction, abuse, overdose, and respiratory depression, Manufacturing Defendants routinely ignored the risks of hyperalgesia, a "known serious risk associated with chronic opioid analgesic therapy," in which the patient becomes more sensitive to pain over time, hormonal dysfunction; decline in immune function; mental clouding, confusion, and dizziness; increased falls and fractures in the elderly; neonatal abstinence syndrome (when an infant exposed to opioids prenatally withdraws from the drugs after birth); and potentially fatal interactions with alcohol or benzodiazepines, which are used to treat post-traumatic stress disorder and anxiety (often among veterans, for example, post-traumatic stress disorder and anxiety also can accompany chronic pain symptoms).

108. Purdue and Teva sponsored APF's Treatment Options: *A Guide for People Living with Pain* (2007), which counseled patients that opioids differ from NSAIDs in that they have "no ceiling dose" and are therefore the most appropriate treatment for severe pain. The publication inaccurately attributes 10,000 to 20,000 deaths annually to NSAIDs (the actual figure

is approximately 3,200, far fewer than from opioids).[10] This publication also warned that risks of NSAIDs increase if "taken for more than a period of months," with no corresponding warning about opioids.

109. APF's *Exit Wounds*, sponsored by Purdue and Endo and aimed at veterans, omits warnings of the potentially fatal risk of interactions between opioids and benzodiazepines, a class of drug commonly prescribed to veterans with post-traumatic stress disorder. This book is available from Amazon.com and other retailers.

110. Purdue sponsored a CME program, *Overview of Management Options*, published by the American Medical Association in 2003, 2007, 2010, and 2013, and discussed further below. The CME was edited by Dr. Russell Portenoy, among others, and taught that NSAIDs and other drugs, but not opioids, are unsafe at high doses.

111. Manufacturing Defendants frequently contrasted the lack of a ceiling dosage for opioids with the risks of a competing class of analgesics: over-the-counter nonsteroidal anti-inflammatories (or NSAIDs). These Defendants deceptively describe the risks from NSAIDs while failing to disclose the risks from opioids. (*See e.g., Case Challenges in Pain Management: Opioid Therapy for Chronic Pain* (Endo) [describing massive gastrointestinal bleeds from long-term use of NSAIDs and recommending opioids]; *Finding Relief: Pain Management for Older Adults* (Janssen) [NSAIDs caused kidney or liver damage and increased risk of heart attack and stroke, versus opioids, which cause temporary "upset stomach or sleepiness" and constipation].)

112. These omissions are significant and material to patients and prescribers. A Cochrane Collaboration review of evidence relating to the use of opioids for chronic pain found

[10] The higher figure reflects deaths from all causes.

that 22% of patients in opioid trials dropped out before the study began because of the "intolerable effects" of opioids.

113. Manufacturing Defendants' misrepresentations were effective. A study of 7.8 million doctor-patient visits nationwide between 2000 and 2010 found that the percentage of visits during which an opioid was prescribed increased from 11.3% to 19.6% of visits, while NSAID and acetaminophen prescriptions fell during that time period from 38% to 29%. The CDC reports that the quantity of opioids dispensed per capita trebled from 1999 to 2015.

D. Manufacturing Defendants Continued To Tell Doctors That Opioids Could Be Taken In Ever Higher Doses Without Disclosing Their Greater Risks.

114. Manufacturing Defendants falsely claimed to prescribers and consumers that opioids could be taken in ever-increasing strengths to obtain pain relief (i.e., no ceiling dose), without disclosing that higher doses increased the risk of addiction and overdose. This was particularly important because patients on opioids for more than a brief period develop tolerance, requiring increasingly high doses to achieve pain relief.

115. For example, Purdue-sponsored publications and CMEs available, upon information and belief, in the City misleadingly suggested that higher opioid doses carried no added risk.

116. Though at least June 2015, Purdue's *In the Face of Pain* website promoted the notion that if a patient's doctor did not prescribe a sufficient dose of opioids, the patient should see different doctors until finding a doctor who would.

117. *A Policymaker's Guide*, the 2011 publication on which, upon information and belief Purdue collaborated with APF, taught that dose escalations are "sometimes necessary" but did not disclose the risks from high dose opioids.

118. The Purdue-sponsored CME, *Overview of Management Options*, discussed above, again instructed physicians that NSAIDs (like ibuprofen) are unsafe at high doses (because of risks to patients' kidneys), but did not disclose risks from opioids at high doses.

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

120. Endo distributed a pamphlet edited by Dr. Russell Portenoy entitled *Understanding Your Pain: Taking Oral Opioid Analgesics*, which was still available after May 21, 2011 on Endo's website. In Q&A format, it asked "If I take the opioid now, will it work later when I really need it?" The response is, "The dose can be increased. . . . You won't 'run out' of pain relief."

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

122. These claims conflict with the scientific evidence. Patients receiving high doses of opioids (e.g., doses greater than 100 mg morphine equivalent dose ("MED") per day) as part of long-term opioid therapy are three to nine times more likely to suffer overdose from opioid-related causes than those on low doses. As compared to available alternative pain remedies, scholars have suggested that tolerance to the respiratory depressive effects of opioids develops at a slower rate than tolerance to opioids' analgesic effects. Accordingly, the practice of continuously escalating doses to match pain tolerance can, in fact, lead to overdose even where opioids are taken as recommended. The CDC Guideline concludes that the "[b]enefits of high-dose opioids for chronic pain are not established" while "there is an increased risk for serious

harms related to long-term opioid therapy that appears to be dose-dependent." That is why the CDC advises doctors to "avoid increasing doses" above 90 mg MED.

E. Purdue Misleadingly Promoted Oxycontin As Supplying 12 Hours Of Pain Relief When Purdue Knew That, For Many Patients, It Did Not.

123. To convince prescribers and patients to use OxyContin, Purdue misleadingly promoted the drug as providing 12 continuous hours of pain relief with each dose. In reality, OxyContin does not last for 12 hours in many patients, a fact Purdue has known since the product's launch.

124. These misrepresentations, which Purdue continues to make, are particularly dangerous because inadequate dosing helps fuel addiction, as explained below. Purdue conveyed to prescribers that the solution to end of dose failure is not more frequent dosing but higher doses—which pose greater risks.

125. OxyContin has been FDA-approved for twice-daily—"Q12"—dosing frequency since its debut in 1996. Yet it was Purdue's decision to submit OxyContin for approval with 12-hour rather than 8-hour dosing. Under FDA guidelines for establishing dosing, Purdue merely had to show that OxyContin lasted for 12 hours for at least half of patients, and Purdue submitted a single study that cleared that bar. While the OxyContin label indicates that "[t]here are no well-controlled clinical studies evaluating the safety and efficacy with dosing more frequently than every 12 hours," Purdue has conducted no such studies.

126. From the outset, Purdue leveraged 12-hour dosing to promote OxyContin as providing continuous, round-the-clock pain relief with the convenience of not having to wake to take a third or fourth pill. The 1996 press release for OxyContin touted 12-hour dosing as providing "smooth and sustained pain control all day and all night." But the FDA has never approved such a marketing claim. To the contrary, the FDA found in 2008, in response to a

Citizen Petition by the Connecticut Attorney General, that a "substantial number" of chronic pain patients taking OxyContin experienced "end of dose failure"—i.e., little or no pain relief at the end of the dosing period.

127. Moreover, Purdue itself long has known, dating to its development of OxyContin, that the drug wears off well short of 12 hours in many patients. In one early Purdue clinical trial, a third of patients dropped out because the treatment was ineffective. Researchers changed the rules to allow patients to take supplemental painkillers—"rescue medication"—in between OxyContin doses. In another study, most patients used rescue medication, and 95% resorted to it at least once. In other research conducted by Purdue, the drug wore off in under 6 hours in 25% of patients and in under 10 hours in more than 50%.

128. End-of-dose failure renders OxyContin even more dangerous because patients begin to experience distressing psychological and physical withdrawal symptoms, followed by a euphoric rush with their next dose—a cycle that fuels a craving for OxyContin. For this reason, Dr. Theodore Cicero, a neuropharmacologist at the Washington University School of Medicine in St. Louis, has called OxyContin's 12-hour dosing "the perfect recipe for addiction." Many patients will exacerbate this cycle by taking their next dose ahead of schedule or resorting to a rescue dose of another opioid, increasing the overall amount of opioids they are taking.

129. Purdue has remained committed to 12-hour dosing because it is key to OxyContin's market dominance and comparatively high price; without this advantage, the drug had little to offer over less expensive, short-acting opioids. In a 2004 letter to the FDA, Purdue acknowledged that it had not pursued approval to allow more frequent dosing in the label (e.g., every 8 hours) because 12-hour dosing was "a significant competitive advantage." Purdue also falsely promoted OxyContin as providing "steady state" relief, less likely than other opioids to

create a cycle of crash and cravings that fueled addiction and abuse—a misrepresentation made upon information and belief, in the City.

130. Without appropriate caveats, promotion of 12-hour dosing by itself is misleading because it implies that the pain relief supplied by each dose lasts 12 hours, which Purdue knew to be untrue for many, if not most, patients. FDA approval of OxyContin for 12-hour dosing does not give Purdue license to misrepresent the duration of pain relief it provides to patients; moreover, Purdue had a responsibility to correct its label to reflect appropriate dosing, to disclose to prescribers what it knew about OxyContin's actual duration, and not to promote more dangerous higher dosing, rather than increased frequency of use, regardless of any marketing advantage.[11]

131. Purdue was also aware of some physicians' practice of prescribing OxyContin more frequently than 12 hours—a common occurrence. Purdue's promoted solution to this problem was to increase the dose, rather than the frequency, of prescriptions, even though higher dosing carries its own risks—including increased danger of addiction, overdose, and death. It means that patients will experience higher highs and lower lows, increasing their craving for their next pill. Nationwide, based on an analysis by the Los Angeles Times, more than 52% of patients taking OxyContin longer than three months are on doses greater than 60 milligrams per day—which converts to the 90 milligrams of morphine equivalent that the CDC Guideline urges prescribers to "avoid" or "carefully justify."

F. Purdue And Endo Overstated The Efficacy Of Abuse-Deterrent Opioid Formulations.

[11] For example, Kadian, an opioid manufactured by Allergan, was designed to be taken once a day, but the label acknowledges and advises dosing of up to every 12 hours for certain patients.

132. Rather than take the widespread abuse and addiction to opioids as reason to cease their untruthful marketing claims and efforts, Defendants Purdue and Endo seized them as a market opportunity. These companies oversold their abuse-deterrent formulations ("ADF") as a solution to opioid abuse and as a reason that doctors could continue to safely prescribe their opioids. Purdue's and Endo's false and misleading marketing of the benefits of its ADF opioids preserved and expanded its sales and enabled prescribers to discount evidence of opioid addiction and abuse and attribute it to other, less safe opioids – and thereby prolonged the opioid epidemic in the City.

1. Purdue's deceptive marketing of reformulated OxyContin and Hysingla ER.

133. Reformulated, ADF OxyContin was approved by the FDA in April 2010. However, the FDA noted that "the tamper-resistant properties will have no effect on abuse by the oral route (the most common mode of abuse)." It was not until 2013 that the FDA, in response to a Citizen Petition filed by Purdue, permitted reference to the abuse-deterrent properties in the label. When Hysingla ER (extended-release hydrocodone) launched in 2014, the product included similar abuse-deterrent properties.

134. Reformulated OxyContin was introduced shortly before generic versions of OxyContin were to become available, threatening to erode Purdue's market share and the price it could charge. Through a Citizen Petition, Purdue was able to secure a determination by the FDA in April 2013 that original OxyContin should be removed from the market as unsafe (lacking abuse-deterrent properties), and thus non-ADF generic copies could not be sold either. As a result, Purdue extended its branded exclusivity for OxyContin until the patent protection on the abuse-deterrent coating expires.

135. Purdue nonetheless touted its introduction of ADF opioids as evidence of its good corporate citizenship and commitment to address the opioid crisis. For example, in full-page advertisements that ran in the New York Times and the Wall Street Journal in late 2017 and early 2018, Purdue claims to have been spurred "to redouble [its] efforts in the fight against the prescription and illicit opioid abuse crisis." The advertisements then promote Purdue's ADFs as evidence of its efforts to take meaningful action to reduce opioid abuse.

136. Purdue sales representatives also regularly overstated and misstated the evidence for and impact of the abuse-deterrent features of these opioids. Specifically, Purdue detailers:

a. claimed that Purdue's ADF opioids prevent tampering and that its ADF products could not be crushed or snorted.

b. claimed that Purdue's ADF opioids reduce opioid abuse and diversion.

c. asserted or suggested that Purdue's ADF opioids are "safer" than other opioids.

d. failed to disclose that Purdue's ADF opioids do not impact oral abuse or misuse.

137. These statements and omissions by Purdue are false and misleading and are inconsistent with the FDA-approved labels for Purdue's ADF opioids—which indicate that abusers seek them because of their high likeability when snorted, that their abuse deterrent properties can be defeated, and that they can be abused orally notwithstanding their abuse-deterrent properties, and which do not indicate that ADF opioids prevent or reduce abuse, misuse, or diversion.

138. Purdue knew or should have known that "reformulated OxyContin is not better at tamper resistance than the original OxyContin" and is still regularly tampered with and abused. Websites and message boards used by drug abusers, such as bluelight.org and reddit, also report a variety of ways to tamper with OxyContin and Hysingla ER, including through grinding, microwaving then freezing, or drinking soda or fruit juice in which a tablet is dissolved. A

publicly available Citizen Petition submitted to the FDA in 2016 by a drug manufacturing firm challenged Purdue's abuse-deterrent labeling based on the firm's ability to easily prepare so-called abuse deterrent OxyContin to be snorted or injected. Opioid addicts in the City also, upon information and belief, continued to crush, snort, and inject abuse-deterrent formulations pf their drugs, including OxyContin.

139. Further, *one-third* of the patients in a 2015 study defeated the ADF mechanism and were able to continue inhaling or injecting the drug. To the extent that the abuse of Purdue's ADF opioids was reduced, those addicts simply shifted to other drugs such as heroin.

140. A 2013 article presented by Purdue employees based on review of data from poison control centers, while concluding that ADF OxyContin can reduce abuse, ignored important negative findings. The study reveals that abuse merely shifted to other drugs and that, when the actual incidence of harmful exposures was calculated, there were more harmful exposures to opioids (including heroin) after the reformulation of OxyContin. In short, the article emphasized the advantages and ignored disadvantages of ADF OxyContin.

141. The CDC Guideline confirms that "[n]o studies" support the notion that "abuse-deterrent technologies [are] a risk mitigation strategy for deterring or preventing abuse," noting that the technologies "do not prevent opioid abuse through oral intake, the most common route of opioid abuse, and can still be abused by non-oral routes." Tom Frieden, the Director of the CDC, reported that his staff could not find "any evidence showing the updated opioids [ADF opioids] actually reduce rates of addiction, overdoses, or death."

142. In 2015, claiming a need to further assess its data, Purdue abruptly withdrew a supplemental new drug application related to reformulated OxyContin one day before FDA staff were to release its assessment of the application. The staff review preceded an FDA advisory

committee meeting related to new studies by Purdue "evaluating the misuse and/or abuse of reformulated OxyContin" and whether those studies "have demonstrated that the reformulated product has a meaningful impact on abuse." Upon information and belief, Purdue never presented the data to the FDA because the data would not have supported claims that OxyContin's ADF properties reduced abuse or misuse.

143. Yet despite the qualifying language in Purdue's label and its own evidence—and lack of evidence—regarding the impact of its ADF opioids in reducing abuse, Dr. J. David Haddox, the Vice President of Health Policy for Purdue, falsely claimed in 2016 that the evidence does not show that Purdue's ADF opioids are being abused in large numbers.

2. Endo's deceptive marketing of reformulated Opana ER.

144. In a strategy that closely resembled Purdue's, Endo also made abuse-deterrence a key to its marketing strategy and its ability to maintain and increase profits from Opana ER, as the expiration of its patent exclusivity for Opana ER neared.

145. In December 2011, Endo obtained approval for a new formulation of Opana ER that added a hard coating that the company claimed made it crush-resistant. Even prior to its approval, the FDA advised Endo in January 2011 that it would not be permitted to market Opana ER, even after the reformulation, as abuse-deterrent. The FDA found that such promotional claims "may provide a false sense of security since the product may be chewed and ground for subsequent abuse." In other words, Opana ER was still crushable. Indeed, in its approval package, Endo admitted that "[i]t has not been established that this new formulation of Opana ER is less subject to misuse, abuse, diversion, overdose, or addiction."

146. In August of 2012, Endo submitted a confidential Citizen Petition asking the FDA for permission to change its label to indicate that Opana ER was abuse-resistant, both in that it was less able to be crushed and snorted, and that it was resistant to "aqueous extraction," or

injection by syringe. Borrowing a page from Purdue's playbook, Endo announced it would withdraw original Opana ER from the market and sought a determination that its decision was made for safety reasons (its lack of abuse deterrence). That would prevent generic copies of original Opana ER from competitors, such as Impax Laboratories ("Impax"), which had sought approval to sell a generic version of the drug, and also help preserve the market for branded Opana ER, which could be sold at non-competitive prices.

147. Endo then sued the FDA, seeking to force expedited consideration of its Citizen Petition. The court filings confirmed its true motives: in a declaration submitted with its lawsuit, Endo's chief operating officer indicated that a generic version of Opana ER would decrease the company's revenue by up to $135 million per year. Endo also claimed that if the FDA did not block generic competition, $125 million, which Endo spent on developing the reformulated drug to "promote the public welfare," would be lost. The FDA responded that: "Endo's true interest in expedited FDA consideration stems from business concerns rather than protection of the public health."

148. Meanwhile, despite Endo's purported concern with public safety, court filings indicate that not only did Endo continue to distribute original Opana ER for nine months after the reformulated version became available, it declined to recall original Opana ER despite its dangers. In fact, Endo also claimed in September 2012 to be "proud" that "almost all remaining inventory" of the original Opana ER had "been utilized."

149. In its Citizen Petition, Endo asserted that redesigned Opana ER had "safety advantages." However, in rejecting the Petition in a 2013 decision, the FDA found that "study data show that the reformulated version's extended-release features can be compromised when subjected to . . . cutting, grinding, or chewing." The FDA also determined that "reformulated

Opana ER" could also be "readily prepared for injections and more easily injected[.]" In fact, the FDA warned that preliminary data—including in Endo's own studies—suggested that a higher percentage of reformulated Opana ER abuse is via injection than was the case with the original formulation.

150. Over time, evidence confirmed that injection was becoming the preferred means of abusing Opana ER, which made Opana ER *less safe* than the original formulation. This occurred both because injection carries risks of HIV, Hepatitis C, and, in reformulated Opana ER's specific case, the blood-clotting disorder thrombotic thrombocytopenic purpura (TTP), which can cause kidney failure.[12] In 2009, only 3% of Opana ER abuse was by intravenous means. Since the reformulation, injection of Opana ER increased by more than 500% according to data gathered in 2017.

151. Nevertheless, Endo continued to market the drug as tamper-resistant and deterring abuse. Indeed, upon information and belief, detailers for Endo have informed doctors in the City that Opana ER was abuse-deterrent. In addition, upon information and belief, Endo sales representatives did not disclose evidence that Opana was easier to abuse intravenously and, if pressed by prescribers, claimed that while some outlying patients might find a way to abuse the drug, most would be protected.

152. Likewise, a review of nationally-collected surveys of prescribers regarding their "take-aways" from pharmaceutical detailing confirms that prescribers remember being told

[12] The CDC does not know why the redesigned Opana ER causes TTP, but it notes it did not appear in other prescription opioids prepared for injection. "Thrombotic Thrombocytopenic Purpura (TTP)–Like Illness Associated with Intravenous Opana ER Abuse — Tennessee, 2012," *Morbidity and Mortality Weekly Report* (Jan. 11, 2013). The CDC suggested it could be linked to inactive ingredients that make the product more difficult to crush or grind. No reports of Opana ER and TTP occurred prior to the reformulation.

Opana ER was tamper resistant, even after the May 2013 denial of Endo's Citizen Petition. Endo also tracked messages that doctors took from its in-person marketing. Among the advantages of Opana ER, according to participating doctors, was its "low abuse potential."

153. In its written materials, Endo marketed Opana ER as having been ***designed*** to be crush resistant, knowing that this would (falsely) imply that Opana ER actually ***was*** crush resistant and that this crush-resistant quality would make Opana ER less likely to be abused. For example, a June 14, 2012 Endo press release announced "the completion of the company's transition of its OPANA ER franchise to the new formulation designed to be crush resistant." The press release further stated that: "We firmly believe that the new formulation of OPANA ER, coupled with our long-term commitment to awareness and education around appropriate use of opioids will benefit patients, physicians and payers." In September 2012, another Endo press release stressed that reformulated Opana ER employed "INTAC Technology" and continued to describe the drug as "designed to be crush-resistant."

154. Similarly, journal advertisements that appeared in April 2013 stated Opana ER was "designed to be crush resistant." A January 2013 article in Pain Medicine News, based in part on an Endo press release, described Opana ER as "crush-resistant." This article was posted on the Pain Medicine News website, which was accessible to patients and prescribers nationally.

155. In a 2016 settlement with Endo, the New York Attorney General ("NY AG") found that statements that Opana ER was "designed to be, or is crush resistant" were false and misleading because there was no difference in the ability to extract the narcotic from Opana ER. The NY AG also found that Endo failed to disclose its own knowledge of the crushability of redesigned Opana ER in its marketing to formulary committees and pharmacy benefit managers.

G. Defendants Deliberately Disregarded Their Duties To Report Suspicious Orders or Prescriptions And To Exercise Reasonable Care.

1. Distributor Defendants have a duty to report suspicious pharmacy orders and to exercise reasonable care before shipping.

156. The conduct of the Distributor Defendants compounded the harm created by the Manufacturing Defendants by facilitating the supply of far more opioids that could have been justified to serve the market. The failure of Distributor Defendants to investigate, report, and terminate orders that they knew or should have known were suspicious breached their duties to the City.

157. First, by flooding the City with more opioids than could be used for legitimate medical purposes and by filling and failing to report orders that it should have realized were likely being diverted for illicit uses, Distributor Defendants breached their duty under Pennsylvania common law to exercise reasonable care in delivering narcotic substances within the City, which both created and failed to prevent a foreseeable risk of harm to the City.

158. Second, Distributor Defendants violated their statutory obligations under the federal Controlled Substances Act, 21 U.S.C. § 801, et seq. and its implementing regulations. See 21 U.S.C. § 823(b)(1) (requiring that registrants maintain "effective control against diversion of particular controlled substances into other than legitimate medical, scientific, and industrial channels."); 21 C.F.R. § 1301.74(b) ("The registrant shall inform the Field Division Office of the [DEA] in his area of suspicious orders when discovered by the registrant."). Suspicious orders include orders of "unusual size, orders deviating substantially from a normal pattern, and orders of unusual frequency." 21 C.F.R. §1301.74(b).

159. Any of the red flags identified by law—size, deviation, or frequency—trigger a duty to report. However, this list is not exclusive. Other factors—such as whether the order is skewed toward high dose pills, which are more attractive to abusers and diverters, or orders that are composed largely of drugs valued for abuse (opioids, as well as drugs like benzodiazepines),

instead of other high-volume drugs, such as cholesterol medicines—also should alert distributors to potential problems. The distributor's own observations—cash transactions or young and seemingly healthy patients filling prescriptions for opioids at a pharmacy they supply—can trigger reasonable suspicion. A single order can warrant scrutiny, or it may be a pattern of orders or an order that is unusual given the customer's individual history or its comparison to other customers in the area. Thus, the determination of whether an order is suspicious depends not only on the ordering patterns of the particular customer but also on the customary activity of other customers of similar size or in the same area.

160. Under the CSA and the Pennsylvania Controlled Substance, Drug, Device and Cosmetic Act, Distributor Defendants and Manufacturing Defendants are required to register annually. 21 U.S.C. § 822(a)(1); 35 P.S. § 780-106(a). Any registration must be consistent with the public interest based on a consideration of, among other factors:

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

21 U.S.C. § 823; see also 35 P.S. § 780-106(e)(ii) (authorizing license suspension for any manufacturer or distributor who has been convicted of a violation of any Commonwealth or federal law relating to controlled substances).

161. Federal regulations mandate that all registrants, manufacturers and distributors "design and operate a system to disclose to the registrant suspicious orders of controlled substances." 21 C.F.R. § 1301.74(b). Registrants are not entitled to be passive (but profitable) observers, but rather "shall inform the Field Division Office of the Administration in his area of

suspicious orders when discovered by the registrant." Id. Suspicious orders include orders of unusual size, orders deviating substantially from a normal pattern, and orders of unusual frequency. Id. Other red flags may include, for example, "[o]rdering the same controlled substance from multiple distributors."

162. In sum, Defendants have several responsibilities with respect to suspicious orders of opioids. First, they must set up a system designed to detect such orders. That would include reviewing their own data, relying on their observations of prescribers and pharmacies, and following up on reports or concerns of potential diversion. Second, they must also stop shipment on any order which is flagged as suspicious and only ship orders which were flagged as potentially suspicious if, after conducting due diligence, they can determine that the order is not likely to be diverted into illegal channels. And, third, all flagged orders must be reported to relevant enforcement authorities.

2. Distributor Defendants understood the importance of their reporting obligations.

163. The purpose of the reporting rules is to create a "closed" system intended to reduce the diversion of these drugs out of legitimate channels into the illicit market, while at the same time providing the legitimate drug industry with a unified approach to narcotic and dangerous drug control.

164. The Distributor Defendants and the Manufacturing Defendants were well aware they had an important role to play in this system, and also knew or should have known that their failure to comply with their reporting obligations would have serious consequences.

165. Trade organizations to which the Distributor Defendants belong have acknowledged that wholesale distributors such as the Distributor Defendants have been responsible for reporting suspicious orders for more than 40 years. The Healthcare Distribution

Management Association ("HDMA," now known as the Healthcare Distribution Alliance ("HDA")), a trade association of pharmaceutical distributors to which Distributor Defendants belong, has long taken the position that distributors have responsibilities to "prevent diversion of controlled prescription drugs" not only because they have statutory and regulatory obligations do so, but "as responsible members of society." Guidelines established by the HDA also explain that distributors, "[a]t the center of a sophisticated supply chain . . . are uniquely situated to perform due diligence in order to help support the security of the controlled substances they deliver to their customer."

166. The DEA also repeatedly has made clear that Defendant Distributors' and Manufacturers' obligations under federal law obligate them to report and decline to fill suspicious orders. The DEA, for example, advised in a September 27, 2006 letter to every commercial entity registered to distribute controlled substances that they are "one of the key components of the distribution chain. If the closed system is to function properly . . . distributors must be vigilant in deciding whether a prospective customer can be trusted to deliver controlled substances only for lawful purposes. This responsibility is critical, as . . . the illegal distribution of controlled substances has a substantial and detrimental effect on the health and general welfare of the American people." The DEA's September 27, 2006 letter also expressly reminded them that registrants, *in addition* to reporting suspicious orders, have a "statutory responsibility to exercise due diligence to avoid filling suspicious orders that might be diverted into other than legitimate medical, scientific, and industrial channels."

167. The DEA sent another letter to each of the Distributor Defendants, and to the Manufacturing Defendants as well, on December 27, 2007, reminding them that, as registered manufacturers and distributors of controlled substances, they share, and must each abide by,

statutory and regulatory duties to "maintain effective controls against diversion" and "design and operate a system to disclose to the registrant suspicious orders of controlled substances." The DEA's December 27, 2007 letter reiterated the obligation to detect, report, and not fill suspicious orders and provided detailed guidance on what constitutes a suspicious order and how to report (e.g., by specifically identifying an order as suspicious, not merely transmitting data to the DEA). Finally, the letter references the Revocation of Registration issued in Southwood Pharmaceuticals, Inc., 72 Fed. Reg. 36,487-01 (July 3, 2007), which discusses the obligation to report suspicious orders and "some criteria to use when determining whether an order is suspicious."

3. Mallinckrodt failed its duty to maintain effective controls against diversion and report suspicious prescribing.

168. Recently, Mallinckrodt admitted in a settlement with the DEA that "[a]s a registrant under the CSA, Mallinckrodt had a responsibility to maintain effective controls against diversion, including a requirement that it review and monitor these sales and report suspicious orders to DEA."

169. The Department of Justice has recently confirmed the suspicious order obligations clearly imposed by federal law upon opioid manufacturers and distributors, fining Mallinckrodt $35 million for failure to report suspicious orders of controlled substances, including opioids, and for violating recordkeeping requirements. The Department of Justice and DEA determined that Mallinckrodt ignored its responsibility to report suspicious orders of as many as 500 million of its pills that were sent to Florida from 2008 and 2012, which was 66% of all oxycodone sold in the state.

170. In the press release accompanying the settlement, the Department of Justice stated: "Mallinckrodt did not meet its obligations to detect and notify DEA of suspicious orders

of controlled substances such as oxycodone, the abuse of which is part of the current opioid epidemic. These suspicious order monitoring requirements exist to prevent excessive sales of controlled substances, like oxycodone . . . . Mallinckrodt's actions and omissions formed a link in the chain of supply that resulted in millions of oxycodone pills being sold on the street. . . . Manufacturers and distributors have a crucial responsibility to ensure that controlled substances do not get into the wrong hands. . . ."

171. Among the allegations resolved by the settlement, the government alleged "Mallinckrodt failed to design and implement an effective system to detect and report 'suspicious orders' for controlled substances – orders that are unusual in their frequency, size, or other patterns . . . [and] Mallinckrodt supplied distributors, and the distributors then supplied various U.S. pharmacies and pain clinics, an increasingly excessive quantity of oxycodone pills without notifying DEA of these suspicious orders."

172. The Memorandum of Agreement entered into by Mallinckrodt ("2017 Mallinckrodt MOA") avers "[a]s a registrant under the CSA, Mallinckrodt had a responsibility to maintain effective controls against diversion, including a requirement that it review and monitor these sales and report suspicious orders to DEA."

173. The 2017 Mallinckrodt MOA further details the DEA's allegations regarding Mallinckrodt's failures to fulfill its legal duties as an opioid manufacturer:

> With respect to its distribution of oxycodone and hydrocodone products, Mallinckrodt's alleged failure to distribute these controlled substances in a manner authorized by its registration and Mallinckrodt's alleged failure to operate an effective suspicious order monitoring system and to report suspicious orders to the DEA when discovered as required by and in violation of 21 C.F.R. § 1301.74(b). The above includes, but is not limited to Mallinckrodt's alleged failure to:
>
> i. detect and report to the DEA orders of unusual size and frequency;

ii. detect and report to the DEA orders deviating substantially from normal patterns including, but not limited to, those identified in letters from the DEA Deputy Assistant Administrator, Office of Diversion Control, to registrants dated September 27, 2006 and December 27, 2007:

1. orders that resulted in a disproportionate amount of a substance which is most often abused going to a particular geographic region where there was known diversion,

2. orders that purchased a disproportionate amount of a substance which is most often abused compared to other products, and

3. orders from downstream customers to distributors who were purchasing from multiple different distributors, of which Mallinckrodt was aware;

iii. use "chargeback" information from its distributors to evaluate suspicious orders. Chargebacks include downstream purchasing information tied to certain discounts, providing Mallinckrodt with data on buying patterns for Mallinckrodt products; and

iv. take sufficient action to prevent recurrence of diversion by downstream customers after receiving concrete information of diversion of Mallinckrodt product by those downstream customers.

174. Mallinckrodt agreed that its "system to monitor and detect suspicious orders did not meet the standards outlined in letters from the DEA Deputy Administrator, Office of Diversion Control, to registrants dated September 27, 2006 and December 27, 2007." Mallinckrodt further agreed that it "recognizes the importance of the prevention of diversion of the controlled substances they manufacture" and would "design and operate a system that meets the requirements of 21 CFR 1301.74(b) . . . [such that it would] utilize all available transaction information to identify suspicious orders of any Mallinckrodt product. Mallinckrodt agrees to notify DEA of any diversion and/or suspicious circumstances involving any Mallinckrodt controlled substances that Mallinckrodt discovers."

175. Mallinckrodt acknowledged that "[a]s part of their business model Mallinckrodt collects transaction information, referred to as chargeback data, from their direct customers (distributors). The transaction information contains data relating to the direct customer sales of controlled substances to 'downstream' registrants." Mallinckrodt agreed that, from this data, it would "report to the DEA when Mallinckrodt concludes that the chargeback data or other information indicates that a downstream registrant poses a risk of diversion."

4. Manufacturer and distributor defendants have repeatedly violated their reporting requirements.

176. Defendant Distributors have faced repeated enforcement actions from all over the country for their failure to comply with their obligations to report and decline suspicious orders, making clear both that they were repeatedly reminded of their duties, and that they frequently failed to meet them.

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

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

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

d. On December 7, 2007, the DEA issued an *Order to Show Cause and Immediate Suspension Order* against the Cardinal Health Swedesboro, New Jersey Distribution Center ("Swedesboro Facility"), which is just across the Pennsylvania border, for failure to maintain effective controls against diversion of hydrocodone;

e. On January 30, 2008, the DEA issued an *Order to Show Cause and Immediate Suspension Order* against the Cardinal Health Stafford, Texas Distribution Center

("Stafford Facility") for failure to maintain effective controls against diversion of hydrocodone;

f. On May 2, 2008, McKesson Corporation entered into an *Administrative Memorandum of Agreement* ("2008 MOA") with the DEA which provided that McKesson would "maintain a compliance program designed to detect and prevent the diversion of controlled substances, inform DEA of suspicious 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"); and

h. On February 2, 2012, the DEA issued an Order to Show Cause and Immediate Suspension Order against the Cardinal Health Lakeland, Florida Distribution Center ("Lakeland Facility") for failure to maintain effective controls against diversion of oxycodone. The Order alleged, among other things, that Cardinal Lakeland failed to conduct "meaningful due diligence of its retail pharmacy customers, including its retail chain pharmacy customers, to ensure that controlled substances were not diverted into other than legitimate channels." The Order resulted in a two-year suspension of Cardinal's registration to distribute Class II narcotics from the Lakeland Facility.

177. These violations reflect a pervasive pattern and practice over the last decade of failing to report and stop suspicious orders that would have affected Defendant Distributors' operations in Pennsylvania and the supply of opioids into the City.

178. Defendant McKesson recently admitted to breach of its duties to monitor, report, and prevent suspicious orders and agreed to pay a $150 million civil penalty for the violations. Pursuant to an Administrative Memorandum of Agreement ("2017 Agreement") entered into between McKesson and the DEA in January 2017, McKesson admitted that, at various times during the period from January 1, 2009 through the effective date of the Agreement (January 17, 2017) it "did not identify or report to [the] DEA certain orders placed by certain pharmacies

which should have been detected by McKesson as suspicious based on the guidance contained in the DEA Letters." Further, the 2017 Agreement specifically finds that McKesson "distributed controlled substances to pharmacies even though those McKesson Distribution Centers should have known that the pharmacists practicing within those pharmacies had failed to fulfill their corresponding responsibility to ensure that controlled substances were dispensed pursuant to prescriptions issued for legitimate medical purposes by practitioners acting in the usual course of their professional practice, as required by 21 C.F.R § 1306.04(a)." McKesson admitted that, during this time period, it "failed to maintain effective controls against diversion of particular controlled substances into other than legitimate medical, scientific and industrial channels by sales to certain of its customers in violation of the CSA and the CSA's implementing regulations, 21 C.F.R. Part 1300, et seq., at the McKesson Distribution Centers".

179. As the *Washington Post* and *60 Minutes* recently reported, DEA staff recommended a much larger penalty, as much as $1 billion dollars, and delicensing of certain facilities. A DEA memo outlining the investigative findings in connection with the administrative case against 12 McKesson distribution centers included in the 2017 Settlement stated that McKesson "[s]upplied controlled substances in support of criminal diversion activities"; "[i]gnored blatant diversion"; had a "[p]attern of raising thresholds arbitrarily"; "[f]ailed to review orders or suspicious activity"; and "[i]gnored [the company's] own procedures designed to prevent diversion."

180. In short, McKesson, was "neither rehabilitated nor deterred by the 2008 [agreement],'" as a DEA official working on the case noted. Quite the opposite, "'their bad acts continued and escalated to a level of egregiousness not seen before.'" According to statements of "DEA investigators, agents and supervisors who worked on the McKesson case" reported in

the Washington Post, "the company paid little or no attention to the unusually large and frequent orders placed by pharmacies, some of them knowingly supplying the drug rings." "Instead, the DEA officials said, the company raised its own self-imposed limits, known as thresholds, on orders from pharmacies and continued to ship increasing amounts of drugs in the face of numerous red flags."

181. Purdue's failure to report suspicious activity was the subject of detailed reporting by the Los Angeles Times, which relied, in part, on internal Purdue documents and interviews with former employees and law enforcement. Since at least 2002, Purdue has maintained a database of health care providers suspected of inappropriately prescribing OxyContin or other opioids. Physicians could be added to this database based on observed indicators of illicit prescribing such as excessive numbers of patients, cash transactions, patient overdoses, and unusual prescribing of the highest-strength pills (80 mg OxyContin pills or "80s," as they were known on the street, were a prime target for diversion). Health care providers added to the database were supposedly no longer detailed, and sales representatives received no compensation tied to these providers' prescriptions.

182. Yet, Purdue failed to cut off these providers' opioid supply at the pharmacy level—meaning Purdue continued to generate sales revenue from their prescriptions—and failed to report these providers to state medical boards or law enforcement. In an interview with the *Los Angeles Times*, which first reported this story, Purdue's former senior compliance officer acknowledged that in five years of investigating suspicious pharmacies, the company never stopped the supply of its opioids to a pharmacy, even where Purdue employees personally witnessed the diversion of its drugs.

183. The same was true of Purdue's failure to report prescribers. For example, despite Purdue's knowledge of illicit prescribing from one Los Angeles, CA clinic which its district manager called an "organized drug ring," Purdue did not report its suspicions from 2009 until 2013—long after law enforcement shut it down and not until the ring prescribed more than 1.1 million OxyContin tablets.

184. The New York Attorney General found that Purdue placed 103 New York health care providers on its No-Call List between January 1 2008 and March 7, 2015, and that Purdue's sales representatives had detailed approximately two-thirds of these providers, some quite extensively, making more than a total of 1,800 sales calls to their offices over a six-year period" and spending approximately $3,000 dollars in meal expenses for 38 of these providers.

185. The New York Attorney General similarly found that Endo knew, as early as 2011, that Opana was being abused in New York, but certain sales representatives who detailed New York health care providers testified that they did not know about any policy or duty to report problematic conduct. The New York Attorney General further determined that Endo detailed health care providers who were subsequently arrested or convicted for illegal prescribing of opioids a total of 326 times, and these prescribers collectively wrote 1,370 prescriptions for Opana ER (although the subsequent criminal charges at issue did not involve Opana ER).

186. Upon information and belief, based on a nationwide and industry-wide pattern or practice, each Defendant similarly has failed to report suspicious orders or prescribing of which it is aware, or should be aware, that takes place in the City, and has failed to take other steps reasonably available to it to protect the City from part of the escalating opioid crisis.

5. Distributor and manufacturing defendants worked together to sustain their markets and boost their products.

187. Upon information and belief, each of the Distributor and Manufacturing Defendants worked with trade or other organizations, such as the HDA and Pain Care Forum ("PCF"), to safeguard the market for Manufacturing Defendants' opioids.

188. HDA's website indicates that each of the Distributor Defendants and the Manufacturing Defendants were members of the HDA. Upon information and belief, the HDA and the Distributor Defendants sought the active membership and participation of the Manufacturing Defendants by advocating that one of the benefits of membership included the ability to develop direct relationships between Manufacturers and Distributors at high executive levels. The HDA touted the benefits of membership to the Manufacturing Defendants, advocating that membership included the ability to, among other things, "network one on one with manufacturer executives at HDA's members-only Business and Leadership Conference," "networking with HDA wholesale distributor members," "opportunities to host and sponsor HDA Board of Directors events," "participate on HDA committees, task forces and working groups with peers and trading partners," and "make connections."

189. After becoming members, the Distributors and Manufacturers were eligible to participate on councils, committees, task forces and working groups, including:

a. Industry Relations Council,

b. Business Technology Committee,

c. Logistics Operation Committee,

d. Manufacturer Government Affairs Advisory Committee, and

e. Contracts and Chargebacks Working Group

190. HDA also offers a multitude of conferences, including annual business and leadership conferences. HDA advertises these conferences to Manufacturing Defendants as an opportunity to "bring together high-level executives, thought leaders and influential managers . .

. to hold strategic business discussions on the most pressing industry issues." These conferences provided HDA members "unmatched opportunities to network with [their] peers and trading partners at all levels of the healthcare distribution industry" and an opportunity for Manufacturing and Distributor Defendants to work together.

191. Distributor Defendants and Manufacturing Defendants also coordinated in other ways, including, according to articles published by the Center for Public Integrity and the Associated Press, the Pain Care Forum—whose members include the Manufacturing Defendants and the Distributors' trade association, the HDA—has been lobbying on behalf of opioid manufacturers and distributors for "more than a decade." This coordination in their lobbying further supports an inference that Distributor Defendants and Manufacturing Defendants worked together in other ways, including through the enterprises described in this Complaint.

6. Manufacturing Defendants and Distributors ignored red flags of abuse and diversion.

192. The data that reveals and/or confirms the identity of each wrongful opioid distributor is hidden from public view in the DEA's confidential ARCOS (Automation of Reports and Consolidated Orders System) database. The data necessary to identify with specificity the transactions that were suspicious is in possession of the Distributor Defendants, but has not been disclosed to the public.

193. Yet, publicly available information confirms that Manufacturing and Distributor Defendants funneled far more opioids into the City than could have been expected to serve legitimate medical use, and ignored other red flags of suspicious orders. This information, along with the information known only to Manufacturing and Distributor Defendants, would have alerted them to potentially suspicious orders of opioids in and affecting the City.

194. The City's information and belief rests upon the following facts:

a. distributors and manufacturers have access to detailed transaction-level data on the sale and distribution of opioids, which can be broken down by zip code, prescriber, and pharmacy and includes the volume of opioids, dose, and the distribution of other controlled and non-controlled substances;

b. manufacturers make use of that data to target their marketing and, for that purpose, regularly monitor the activity of doctors and pharmacies;

c. manufacturers regularly visit pharmacies and doctors to promote and provide their products and services, which allows them to observe red flags of diversion, as described above;

d. Distributor Defendants together account for approximately 90% of all revenues from prescription drug distribution in the United States, and each plays such a large part in the distribution of opioids that their own volume provides a ready vehicle for measuring the overall flow of opioids into a pharmacy or geographic area; and

e. Manufacturing Defendants purchased chargeback data (in return for discounts to Distributor Defendants) that allowed them to monitor the combined flow of opioids into a pharmacy or geographic area.

195. Upon information and belief, Manufacturing and Distributor Defendants engaged in this practice of paying rebates and/or chargebacks to wholesale drug distributors for sales of prescription opioids as a way to help them boost sales and better target their marketing efforts. The Washington Post has described the practice as industry-wide.

196. ARCOS data show the high volume of opioids, per capita, distributed in the City. With a population of approximately 300,000 residents, the City received an average of 525.6 milligrams of opioids per resident, per year from 2010-2016. To be more specific, during this time period, an average of 20.6 milligrams of oxymorphone per person was distributed in the City, which is 280% higher than the national average. The distribution of oxycodone was 40% higher than the national average. Hydromorphone and morphine shipments into the City were also higher than the national averages. This volume of opioids ordered and distributed in the City should have raised a red flag that not all of the prescriptions being filled were for legitimate medical uses.

197. In addition, the increase in fatal overdoses has been widely publicized for years. A total of approximately 231 people in the City died of opioid drug overdoses in 2017, up from just 64 in 2010. The CDC estimates that for every opioid-related death, there are 733 non-medical users. The Defendants thus had every reason to believe that illegal diversion was occurring in the City.

198. Further, in the summer of 2017, U.S. Attorney General Jeff Sessions announced the formation of a U.S. Justice Department Opioid and Abuse Detection Unit that uses data to target physicians and other health care providers who are contributing to opioid abuse in 12 districts across the United States, including the Pittsburgh area. In October 2017, federal agents arrested Dr. Andrzej Zielke of the Medical Frontiers Clinic and charged him with illegally prescribing narcotic painkillers to patients with no medical need and without performing any tests, resulting in the overdose deaths of at least three of his "patients." According to reporting, almost all of Dr. Zielke's prescriptions were filled at a pharmacy called the Medicine Shoppe in Oakmont, a municipality close to Pittsburgh, and his practices had been ongoing since at least 2014. Upon information and belief, Dr. Zielke's "patients" to whom he gave opioid prescriptions which were filled at the Medicine Shoppe included City residents.

199. Upon information and belief, this prescriber, and the pharmacy at which his patients filled prescriptions for opioids, yielded orders of unusual size, frequency, or deviation, or raised other warning signs that should have alerted Defendants to these specific instances of diversion.

200. Based upon all of these red flags, it can be fairly inferred that Distributor and Manufacturing Defendants failed to exercise due diligence as drugs were diverted into illicit uses in the City.

H. The Distributor And Manufacturing Defendants Hid Their Lack Of Cooperation With Law Enforcement And Falsely Claimed To Be Actively Working To Prevent Diversion.

201. After being caught failing to comply with particular obligations at particular facilities, Distributor Defendants made broad promises to correct their actions and insisted that they sought to be good corporate citizens. As part of McKesson's 2008 Settlement with the DEA, McKesson claimed to have "taken steps to prevent such conduct from occurring in the future" including specific measures delineated in a "Compliance Addendum" to the Settlement. Yet, in 2017, McKesson paid $150 million to resolve an investigation by the U.S. DOJ for again failing to report suspicious orders of certain drugs, including opioids.

202. More generally, the Distributor Defendants publicly portrayed themselves as committed to working with law enforcement, opioid manufacturers, and others, to prevent diversion of these dangerous drugs. For example, Defendant Cardinal claims that, "We challenge ourselves to best utilize our assets, expertise and influence to make our communities stronger and our world more sustainable, while governing our activities as a good corporate citizen in compliance with all regulatory requirements and with a belief that doing 'the right thing' serves everyone." Defendant Cardinal likewise claims to "lead [its] industry in anti-diversion strategies to help prevent opioids from being diverted for misuse or abuse." Along the same lines, it claims to "maintain a sophisticated, state-of-the-art program to identify, block and report to regulators those orders of prescription controlled medications that do not meet [its] strict criteria." Defendant Cardinal also promotes funding it provides for "Generation Rx," which funds grants related to prescription drug misuse.

203. These public statements created the false and misleading impression that the Distributer Defendants rigorously carried out their duty to report suspicious orders and exercise due diligence to prevent diversion of these dangerous drugs, and also worked voluntarily to

prevent diversion as a matter of corporate responsibility to the communities their business practices would necessarily impact.

I. Purdue Made Deceptive Statements About Its Efforts To Address The Opioid Crisis.

204. Purdue failed to report to authorities illicit or suspicious prescribing of its opioids, even as it has publicly and repeatedly touted its "constructive role in the fight against opioid abuse," including its commitment to ADF opioids and its "strong record of coordination with law enforcement."

205. Purdue's public stance long has been that "bad apple" patients and drug diversion to illicit secondary channels—and not widespread prescribing of OxyContin and other opioids for chronic pain—are to blame for widespread addiction and abuse. To address the problems of illicit use and diversion, Purdue promotes its funding of various drug abuse and diversion prevention programs and introduction of ADF opioids. This allows Purdue to present itself as a responsible corporate citizen while continuing to profit from the commonplace prescribing of its drugs, even at high doses for long-term use.

206. At the heart of Purdue's public outreach is the claim that it works hand-in-glove with law enforcement and government agencies to combat opioid abuse and diversion. Purdue has consistently trumpeted this partnership since at least 2008, and the message of close cooperation in virtually all of Purdue's recent pronouncements in response to the opioid abuse.

207. Touting the benefits of ADF opioids, Purdue's website asserts: "[W]e are acutely aware of the public health risks these powerful medications create . . . . That's why we work with health experts, law enforcement, and government agencies on efforts to reduce the risks of opioid abuse and misuse . . . ." Purdue's statement on "Opioids Corporate Responsibility" likewise states that "[f]or many years, Purdue has committed substantial resources to combat opioid abuse

by partnering with . . . communities, law enforcement, and government." And, responding to criticism of Purdue's failure to report suspicious prescribing to government regulatory and enforcement authorities, the website similarly proclaims that Purdue "ha[s] a long record of close coordination with the DEA and other law enforcement stakeholders to detect and reduce drug diversion."

208. These public pronouncements create the misimpression that Purdue is proactively working with law enforcement and government authorities nationwide to root out drug diversion, including the illicit prescribing that can lead to diversion. They aim to distance Purdue from its past conduct in deceptively marketing opioids and make its current marketing seem more trustworthy and truthful.

J. By Increasing Opioid Prescriptions And Use, Defendants Collectively Fueled The Opioid Epidemic And Significantly Harmed The City And Its Citizens.

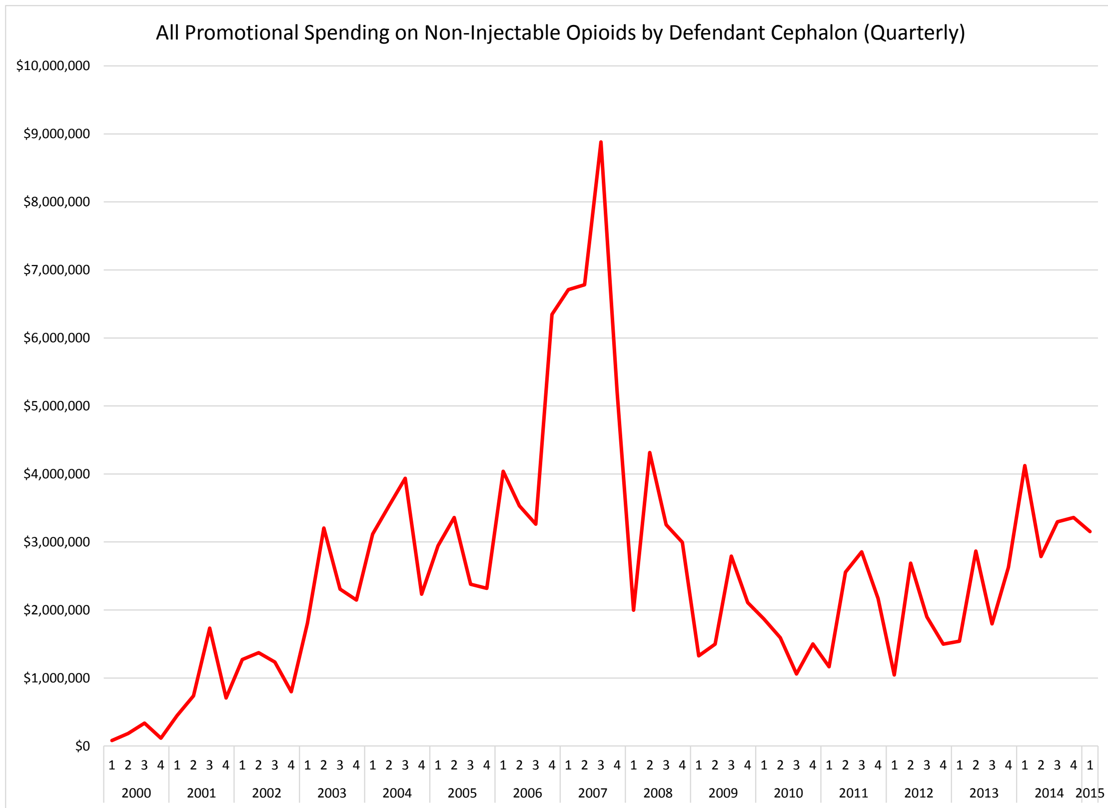
209. Manufacturing Defendants' misrepresentations prompted health care providers in the City to prescribe, patients to take, and payors to cover opioids for the treatment of chronic pain. Through its early marketing, Purdue overcame barriers to widespread prescribing of opioids for chronic pain with deceptive messages about the risks and benefits of long-term opioid use. Through their continued deceptive marketing, including to the present, Manufacturing Defendants have both benefited from and extended their prior misrepresentations, sustaining and expanding a market for their opioids. The opioids that flooded into and were dispensed throughout the City as a result of Defendants' wrongful conduct have devastated the City and its residents. Distributor Defendants compounded these harms by supplying opioids beyond even what this expanded market could bear, funneling so many opioids into the City that they could only have been delivering opioids for diversion and illicit use.

210. Manufacturing Defendants' deceptive marketing substantially contributed to an explosion in the use of opioids across the country. Approximately 20% of the population between the ages of 30 and 44, and nearly 30% of the population over 45, have used opioids. Opioids are the most common treatment for chronic pain, and 20% of office visits now include the prescription of an opioid.

211. Overall sales of opioids in Pennsylvania have skyrocketed, and sales in the City are no exception. OxyContin and Opana ER are the most prescribed brand name opioids in the City's healthcare and workers' compensation programs, with Purdue's opioids accounting for more than 37% of the opioid spending in the healthcare program.

212. Manufacturing Defendants devoted and continue to devote substantial resources to direct sales contacts with doctors. From August 2013 to December 2015, Manufacturing Defendants spent over $18.6 million in payments to doctors while detailing branded opioids. The amount includes $11.4 million spent by Purdue, $2.85 million by Teva, $2 million by Janssen, $1.6 million by Mallinckrodt, and $800,000 by Endo.

213. Cephalon's quarterly promotional spending steadily climbed from below $1 million in 2000 to more than $3 million in 2014 (and more than $13 million for the year), with a peak, coinciding with the launch of Fentora, of nearly $9 million for one quarter of 2007 (and more than $27 million for the year), as shown below:


All Promotional Spending on Non-Injectable Opioids by Defendant Cephalon (Quarterly)
$10,000,000
$9,000,000
$8,000,000
$7,000,000
$6,000,000
$5,000,000
$4,000,000
$3,000,000
$2,000,000
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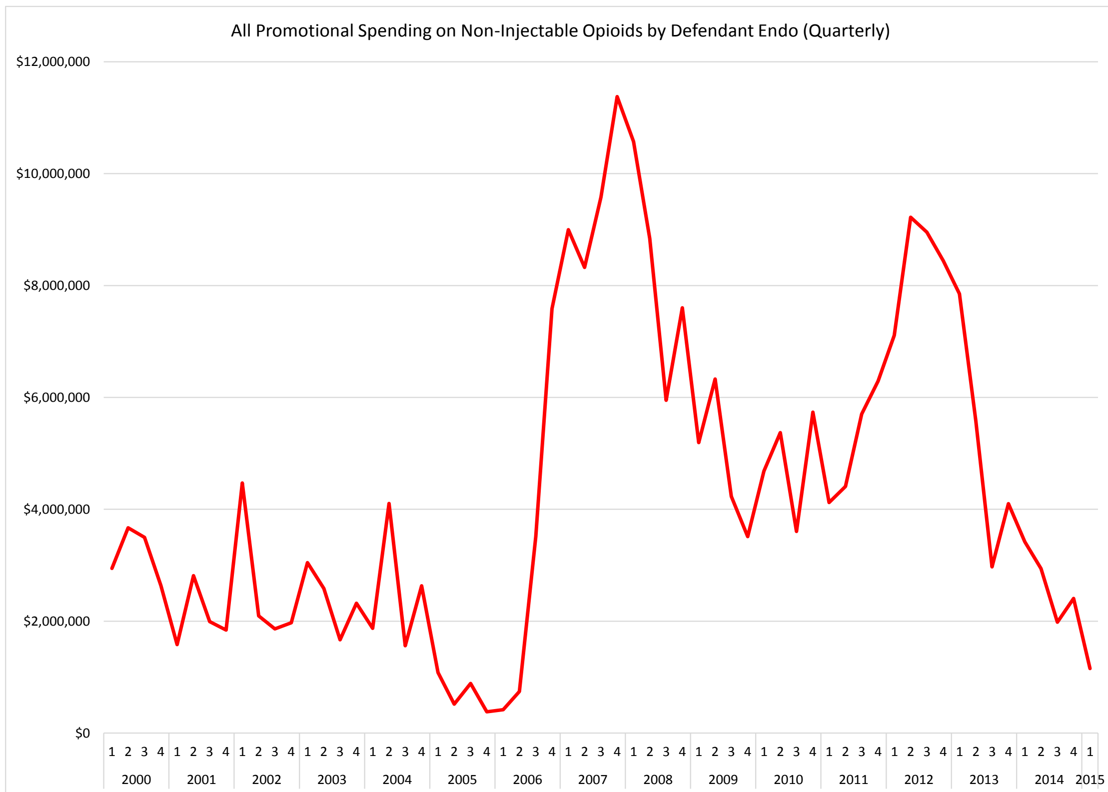
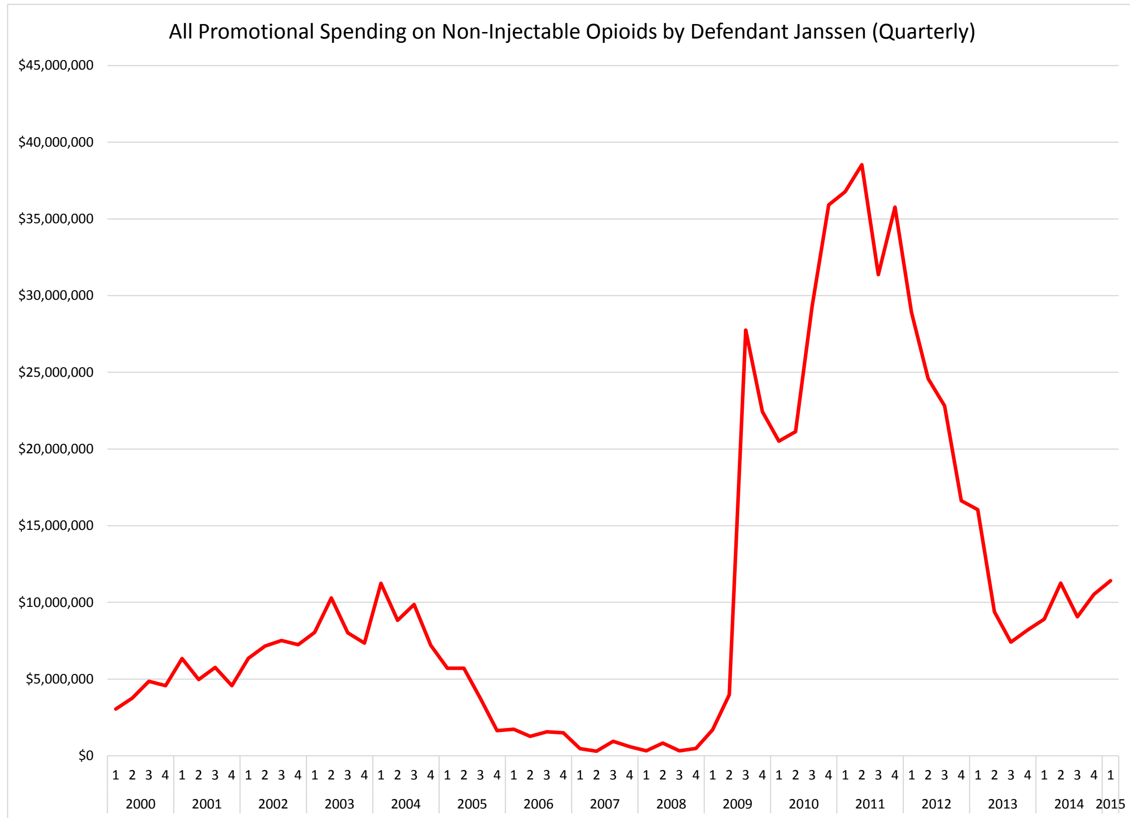
2014
2015

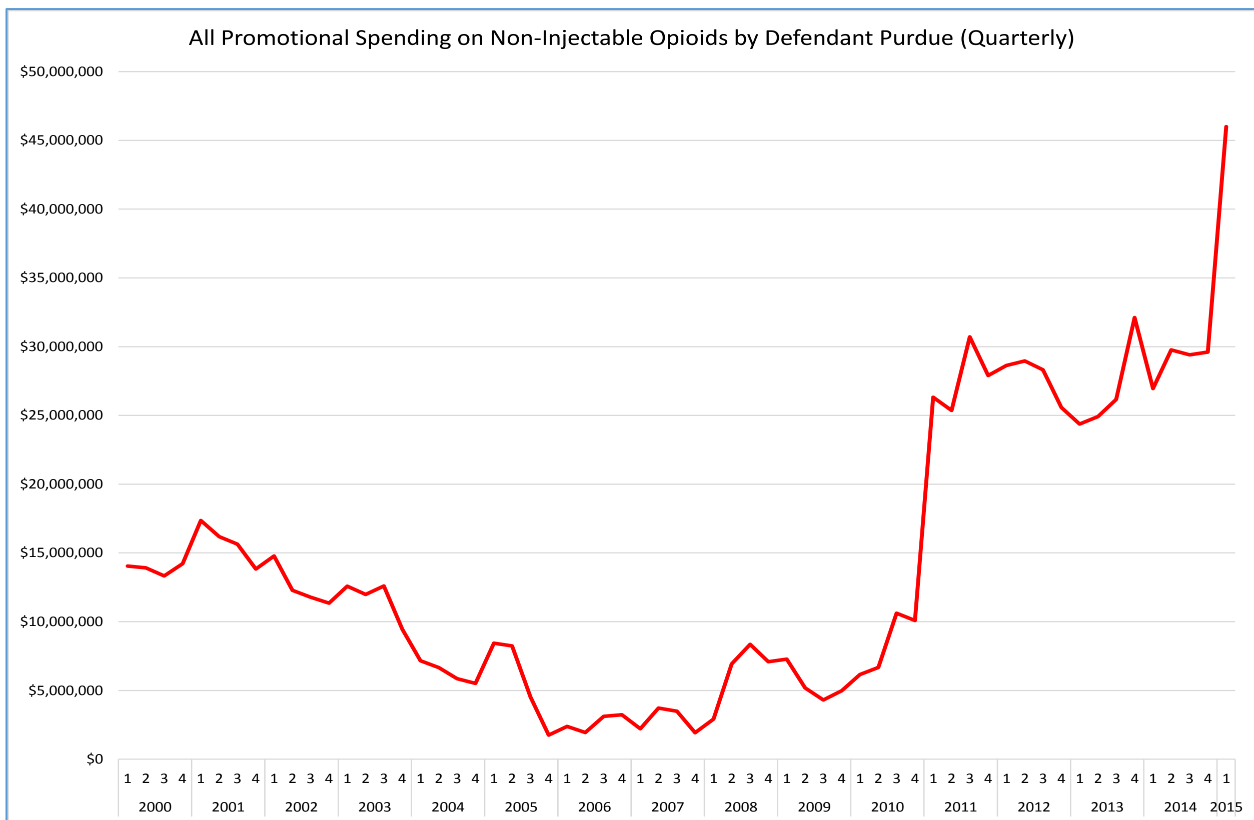
214. Endo's quarterly promotional spending went from the $2 million to $4 million range in 2000-2004 to more than $10 million following the launch of Opana ER in mid-2006 (and more than $38 million for the year in 2007) and more than $8 million coinciding with the launch of a reformulated version in 2012 (and nearly $34 million for the year):



215. Janssen's quarterly promotional spending dramatically rose from less than $5 million in 2000 to more than $30 million in 2011, coinciding with the launch of Nucynta ER (with yearly spending at $142 million for 2011), as shown below:



216. Purdue spent roughly $15 million per quarter in 2000 on marketing. Its promotional spending decreased from 2000 to 2007, as the company came under investigation by the U.S. Department of Justice and various state attorneys general. But by 2010, with the introduction of Butrans and reformulated OxyContin, Purdue ramped up its marketing once again. In 2011, Purdue's marketing spiked to more than $25 million per quarter, and by the end



of 2015, with the introduction of Hysingla ER, it soared to more than $40 million per quarter.

217. By 2000, Purdue had approximately 94,000 doctors on its physician call list. Purdue also recruited and paid respected health care professionals as "speakers" who presented Purdue-approved programs to other prescribers at lunch and dinner events. From 1996 to 2001, Purdue held more than 40 national conferences and more than 5,000 physicians, pharmacist, and nurses attended these speaker conferences. In addition to speaker programs, Purdue targeted

doctors with "educational" programing and funded more than 20,000 pain-related educational programs through direct sponsorship or financial grants by July 2002.

218. Defendants' detailing to doctors is effective. Numerous studies indicate that marketing impacts prescribing habits, with face-to-face detailing having the greatest influence.

219. The sharp increase in opioid use resulting from Defendants' marketing has led directly to a dramatic increase in opioid abuse, addiction, overdose, and death throughout the United States, including in the City. Representing the NIH's National Institute of Drug Abuse in hearings before the Senate Caucus on International Narcotics Control in May 2014, Dr. Nora Volkow explained that "aggressive marketing by pharmaceutical companies" is "likely to have contributed to the severity of the current prescription drug abuse problem."

220. In August 2016, then U.S. Surgeon General Vivek Murthy published an open letter to physicians nationwide, enlisting their help in combating this "urgent health crisis" and linking that crisis to deceptive marketing. He wrote that the push to aggressively treat pain, and the "devastating" results that followed, had "coincided with heavy marketing to doctors . . . . [m]any of [whom] were even taught—incorrectly—that opioids are not addictive when prescribed for legitimate pain."

221. Scientific evidence demonstrates a close link between opioid prescriptions and opioid abuse. For example, a 2007 study found "a very strong correlation between therapeutic exposure to opioid analgesics, as measured by prescriptions filled, and their abuse," with particularly compelling data for extended release oxycodone—*i.e.*, OxyContin.

222. There is a "parallel relationship between the availability of prescription opioid analgesics through legitimate pharmacy channels and the diversion and abuse of these drugs and

associated adverse outcomes." The opioid epidemic is "directly related to the increasingly widespread misuse of powerful opioid pain medications."

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

224. By continuing to fill suspicious orders of opioids, Defendant Distributors have enabled an oversupply of opioids, which allows non-patients to become exposed to opioids, and facilitates access to opioids for both patients who could no longer access or afford prescription opioids and addicts struggling with relapse. Distributor Defendants had financial incentives to distribute higher volumes and not to report suspicious orders or guard against diversion. Wholesale drug distributors acquire pharmaceuticals, including opioids, from manufacturers at an established wholesale acquisition cost. Discounts and rebates from this cost may be offered by manufacturers based on market share and volume. As a result, higher volumes may decrease the cost per pill to distributors. Decreased cost per pill in turn, allows wholesale distributors to offer more competitive prices, or alternatively, pocket the difference as additional profit. Either way, the increased sales volumes result in increased profits.

225. Nationally, opioids were involved in 42% of all fatal drug overdoses in 2015, and another 25% involved heroin. According to the CDC, between 1999 and 2015, more than 194,000 people died in the United States from prescription-related overdoses In 2016, a total of 218 people in the City died of opioid overdoses. In 2017, the number of fatal opioid drug

overdoses rose to 231 lives that were lost. Over 1,000 City residents lost their lives to opioids in the past eight years.

226. Overdose deaths are only one consequence. Opioid addiction and misuse also result in an increase in emergency room visits, emergency medical service ("EMS") responses, and emergency medical technicians' administration of Narcan (naloxone)—the antidote to opioid overdose. Over the past eight years, the Pittsburgh EMS has purchased an average of over 200 doses of naloxone per year, costing an eight-year total of $11,396.84. In 2017, the Pittsburgh Bureau of Fire had to administer 882 doses of Narcan. Without Narcan and the quick action of City EMS personnel, the number of opioid overdose deaths would be much higher.

227. Rising opioid use and abuse have negative social and economic consequences far beyond overdoses. According to a recent analysis by a Princeton University economist, approximately one out of every three working age men who are not in the labor force take daily prescription pain medication. The same research finds that opioid prescribing alone accounts for 20% of the overall decline in the labor force participation for this group from 2014-16, and 25% of the smaller decline in labor force participation among women. Many of those taking painkillers still said they experienced pain daily.

228. Manufacturing Defendants' conduct has significantly harmed veterans. Sixty percent (60%) of veterans returning from deployment suffer from chronic pain, double the national average of thirty percent (30%) of U.S. citizens. Veterans are twice as likely to suffer addiction, and to die from opioid abuse, than non-veterans according to a 2011 Veterans Administration study.

229. The abuse of opioids has caused additional medical conditions that have injured City residents and required care often paid for by the City. There are swelling costs from the

growing universe of medications aimed at treating secondary effects of opioids—including not only addiction and overdose, but also side effects like constipation and sedation. According to a recent analysis by *The Washington Post*, working age women and men on opioids are much more likely to have four or more prescriptions from a physician (57% and 41%, respectively) than their counterparts who do not take opioids (14% and 9%, respectively). These secondary-effects medications—essentially, drugs to treat the effects of opioids—generated at least $4.6 billion in spending nationally in 2015, on top of $9.57 billion in spending on opioids themselves. In addition, there are also the costs of dispensing opioids—in office visits to obtain refills, count pills, or obtain toxicology screens to monitor potential abuse. All of these costs were born by the City in its employee healthcare and workers' compensation plans. From 2011 through 2017, the City spent over $2.2 million on opioid prescriptions alone in its healthcare program.

230. The deceptive marketing and overprescribing of opioids also had a significant detrimental impact on children. Prescription opioid use before high school graduation is related to a 33% increase in the risk of later opioid misuse. Additionally, the adolescent misuse of opioid medications greatly predicts the later use of heroin. However, according to the CDC Guidelines, there has been a significant increase in prescribing of opioids to adolescents and children for headaches and injuries.

231. Even infants have not been immune to the impact of opioid abuse. There has been a dramatic rise in the number of infants who are born addicted to opioids due to prenatal exposure and suffer from neonatal abstinence syndrome ("NAS," also known as neonatal opioid withdrawal syndrome, or "NOWS"). These infants painfully withdraw from the drug once they are born, cry nonstop from the pain and stress of withdrawal, experience convulsions or tremors, have difficulty sleeping and feeding, and suffer from diarrhea, vomiting, and low weight gain,

among other serious symptoms. The long-term developmental effects are still unknown, though research in other states has indicated that these children are likely to suffer from continued, serious neurologic and cognitive impacts, including hyperactivity, attention deficit disorder, lack of impulse control, and a higher risk of future addiction. When untreated, NAS can be life-threatening. In 2009, more than 13,000 infants in the United States were born with NAS, or about one every hour.

232. In 2016, 190 newborns in the Pittsburgh region (Allegheny County) showed signs of drug withdrawal or were affected by narcotics, a 12% increase from 170 babies the year before. Many of these children must receive in-home services and some must be placed in foster care.

233. Defendants' success in extending the market for opioids to new patients and chronic conditions also created an abundance of drugs available for non-medical or criminal use and fueled a new wave of addiction, abuse, and injury.

234. Contrary to Defendants' misrepresentations, most of the illicit use originates from *prescribed* opioids. It has been estimated that 60% of the opioids that are abused come, directly or indirectly, through physicians' prescriptions. In 2011, 71% of people who abused prescription opioids throughout the country got them through friends or relatives, not from drug dealers or the internet. This is consistent with information provided by addiction treatment personnel in the City. According to one treatment provider, who has seen thousands of patients, about 90% of heroin users started with prescription pills; other providers have found about 90% of their opioid addiction patients started with legitimate prescriptions.

235. In fact, people who are addicted to prescription opioid painkillers are 40 times more likely to be addicted to heroin. The CDC identified addiction to prescription pain

medication as the strongest risk factor for heroin addiction. A recent, even more deadly problem stemming from the prescription opioid epidemic involves fentanyl—a powerful opioid carefully prescribed for cancer pain or in hospital settings that, in synthetic form, has made its way into the City's communities.

236. In addition, the City has incurred substantial expense in paying for opioid prescriptions through its employee healthcare and workers' compensation programs. The expenditures from the City's healthcare plan on opioid prescriptions alone were over $2.2 million during the past seven years, not including associated expenses for doctors' visits and drug screening and for treating the adverse effects associated with opioids. During the past five years, the workers' compensation program has spent more than $885,000 on opioid prescriptions alone.

K. Defendants Fraudulently Concealed Their Misconduct.

237. Defendants promoted, and profited from their misrepresentations about the risks and benefits of opioids for chronic pain even though they knew that their marketing was false and misleading. The history of opioids, as well as research and clinical experience over the last 20 years, established that opioids were highly addictive and responsible for a long list of very serious adverse outcomes. The FDA and other regulators warned Manufacturing Defendants of this, and likewise, Purdue and Teva paid hundreds of millions of dollars to address similar misconduct that occurred before 2008. Manufacturing Defendants had access to scientific studies, detailed prescription data, and reports of adverse events, including reports of addiction, hospitalization, and deaths—all of which made clear the harms from long-term opioid use and that patients are suffering from addiction, overdoses, and death in alarming numbers. More recently, the FDA and CDC have issued pronouncements based on existing medical evidence that conclusively expose the known falsity of these Defendants' misrepresentations.

238. Notwithstanding this knowledge, at all times relevant to this Complaint, Manufacturing Defendants took steps to avoid detection of and to fraudulently conceal their deceptive marketing and unlawful, unfair, and fraudulent conduct. Manufacturing Defendants disguised their own role in the deceptive marketing of chronic opioid therapy by funding and working through biased science, unbranded marketing, third-party advocates, and professional associations. Manufacturing Defendants purposefully hid behind the assumed credibility of these sources and relied on them to establish the accuracy and integrity of Manufacturing Defendants' false and misleading messages about the risks and benefits of long-term opioid use for chronic pain. Manufacturing Defendants masked or never disclosed their role in shaping, editing, and approving the content of this information. Defendants also distorted the meaning or import of studies they cited and offered them as evidence for propositions the studies did not support.

239. Manufacturing Defendants thus successfully concealed from the medical community, patients, and the City facts sufficient to arouse suspicion of the claims that the City now asserts. The City did not know of the existence or scope of the Defendants' fraud and could not have acquired such knowledge earlier through the exercise of reasonable diligence.

240. The Distributor Defendants also fraudulently concealed their misconduct. They have declined to release the ARCOS data which provides detailed tracking information about their shipments. In addition, as explained above, these Defendants publicly portray themselves as maintaining sophisticated technology as part of a concerted effort to thwart diversion, and publicly portray themselves as committed to fighting the opioid epidemic, while failing to prevent diversion.

241. In light of Defendants' failures to disclose suspicious prescriptions and orders of opioids and maintain adequate controls to prevent diversion, the City 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 prescriptions and orders of opioids Defendants were required to disclose—but did not—was information that the Defendants, given their placement in the supply chain, are uniquely positioned to possess and which was otherwise unavailable to the City.

242. Further, Defendants misleadingly portrayed themselves as cooperating with law enforcement and actively working to combat the opioid epidemic when, in reality, Defendants failed to satisfy even their minimum, legally-required obligations to report suspicious prescribers and pharmacy orders.

V. CAUSES OF ACTION

COUNT I
Public Nuisance
(Against All Defendants)

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

244. Defendants, individually and acting through their employees and agents, and in concert with each other, have intentionally, recklessly, or negligently engaged in conduct or omissions which endanger or injure the property, health, safety or comfort of the public in the City. In particular, Manufacturing Defendants unreasonably interfered with rights common to the general public within the City through their unlawful and deceptive promotion, marketing, and sale of opioids for use by residents of the City. In addition, Distributor Defendants have unreasonably interfered with rights common to the general public within the City by unlawfully failing to design and operate a system that would detect and disclose the existence of suspicious

prescriptions and orders of controlled substances and by failing to report and reject suspicious orders of opioids.

245. Defendants have created or assisted in the creation of a condition that is injurious to public health, public safety, public peace, and public comfort and offends the moral standards of the community.

246. Defendants' acts and omissions offend, significantly and unreasonably interfere with, and cause damage to the public rights common to all, such as the public health, public safety, public peace, and the public comfort. The harm is not confined to any City zip code or census tract, or to any demographic group, but affects the public health, safety, order and well-being of the City as a whole. The public nuisance caused by Defendants has significantly harmed the City and a considerable number of City residents.

247. Defendants had control over their conduct in the City and that conduct has had an adverse effect on the public right. Defendants had sufficient control over, and responsibility for, the public nuisance they created—Defendants were in control of the "instrumentality" of the nuisance, namely prescription opioids, including the process of distribution, marketing and promotion and creation and maintenance of the demand for prescription opioids at all relevant times, which included control of the misleading representations they conveyed through branded and unbranded marketing and product promotion.

248. Defendants' conduct is not insubstantial or fleeting. It has caused deaths, serious injuries, and a severe disruption of public peace, health, order and safety; it is ongoing, and it is producing permanent and long-lasting damage.

249. Defendants' conduct is unreasonable, intentional, and unlawful, including, without limitation, because it violates the Pennsylvania Unfair Trade Practices and Consumer

Protection Law, 73 Pa. Stat. Ann. §§ 201-1 through 201-9.3, as alleged more fully in Count II, the Controlled Substances Act, 21 U.S.C. § 823(a)(1), and its implementing regulations, 21 C.F.R. § 1301.74(b).

250. Defendants knew and should have known that their unlawful and unfair actions would create or assist in the creation of the public nuisance.

251. The public nuisance is substantial and unreasonable. Defendants' actions caused and continue to cause the public health epidemic and state of emergency described in the Complaint.

252. Defendants' conduct directly and proximately caused injury to Plaintiff and its residents. Manufacturing and Distributor Defendants' actions were, at the very least, a substantial factor in opioids becoming widely available and widely used in the City. Manufacturing Defendants' actions were a substantial factor in deceiving doctors and patients about the risks and benefits of opioids for the treatment of chronic pain. Manufacturing Defendants controlled these actions and, therefore, willingly participated to a substantial extent in creating and maintaining the public nuisance. Distributor Defendants turned a blind eye toward the quantity of opioids they were shipping into the City, which significantly contributed to the nuisance. Without all of the Defendants' actions, opioid use, misuse, abuse, and addiction would not have become so widespread, and the opioid epidemic that now exists would have been averted or much less severe.

253. The City suffered special injuries distinguishable from those suffered by the general public. As discussed herein, it has incurred substantial costs from investigating, monitoring, treating, policing, and remediating the opioid epidemic. The City's damages are not derivative of harm to third parties.

254. The public nuisance—i.e., the opioid epidemic—created, perpetuated, and maintained by Defendants can be abated and further recurrence of such harm and inconvenience can be abated.

255. The misconduct alleged in this case does not concern a discrete event or discrete emergency of the sort a political subdivision would reasonably expect to occur, and is not part of the normal and expected costs of a local government's existence.

256. WHEREFORE, the City demands judgment in its favor against the Defendants for compensatory damages in an amount to be determined by a jury, abatement of the public nuisance, and injunctive relief together with all the costs of this action, including prejudgment interest, post-judgment interest, costs and expenses, attorney fees, and such other relief as this Court deems just and equitable.

COUNT II
Pennsylvania Unfair Trade Practices and Consumer Protection Law
73 Pa. Stat. Ann. §§ 201-1 through 201-9.3
(Against All Defendants)

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

258. Pennsylvania's Unfair Trade Practices and Consumer Protection Law ("CPL") provides:

> Unfair methods of competition and unfair or deceptive acts or practices in the conduct of any trade or commerce . . . are hereby declared unlawful.

73 Pa. Stat. Ann. § 201-3.

259. Defendants have violated Pennsylvania's CPL because they engaged in unfair or deceptive acts or practices in the conduct of commerce.

260. In overstating the benefits of, and evidence for, the use of opioids for chronic pain and understating the very serious risks, including the risk of addiction; in disseminating misleading information regarding the appropriateness of their opioids for certain conditions; in falsely promoting abuse-deterrent formulations as reducing abuse; in falsely claiming that OxyContin provides 12 hours of relief; and in falsely portraying their efforts or commitment to rein in the diversion and abuse of opioids, Manufacturing Defendants have engaged in unfair or deceptive acts.

261. Specifically, the Manufacturing Defendants' deceptive acts include, but are not limited to:

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

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

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

d. Defendants' claims that opioid doses can be increased until pain relief is achieved;

e. Defendants' claims that opioids differ from NSAIDS in that they have no ceiling dose;

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

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

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

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

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

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

for such use.

262. All Defendants engaged in deceptive acts under the CPL when they held themselves out to be working with law enforcement to address the opioid crisis.

263. All Defendants engaged in unfair practices under the CPL by failing to implement sufficient controls to prevent diversion; and by failing to report suspicious prescriptions and pharmacy orders.

264. The City of Pittsburgh, as a legal entity, is a "person" as defined in Pa. Stat. Ann. § 201-2 that purchases goods and services (i.e., pays for opioid prescriptions, toxicology screens and doctor visits) primarily for the personal, family or household purposes of its healthcare plan beneficiaries, and therefore may bring a private action under Pa. Stat. Ann. § 201-9.2 to recover up to three times the actual damages sustained.

265. The City has been injured and suffered actual damages as a direct and proximate result of Defendants' violations of the CPL as alleged in this Complaint.

266. Had the City known that Defendants misrepresented the risks, benefits, and evidence regarding the use of opioids for chronic pain, the City would have undertaken efforts to avoid payments of related claims.

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

268. WHEREFORE, the City demands judgment in its favor against the Defendants for treble damages pursuant to Pa. Stat. Ann § 201-1 through 201-9.3 together with all the costs of this action, including prejudgment interest, post-judgment interest, costs and expenses, attorney fees, and such other relief as this Court deems just and equitable.

COUNT III
Fraudulent Misrepresentation
(Against Manufacturing Defendants)

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

270. Defendants, individually and acting through their employees and agents, made misrepresentations and omissions of facts material to Plaintiff and its residents to induce them to purchase, administer, and consume opioids as set forth in detail above.

271. In overstating the benefits of and evidence for the use of opioids for chronic pain and understating their very serious risks, including the risk of addiction; in falsely promoting abuse-deterrent formulations as reducing abuse; in falsely claiming that OxyContin provides 12 hours of relief; in falsely portraying their efforts or commitment to rein in the diversion and abuse of opioids; and with every other unfair or deceptive practice alleged in this Complaint, Manufacturing Defendants have engaged in misrepresentations and knowing omissions of material fact.

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

273. Defendants knew at the time that they made their misrepresentations and omissions that they were false.

274. Defendants intended that the City and its residents would rely on their misrepresentations and omissions, knew that the City and its residents would rely on their misrepresentations, and that such reliance would cause the City to suffer loss.

275. Healthcare providers and residents in the City reasonably relied on Defendants' misrepresentations and omissions in writing, filling, and using prescriptions for Defendants'

opioids, and the City and its agents reasonably relied on these misrepresentations and omissions in covering and paying for Defendants' opioids for chronic pain.

276. Had the City known that Defendants misrepresented the risks, benefits, and evidence regarding the use of opioids for chronic pain, the City would have undertaken efforts to avoid payments of related claims.

277. By reason of their reliance on Defendants' misrepresentations and omissions of material fact the City suffered actual pecuniary damage.

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

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

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

COUNT IV
Negligent Misrepresentation
(Against Manufacturing Defendants)

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

282. Manufacturing Defendants, individually and acting through their employees and agents, made misrepresentations and omissions of facts material to Plaintiff and its residents to induce them to purchase, administer, and consume opioids as set forth in detail above.

283. Manufacturing Defendants had a duty to exercise reasonable care in marketing and selling highly dangerous opioid drugs in the City.

284. Manufacturing Defendants negligently asserted false statements and omitted material facts regarding the benefits of and evidence for the use of opioids for chronic pain, while understating their very serious risks, including the risk of addiction, with every unfair or deceptive practice alleged in this Complaint.

285. Defendants intended that the City and its residents would rely on their misrepresentations and omissions, knew that the City and its residents would rely on their misrepresentations, and that such reliance would cause the City to suffer loss.

286. Healthcare providers and residents in the City reasonably relied on Defendants' misrepresentations and omissions in writing, filling, and using prescriptions for Defendants' opioids, and the City and its agents reasonably relied on these misrepresentations and omissions in covering and paying for Defendants' opioids for chronic pain.

287. Had the City known that Defendants misrepresented the risks, benefits, and evidence regarding the use of opioids for chronic pain, the City would have undertaken efforts to avoid payments of related claims.

288. By reason of their reliance on Defendants' misrepresentations and omissions of material fact the City suffered actual pecuniary damage.

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

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

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

COUNT V
Negligence
(Against All Defendants)

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

293. Under Pennsylvania law, to establish actionable negligence, the City must show, in addition to the existence of a duty, a breach of that duty, and injury resulting proximately therefrom. All such elements exist here.

294. Defendants have a duty to exercise reasonable care in manufacturing, marketing, selling, and distributing highly dangerous opioid drugs in the City.

295. Defendants have a duty to exercise reasonable care under the circumstances, in light of the risks. This includes a duty not to cause foreseeable harm to others. In addition, these Defendants, having engaged in conduct that created an unreasonable risk of harm to others, had, and still have, a duty to exercise reasonable care to prevent the threatened harm.

296. Upon information and belief, each of the Defendants repeatedly and intentionally breached its duties. These breaches included:

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

b. Using unsafe distribution practices;

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

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

e. Failing to review prescription orders for red flags;

f. Failing to report suspicious orders or refuse to fill them; and

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

297. In addition, the Manufacturing Defendants breached their duty to the City by deceptively marketing opioids, including minimizing the risks of addiction and overdose and exaggerating the purported benefits of long-term use of opioids for the treatment of chronic pain.

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

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

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

301. The foreseeable harm from a breach of these duties also includes abuse, addiction, morbidity and mortality in the City's communities.

302. Reasonably prudent manufacturers and distributors of prescription opioids would have anticipated that the scourge of opioid addiction would wreak havoc on communities and the significant costs which would be imposed upon the governmental entities associated with those communities. The closed system of opioid distribution whereby wholesale distributors are the gatekeepers between manufacturers and pharmacies, and wherein all links in the chain have a duty to prevent diversion, exists for the purpose of controlling dangerous substances such as opioids and preventing diversion and abuse to prevent precisely these types of harms.

303. Reasonably prudent manufacturers and distributors of pharmaceutical products would know that aggressively marketing highly addictive opioids for chronic pain would result

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

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

305. These Defendants' breach of the duties described in this Count directly and proximately resulted in the injuries and damages alleged by the City.

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

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

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

309. WHEREFORE, the City seeks all legal and equitable relief as allowed by law, except as expressly disavowed herein, including *inter* alia injunctive relief, compensatory and punitive damages, and all damages allowed by law to be paid by Defendants, attorney fees and

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

COUNT VI
Gross Negligence
(Against All Defendants)

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

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

312. Defendants have a duty to exercise reasonable care in manufacturing, marketing, and selling highly dangerous opioid drugs in the City.

313. Defendants have a duty to exercise reasonable care under the circumstances, in light of the risks. This includes a duty not to cause foreseeable harm to others. In addition, these Defendants, having engaged in conduct that created an unreasonable risk of harm to others, had, and still have, a duty to exercise reasonable care to prevent the threatened harm.

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

315. Upon information and belief, each of the Defendants repeatedly and intentionally breached its duties. These breaches included:

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

medical purposes;

b. Using unsafe distribution practices;

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

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

e. Failing to review prescription orders for red flags;

f. Failing to report suspicious orders or refuse to fill them; and

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

316. In addition, the Manufacturing Defendants breached their duty to the City by deceptively marketing opioids, including minimizing the risks of addiction and overdose and exaggerating the purported benefits of long-term use of opioids for the treatment of chronic pain.

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

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

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

320. As is described throughout this Complaint, Defendants acted without even slight diligence or scant care, and with indifference, and were negligent in a very high degree,

disregarding the rights and safety of other persons, and said actions have a great probability of causing substantial harm.

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

322. The foreseeable harm from a breach of these duties also includes abuse, addiction, morbidity and mortality in the City's communities.

323. Reasonably prudent manufacturers of prescription opioids would have anticipated that the scourge of opioid addiction would wreak havoc on communities and the significant costs which would be imposed upon the governmental entities associated with those communities.

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

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

326. Defendants' conduct, as described in this Complaint, constitutes an intentional failure to perform a manifest duty in reckless disregard of the consequences as affecting the life

or property of another, including the City, and also implies an indifferent and thoughtless disregard of the consequences without the exertion of any effort to avoid them. Defendants have acted wantonly and willfully by inflicting injury intentionally or, alternatively, they have been utterly indifferent to the rights of others, including the City, in that they acted as if such rights did not exist.

327. The City is not asserting a cause of action under the CSA or other controlled-substances laws cited above. Rather, it seeks to remedy harms caused to it by the breach of duty created by these statutes and under common law.

328. Defendants conduct as described in this Count demonstrates wanton and willful disregard and indifference for others, including the City.

329. These Defendants' breach of the duties described in this Count directly and proximately resulted in the injuries and damages alleged by the City.

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

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

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

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

COUNT VII
Unjust Enrichment
(Against All Defendants)

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

335. As an expected and intended result of their conscious wrongdoing as set forth in this Complaint, Manufacturing Defendants have profited and benefited from opioid purchases made by the City, and all Defendants have profited and benefited from the increase in the distribution and purchase of opioids within the City.

336. In exchange for the opioid purchases, and at the time the City made these payments, the City expected that Manufacturing Defendants had not engaged in deceptive practices or practices contrary to the City's public policy and had not misrepresented any material facts regarding those risks.

337. In addition, the City has expended substantial amounts of money in an effort to remedy or mitigate the societal harms caused by Defendants' conduct.

338. These expenditures include the provision of healthcare services and treatment services to people who use opioids.

339. These expenditures have helped sustain Defendants' businesses.

340. The City has conferred a benefit upon Defendants by paying for Defendants' externalities: the cost of the harms caused by Defendants' improper distribution practices.

341. The City has also conferred a benefit upon Defendants by paying for purchases by unauthorized users of prescription opioids from the Defendants' supply chain for non-medical purposes.

342. By distributing a large volume of opioids within the City and by acting in concert with third parties, Distributor Defendants have unjustly enriched themselves at the City's

expense. By deceptively marketing opioids and engaging in the unlawful and unfair practices described in this Complaint, Manufacturing Defendants have unjustly enriched themselves at the City's expense.

343. The City has paid for the cost of each Defendants' externalities and Defendants have benefited from those payments because they allowed them to continue providing customers with a high volume of opioid products. Because of their conscious failure to exercise due diligence in preventing diversion, Defendants obtained enrichment they would not otherwise have obtained. The enrichment was without justification and Plaintiffs lack a remedy provided by law.

344. In addition, by deceptively marketing opioids and engaging in the unlawful and unfair practices described in this Complaint, Manufacturing Defendants have unjustly enriched themselves at the City's expense. These Defendants have unjustly retained a benefit to the Plaintiffs' detriment, and these Defendants' retention of the benefit violates the fundamental principles of justice, equity, and good conscience. The enrichment was without justification and Plaintiffs lack a remedy provided by law.

345. Defendants have been unjustly enriched at the expense of the City. It would be inequitable for Defendants to retain the profits and benefits they have reaped from the deceptive practices, misrepresentations, and unlawful conduct alleged herein.

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

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

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

349. WHEREFORE, the City seeks all legal and equitable relief as allowed by law, including disgorgement of Defendants' unjust enrichment, benefits, and ill-gotten gains, plus interest, acquired as a result of the unlawful or wrongful conduct alleged herein pursuant to common law and such other relief as this Court deems just and equitable.

COUNT VIII
Civil Conspiracy
(Against All Defendants)

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

351. Each Manufacturing Defendant purposely, intentionally, and without reasonable or lawful excuse, engaged in a common understanding or design to unlawfully increase sales, revenues and profits through the statutory and common law violations described above, with each Distributor Defendant, which likewise acted with purpose, intent and without reasonable or lawful excuse. Defendants reached a mutual understanding to engage in these wrongful and unlawful acts knowing that they would create a public nuisance, violate Pennsylvania's CPL, and constitute tortious behavior and unjust enrichment.

352. Defendants made overt acts in pursuance of their common purpose, including through the actions detailed in Counts I-VII, as well as in the body of the Complaint.

353. Defendants' civil conspiracy, and actions and omissions in furtherance thereof, caused direct and foreseeable injury and damage to the City. The City has incurred expenditures for programs over and above its ordinary public services as a result of the Defendants' civil conspiracy.

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

355. The City seeks economic losses (direct, incidental, or consequential pecuniary losses) resulting from Defendants' civil conspiracy, and actions and omissions in furtherance thereof. The City does not seek damages for the wrongful death, physical personal injury, serious emotional distress, or any physical damage to property caused by Defendants' actions.

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

357. WHEREFORE, the City seeks all legal and equitable relief as allowed by law, except as expressly disavowed herein, including inter alia injunctive relief, compensatory and punitive damages, and all damages allowed by law to be paid by Defendants, attorney fees and costs, and pre- and post-judgment interest.

VI. PRAYER FOR RELIEF

WHEREFORE, the City requests the following relief:

358. A finding that by the acts alleged herein, Defendants violated the Pennsylvania Unfair Trade Practices and Consumer Protection Law, 73 Pa. Stat. Ann. §§ 201-1 through 201-9.3;

359. For treble damages under 73 Pa. Stat. Ann. §§ 201-9.2;

360. A finding that by the acts alleged herein, Defendants have created a public nuisance;

361. For an injunction permanently enjoining Defendants from engaging the acts and practices that caused the public nuisance;

362. For an order directing Defendants to abate and pay damages for the public nuisance;

363. For a finding that Defendants were negligent;

364. For a finding that Defendants were grossly negligent;

365. For a finding that Defendants were unjustly enriched;

366. For a finding that Defendants engaged in a civil conspiracy;

367. For compensatory damages in an amount sufficient to fairly and completely compensate for all damages alleged herein;

368. For punitive damages;

369. For restitution or disgorgement of Defendants' unjust enrichment, benefits, and ill-gotten gains, plus interest, acquired as a result of the unlawful or wrongful conduct alleged herein pursuant to common law;

370. For costs, filing fees, pre- and post-judgment interest, and attorney's fees; and

371. For all other and further relief to which this Court finds it is entitled.

WHEREFORE, Plaintiff has been damaged and claims damages of the defendants, jointly and severally, in an amount in excess of the arbitration jurisdiction of the Court of Common Pleas of Allegheny County, Pennsylvania.

JURY TRIAL DEMANDED

Dated this 15th day of May, 2018.

Respectfully submitted,

By:______________________________________
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pro hac vice motions to be submitted

Attorneys for Plaintiff

VERIFICATION

On behalf of the Plaintiff City of Pittsburgh, I hereby verify that the statements set forth in the foregoing *COMPLAINT IN CIVIL ACTION* are true and correct to the best of my knowledge, information and belief. The factual matters set forth therein are based upon information which has been furnished to, or gathered by, the City, or which has been furnished to, or gathered by, the City's counsel as it pertains to this lawsuit.

I understand that this Verification is made subject to the penalties of 18 Pa. C.S.A. § 4904 relating to unsworn fabrication to authorities, which provides that if I knowingly make false averments, I may be subject to criminal penalties.

Date: May 15, 2018

____

Yvonne Hilton, Esquire
Acting City Solicitor
City of Pittsburgh