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THE CITY OF NEWARK, NEW JERSEY, Plaintiff, vs. PURDUE PHARMA L.P., PURDUE PHARMA, INC.; THE PURDUE FREDERICK COMPANY; TEVA PHARMACEUTICALS USA, INC.; CEPHALON, INC.; JOHNSON & JOHNSON; JANSSEN PHARMACEUTICALS, INC.; ORTHO-MCNEIL-JANSSEN PHARMACEUTICALS, INC. n/k/a JANSSEN PHARMACEUTICALS, INC.; JANSSEN PHARMACEUTICA, INC. n/k/a JANSSEN PHARMACEUTICALS, INC.; ENDO HEALTH SOLUTIONS INC.; and ENDO PHARMACEUTICALS, INC.. Defendants.	Superior Court of New Jersey Law Division, Essex County Docket No. _____ Civil Action **Complaint** **Jury Trial Requested**

Appendix XII-B1

CIVIL CASE INFORMATION STATEMENT (CIS)

Use for initial Law Division
Civil Part pleadings (not motions) under *Rule* 4:5-1
Pleading will be rejected for filing, under *Rule* 1:5-6(c), if information above the black bar is not completed or attorney's signature is not affixed

FOR USE BY CLERK'S OFFICE ONLY
PAYMENT TYPE: ☐ CK ☐ CG ☐ CA
CHG/CK NO.
AMOUNT:
OVERPAYMENT:
BATCH NUMBER:

ATTORNEY / PRO SE NAME	TELEPHONE NUMBER	COUNTY OF VENUE
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FIRM NAME (if applicable)	DOCKET NUMBER (when available)
D'Arcy Johnson Day, P.C.	

OFFICE ADDRESS	DOCUMENT TYPE
3120 Fire Rd., Suite 100 Egg Harbor Twp NJ 08234	Complaint
	JURY DEMAND ■ YES ☐ NO

NAME OF PARTY (e.g., John Doe, Plaintiff)	CAPTION
The City of Newark, New Jersey, plaintiffs	The City of Newark, New Jersey v. Purdue Pharma, L.P., et als

CASE TYPE NUMBER (See reverse side for listing)	HURRICANE SANDY RELATED?	
699	☐ YES ■ NO	IS THIS A PROFESSIONAL MALPRACTICE CASE? ☐ YES ■ NO IF YOU HAVE CHECKED "YES," SEE *N.J.S.A.* 2A:53 A -27 AND APPLICABLE CASE LAW REGARDING YOUR OBLIGATION TO FILE AN AFFIDAVIT OF MERIT.

RELATED CASES PENDING?	IF YES, LIST DOCKET NUMBERS
☐ YES ■ NO	

DO YOU ANTICIPATE ADDING ANY PARTIES (arising out of same transaction or occurrence)?	NAME OF DEFENDANT'S PRIMARY INSURANCE COMPANY (if known)
☐ YES ■ NO	☐ NONE ■ UNKNOWN

THE INFORMATION PROVIDED ON THIS FORM CANNOT BE INTRODUCED INTO EVIDENCE.

CASE CHARACTERISTICS FOR PURPOSES OF DETERMINING IF CASE IS APPROPRIATE FOR MEDIATION

DO PARTIES HAVE A CURRENT, PAST OR RECURRENT RELATIONSHIP?	IF YES, IS THAT RELATIONSHIP:
☐ YES ■ NO	☐ EMPLOYER/EMPLOYEE ☐ FRIEND/NEIGHBOR ☐ OTHER (explain) ☐ FAMILIAL ☐ BUSINESS

DOES THE STATUTE GOVERNING THIS CASE PROVIDE FOR PAYMENT OF FEES BY THE LOSING PARTY? ☐ YES ☐ NO

USE THIS SPACE TO ALERT THE COURT TO ANY SPECIAL CASE CHARACTERISTICS THAT MAY WARRANT INDIVIDUAL MANAGEMENT OR ACCELERATED DISPOSITION

DO YOU OR YOUR CLIENT NEED ANY DISABILITY ACCOMMODATIONS?	IF YES, PLEASE IDENTIFY THE REQUESTED ACCOMMODATION
☐ YES ■ NO	
WILL AN INTERPRETER BE NEEDED?	IF YES, FOR WHAT LANGUAGE?
☐ YES ■ NO	

I certify that confidential personal identifiers have been redacted from documents now submitted to the court, and will be redacted from all documents submitted in the future in accordance with *Rule* 1:38-7(b).

ATTORNEY SIGNATURE:

Side 2

CIVIL CASE INFORMATION STATEMENT
(CIS)

Use for initial pleadings (not motions) under *Rule* 4:5-1

CASE TYPES (Choose one and enter number of case type in appropriate space on the reverse side.)

Track I - 150 days' discovery

151 NAME CHANGE
175 FORFEITURE
302 TENANCY
399 REAL PROPERTY (other than Tenancy, Contract, Condemnation, Complex Commercial or Construction)
502 BOOK ACCOUNT (debt collection matters only)
505 OTHER INSURANCE CLAIM (including declaratory judgment actions)
506 PIP COVERAGE
510 UM or UIM CLAIM (coverage issues only)
511 ACTION ON NEGOTIABLE INSTRUMENT
512 LEMON LAW
801 SUMMARY ACTION
802 OPEN PUBLIC RECORDS ACT (summary action)
999 OTHER (briefly describe nature of action)

Track II - 300 days' discovery

305 CONSTRUCTION
509 EMPLOYMENT (other than CEPA or LAD)
599 CONTRACT/COMMERCIAL TRANSACTION
603N AUTO NEGLIGENCE – PERSONAL INJURY (non-verbal threshold)
603Y AUTO NEGLIGENCE – PERSONAL INJURY (verbal threshold)
605 PERSONAL INJURY
610 AUTO NEGLIGENCE – PROPERTY DAMAGE
621 UM or UIM CLAIM (includes bodily injury)
699 TORT – OTHER

Track III - 450 days' discovery

005 CIVIL RIGHTS
301 CONDEMNATION
602 ASSAULT AND BATTERY
604 MEDICAL MALPRACTICE
606 PRODUCT LIABILITY
607 PROFESSIONAL MALPRACTICE
608 TOXIC TORT
609 DEFAMATION
616 WHISTLEBLOWER / CONSCIENTIOUS EMPLOYEE PROTECTION ACT (CEPA) CASES
617 INVERSE CONDEMNATION
618 LAW AGAINST DISCRIMINATION (LAD) CASES

Track IV - Active Case Management by Individual Judge / 450 days' discovery

156 ENVIRONMENTAL/ENVIRONMENTAL COVERAGE LITIGATION
303 MT. LAUREL
508 COMPLEX COMMERCIAL
513 COMPLEX CONSTRUCTION
514 INSURANCE FRAUD
620 FALSE CLAIMS ACT
701 ACTIONS IN LIEU OF PREROGATIVE WRITS

Multicounty Litigation (Track IV)

271 ACCUTANE/ISOTRETINOIN
274 RISPERDAL/SEROQUEL/ZYPREXA
281 BRISTOL-MYERS SQUIBB ENVIRONMENTAL
282 FOSAMAX
285 STRYKER TRIDENT HIP IMPLANTS
286 LEVAQUIN
287 YAZ/YASMIN/OCELLA
289 REGLAN
290 POMPTON LAKES ENVIRONMENTAL LITIGATION
291 PELVIC MESH/GYNECARE
292 PELVIC MESH/BARD
293 DEPUY ASR HIP IMPLANT LITIGATION
295 ALLODERM REGENERATIVE TISSUE MATRIX
296 STRYKER REJUVENATE/ABG II MODULAR HIP STEM COMPONENTS
297 MIRENA CONTRACEPTIVE DEVICE
299 OLMESARTAN MEDOXOMIL MEDICATIONS/BENICAR
300 TALC-BASED BODY POWDERS
601 ASBESTOS
623 PROPECIA
624 STRYKER LFIT CoCr V40 FEMORAL HEADS

If you believe this case requires a track other than that provided above, please indicate the reason on Side 1, in the space under "Case Characteristics.

Please check off each applicable category ☐ **Putative Class Action** ☐ **Title 59**

PRELIMINARY STATEMENT

1. The City of Newark brings this action pursuant to its statutory and common law authority to redress Purdue Pharma, L.P.'s; Purdue Pharma, Inc.'s, the Purdue Frederick Company's, Teva Pharmaceuticals USA's, Cephalon, Inc.'s, Janssen Pharmaceuticals, Inc.'s, Ortho-McNeil-Janssen Pharmaceuticals, Inc.'s, Janssen Pharmaceutical Inc.'s, Endo Health Solutions Inc.'s, and Endo Pharmaceuticals Inc.'s (together, "Defendants") campaign of unfairly and deceptively marketing and falsely advertising opioids, for creating a public nuisance, for fraud, and for unjust enrichment.

2. Defendants Purdue Pharma, L.P., Purdue Pharma Inc., and the Purdue Frederick Company (collectively "Purdue"), Teva Pharmaceuticals USA, Inc. and Cephalon, Inc. (collectively, "Cephalon"), Janssen Pharmaceuticals, Inc. and Ortho-McNeil-Janssen Pharmaceuticals, Inc., Janssen Pharmaceutica Inc. (collectively "Janssen"), Endo Health Solutions Inc., and Endo Pharmaceuticals Inc. (collectively "Endo") manufacture, market, and sell prescription opioid pain medications, including the brand-name drugs OxyContin, Butrans, Hysingla ER, Actiq, Fentora, Opana/Opana ER, Percodan, Percocet, Zydone and Duragesic.

3. Prescription opioids are narcotics. They are derived from and possess properties similar to opium and heroin, and they are regulated as controlled substances. While opioids can dampen the perception of pain, they also can create an addictive, euphoric high. At higher doses, opioids can slow the user's breathing, causing potentially fatal respiratory depression. Most patients receiving more than a few weeks of opioid therapy will experience often 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.

4. Because the medical community recognized the dangers of opioid use, they originally used opioids 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.[1] Consequently, the market for prescription opioids was sharply restricted.

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

6. Between the 1990s and 2011, prescriptions of oxycodone, an active ingredient in opioid drugs manufactured by Defendants and others, more than doubled in the United States. During the same time period, 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

[1] In this Complaint, "chronic pain" means non-cancer pain lasting three months or longer.

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."

7. Defendants' deceptive marketing efforts continued over the next several years, eventually triggering investigations by numerous 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 (not including New Jersey) and the District of Columbia. However, rather than reforming its opioid marketing to comply with the law, Purdue continued to mislead and obfuscate, as did the other Defendants.

8. To this day, Defendants have failed to correct their earlier misrepresentations, and, in many respects, persist in the same types of misconduct.

9. Defendants spent hundreds of millions of dollars on promotional activities and materials that continued to falsely deny or trivialize the risk of addiction and overstated the benefits of opioids. Defendants deceptively marketed opioids to prescribers and consumers through advertising, websites, and in-person sales calls. Defendants also relied upon continuing medical education ("CME") seminars, non-credit education programs, treatment guidelines, and other publications and programs by patient advocacy groups, professional associations, and physicians that were flawed and misleading, but seemed independent and therefore credible.

10. Through these efforts, Defendants were able to persuade doctors and consumers that opioids were not addictive, despite the previous medical consensus and scientific evidence to the contrary. Defendants convinced prescribers and consumers that, even if opioids had some limited potential to be addictive, any risk of addiction could be managed by doctors carefully supervising their use by appropriate patients. Part of Defendants' message was that doctors

should treat the right patients: legitimate patients who took the drugs as directed (orally) to treat their pain, rather than abusers seeking to snort or inject the drugs for recreation. By defining the class of individuals who should not receive opioids as only these abusers, Defendants gave doctors and consumers a false sense of security that they could safely prescribe opioids to patients they trusted.

11. In persuading doctors that nearly all patients could safely receive opioids, Defendants expressly appealed to the doctors' desire to alleviate their patients' suffering. Doctors were receptive to Defendants' message because, after hearing about the scourge of untreated and undertreated pain, they needed a way to safely and effectively relieve that pain. Once doctors grabbed onto Defendants' narrative, the consequence that doctors stopped worrying about signs of addiction or prescribing too high doses followed.

12. In 2007, Purdue and three of its executives pled guilty to federal charges for misleading doctors, patients, and regulators about the risk of addiction and OxyContin's potential to be abused. As described 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. This was how Purdue explained away what doctors had previously believed about opioids: it was not that opioids were not addictive, but rather opioids would not addict patients under a doctor's care.

13. Purdue's guilty plea seemed to have little effect on Purdue's operations and marketing, or that of other Defendants. In the decade that followed, Defendants created and sustained a multi-billion dollar pain franchise through the same pattern of deceptive marketing. Specifically:

a. Defendants continued to tell doctors and consumers that patients receiving opioid prescriptions for pain generally would not become addicted, and

that doctors could use screening tools to exclude patients who might.

b. Defendants continued to tell doctors and consumers that patients who did appear addicted were not; they were instead "pseudoaddicted" and needed more opioids.

c. Defendants continued to tell doctors and consumers 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.

d. Defendants continued to tell doctors and consumers that opioids could be taken in higher and higher doses without disclosing the ensuing risk to the patient.

e. Defendant Purdue Pharma continued to tell doctors and consumers that OxyContin provided 12 hours of relief when Purdue knew that, for many patients, it did not.

14. Defendants also developed new deceptive marketing practices in response to increasing awareness of the problems with opioids. Rather than admit responsibility, Defendants simply blamed abuse and addiction on people snorting or injecting opioids.

15. In 2010, Purdue obtained approval for an "abuse-deterrent" formulation ("ADF") of OxyContin but deceptively marketed it to doctors and consumers, claiming:

a. Purdue's ADF opioids could not be crushed or snorted, which is false.

b. Purdue's ADF opioids reduced opioid abuse and diversion, which is false. Purdue failed to tell doctors and consumers that its ADF opioids had no impact on oral abuse.

c. Purdue's ADF opioids were safer than other opioids, which is false.

16. Along with the launch of reformulated OxyContin, Purdue also launched a new campaign—capitalizing upon growing concern about the rising tide of opioid addiction, overdose, and death—falsely promoting the effectiveness of its abuse-deterrent opioids in preventing abuse. Like pseudoaddiction, this marketing was intended to, and did, reassure prescribers and consumers who became concerned about addiction that they not only could continue to prescribe and take opioids, but in fact needed to switch to Purdue's opioids because

they were safer.

17. Purdue knew, and evidence showed, that Purdue's reformulated OxyContin, and its later-released Hysingla, which it also promoted as abuse-deterrent could be easily defeated, did not affect oral use, which is the most common means of abuse, and increased harmful outcomes. In 2012, Purdue filed a Citizen Petition[2] seeking a ruling from the FDA that Purdue's removal of the original OxyContin was for safety reasons and generic products approved as bioequivalent to the older formulation should be removed from the market unless they could demonstrate similar tamper resistance. This effort was successful and allowed Purdue to defeat generic competition for the drug just one day before Purdue faced loss of patent protection. Yet, there were no long-term studies to support Purdue's claims, and tellingly, after it successfully removed generic competition, Purdue in 2015 abruptly withdrew a supplemental new drug application related to reformulated OxyContin one day before FDA staff were to release its assessment of the application. A FDA review acknowledged that "unusual means" could result in extraction of the active ingredient for snorting or injection.

18. Similarly, Endo has marketed Opana ER as tamper- or crush-resistant and less prone to misuse and abuse since at least May 21, 2011 even though: (1) the FDA rejected Endo's petition to approve Opana ER as abuse-deterrent in 2012; (2) the FDA warned in a 2013 letter that there was no evidence that Opana ER "would provide a reduction in oral, intranasal or intravenous abuse"; and (3) Endo's own studies, which it failed to disclose, showed that Opana ER could still be ground and chewed. Endo's advertisements for the 2012 reformulation of

[2] *Available at:* http://www.hpm.com/pdf/blog/FDA-2012-P-0760.pdf.

Opana ER falsely claimed that it was designed to be crush resistant, in a way that suggested it was more difficult to abuse. And since 2012, detailers for Endo have informed doctors that Opana ER is harder to abuse.

19. In its 2016 settlement with Endo, the New York Attorney General found statements that Opana ER was "designed to be, or is crush resistant" false and misleading because there was no difference in the ability to extract the narcotic from Opana ER. The New York Attorney General 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.

20. Because Opana ER could be "readily prepared for injection" and was linked to outbreaks of HIV and a serious blood disease, in June 2017, the FDA requested that Endo withdraw Opana ER from the market. Endo has since agreed to stop selling Opana.

21. In the same vein, Purdue and Endo also misrepresented their efforts to rein in the diversion and abuse of opioids, while privately failing to report suspicious prescribing.

22. Defendants' scheme was resoundingly successful. Chronic opioid therapy—the prescribing of opioids long-term to treat chronic pain—has been a commonplace, and often first-line, treatment since at least the mid-2000s. While previously a small minority of opioid sales, today between 80% and 90% of opioids (measured by weight) used are for chronic pain. In 2015, Purdue reaped an estimated $2.4 billion in revenue, virtually all of it from opioids. Since its launch in 1996, OxyContin alone has generated $35 billion in sales.

23. Defendants' deceptive marketing caused prescribing not only of Purdue opioids, but of opioids as a class, to skyrocket. Opioids are now among the most prescribed classes of drugs. In 2015, health care providers wrote enough opioid prescriptions to medicate every

American around the clock for three weeks, and on an average day, more than 650,000 opioid prescriptions are dispensed in the U.S. In 2015, Newark saw more than 1,500 people admitted for opioid (including heroin)-related substance abuse treatment and more than 1,600 people sought treatment for these conditions in 2016.

24. Defendants knew that their representations regarding the risks and benefits of opioids were not supported by and/or were directly contrary to the scientific evidence. Indeed, the U.S. Food and Drug Administration ("FDA") confirmed thefalsity of Defendants' representations in recent public statements (*see* ¶ 63 *infra.*) and the Centers for Disease Control and Prevention ("CDC") exhaustively reviewed the evidence on opioids in its 2016 *Guideline for Prescribing Opioids for Chronic Pain* ("CDC Guideline").

25. Rather than compassionately helping patients, this explosion in opioid use—and Defendants' profits—has come at the expense of chronic pain patients. The CDC concluded in 2016 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."[3]

26. As a direct result of Defendants' dangerously false marketing, the nation is now embroiled in what the CDC called a "public health epidemic" and what the U.S. Surgeon General deemed an "urgent health crisis."[4] The increased volume of opioid prescribing correlates directly to skyrocketing addiction, overdose, and death; black markets for diverted

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[3] Thomas R. Frieden et al., *Reducing the Risks of Relief — The CDC Opioid-Prescribing Guideline*, 374 New Eng. J. Med. 1501-1504 (2016).

[4] CDC, *Examining the Growing Problems of Prescription Drug and Heroin Abuse* (Apr. 29, 2014), http://www.cdc.gov/washington/testimony/2014/t20140429.htm;. Vivek H. Murthy, *Letter from the Surgeon General*, August 2016, available at http://turnthetiderx.org.

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.

27. Every day, 91 people die across the country from an opioid-related overdose and over 1,000 patients are administered emergency treatment for misusing opioids. 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.

28. The outcomes in New Jersey, including Newark, are equally catastrophic—and getting worse. The majority of overdose deaths in Newark in 2017 are attributable to prescription or illicit opioids, and overdoses are a major contributing factor to rising criminal activity in Newark. New Jersey authorities have recognized that the state faces an urgent public health crisis that requires immediate action. Overdoses and addiction have driven crime in the City and first responders are armed with Narcan as a matter of course, at City expense.

29. 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. Sales to patients who doctor-shop (or visit multiple doctors to hide illicit or over-use) constitute approximately only 1% of opioid volume.

30. Defendants' conduct has violated, and continues to violate, the New Jersey Consumer Fraud Act, N.J. Stat. Ann. § 56:8-1 *et seq.* Additionally, Defendants' conduct

constitutes a common law public nuisance, fraud and negligent misrepresentation, and unjust enrichment.

31. 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 deceptive practices.

PARTIES

A. Plaintiff

32. Newark is the largest City in New Jersey and the seat of Essex County. The City provides many services for its residents, including public health, public assistance, and law enforcement services, emergency care, and services for families and children. The City is also self-insured with respect to workers' compensation.

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

B. Defendants

34. Purdue Pharma, L.P. is a limited partnership organized under the laws of Delaware. Purdue Pharma, Inc. is a New Jersey corporation with its principal place of business in Stamford, Connecticut. The Purdue Frederick Company is a Delaware corporation with its principal place of business in Stamford, Connecticut.

35. Purdue manufactures, promotes, sells, and distributes opioids such as OxyContin, MS Contin, Dilaudid and Dilaudid-HP, Butrans, Hysingla ER in the United States and in

Newark.[5] OxyContin is Purdue's best-selling opioid: since 2009, Purdue's annual sales of OxyContin have fluctuated between $2 and $3 billion. Nationwide, OxyContin constitutes roughly 25% of the entire market, by spending, for prescription opioids.

36. Teva Pharmaceuticals USA, Inc. is a wholly-owned subsidiary of Teva Ltd. and is a Delaware corporation with its principal place of business in Pennsylvania. Teva USA acquired Cephalon in October 2011. Cephalon, Inc. is a Delaware corporation with its principal place of business in Frazer, Pennsylvania. Teva Ltd., Teva USA, and Cephalon, Inc. work together closely to market and sell Cephalon products in the United States. Teva Ltd. conducts all sales and marketing activities for Cephalon in the United States through Teva USA and has done so since its October 2011. Teva Ltd. and Teva USA also sell generic opioids in the United States and Newark, including generic opioids previously sold by Allergan plc, whose generics business Teva Ltd. acquired in August 2016. Cephalon, Inc. manufactures, promotes, sells, and distributes opioids such as Actiq and Fentora in the U.S. and Newark. Actiq and Fentora have been approved by the FDA only for the "management of breakthrough cancer pain in patients 16 years of age and older who are already receiving and who are tolerant to opioid therapy for their underlying persistent cancer pain." In 2008, Cephalon pled guilty to a criminal violation of the Federal Food, Drug and Cosmetic Act for its misleading promotion of Actiq and two other drugs and agreed to pay $425 million.

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[5] Purdue has also obtained approval to market Targiniq ER (oxycodone hydrochloride and naloxone hydrochloride) in 2014, but it has not actively marketed it.

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

38. Janssen manufactures, promotes, sells, and distributes drugs in the U.S. and Newark, 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.

39. Endo Health Solutions Inc. is a Delaware corporation with its principal place of business in Malvern, Pennsylvania. Endo Pharmaceuticals Inc. is a wholly-owned subsidiary of Endo Health Solutions Inc. and is a Delaware corporation with its principal place of business in Malvern, Pennsylvania. (Endo Health Solutions Inc. and Endo Pharmaceuticals Inc. are referred to as "Endo.")

40. Endo develops, markets, and sells prescription drugs, including the opioids Opana/Opana ER, Percodan, Percocet, and Zydone, in the U.S. and Newark. Opioids made up roughly $403 million of Endo's overall revenues of $3 billion in 2012. Opana ER yielded $1.15 billion in revenue from 2010 and 2013, and it accounted for 10% of Endo's total revenue in 2012. Endo also manufactures and sells generic opioids such as oxycodone, oxymorphone, hydromorphone, and hydrocodone products in the U.S. and Newark, by itself and through its subsidiary, Qualitest Pharmaceuticals, Inc.

JURISDICTION AND VENUE

41. Jurisdiction over the subject matter of this action is proper in this Court, which has original general jurisdiction throughout the State in all causes under N.J. Stat. And. Const. Art. 6, § 3, ¶ 2.

42. Defendants are subject to personal jurisdiction in this Court, and venue is proper because the cause of action arose in Essex County and because a party to the action is located in Essex County. *See* N.J. Ct. R. R. 4:3-2(A).

ADDITIONAL ALLEGATIONS COMMON TO ALL COUNTS

43. 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 high dose. For these conditions, the risks of addiction and other side effects outweighed any benefit from the drugs. For the last two decades, Defendants have sought successfully to turn that consensus on its head, primarily by covering up the risk of addiction and overstating the benefits of using opioids long-term.

44. Through marketing that was as pervasive as it was deceptive, Purdue, Endo, Cephalon, and Janssen convinced health care providers and consumers 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.

45. 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. Defendants not only marketed opioids for chronic pain conditions, but targeted primary care physicians (along with nurse practitioners and physician assistants), who were most likely to see patients with chronic pain conditions and least likely to have the training and experience to evaluate both Defendants' marketing and patients' pain conditions.

46. 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. DEFENDANTS FALSELY TRIVIALIZED, MISCHARACTERIZED, AND FAILED TO DISCLOSE THE KNOWN, SERIOUS RISK OF ADDICTION.

47. Defendants relied heavily on their sales representatives to convey their marketing messages and materials to prescribers in targeted, in-person settings. Defendants developed national, company-wide marketing strategies, which, upon information and belief based on this large-scale strategy and uniformity of messaging, were applied throughout New Jersey, including in Newark and the surrounding areas.

48. To ensure that sales representatives delivered the desired messages to prescribers, Purdue, Endo, Cephalon, and Janssen 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, Defendants' sales forces in New Jersey used the same deceptive messages about the risks and benefits of its opioids that the companies employed nationwide.

Minimizing or mischaracterizing the risk of addiction

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

50. Defendants' sales representatives regularly omitted from their sales conversations with prescribers 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.

51. Defendants 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 Defendants, doctors can screen patients to identify those who are likely to become addicted, and therefore could safely prescribe to everyone else. 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; 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, Defendants' sales representatives also failed to disclose to prescribers 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.

52. Promotional materials and other publications disseminated or made available by Defendants in the City have included similar messages minimizing the risk of addiction.

53. In addition to deceptively ascribing signs of addiction to pseudoaddiction, as described in Section B below, Defendants falsely portrayed "true" addiction in its narrowest form. *Providing Relief, Preventing Abuse*, a pamphlet published by Purdue in 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.

54. 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.

55. Purdue also disseminated misleading information about opioids and addiction to consumers and prescribers 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.

56. *A Policymaker's Guide to Understanding Pain & Its Management*, a Purdue-sponsored 2011 APF publication, 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*. It is still available to City prescribers and consumers online.[6]

57. Purdue also maintained a website from 2008 to 2015, *In the Face of Pain*, that marketed directly to consumers and downplayed the risks of chronic opioid therapy. Purdue

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[6] *See* American Pain Foundation., *A Policymaker's Guide to Understanding Pain & Its Management* (2011), http://s3.documentcloud.org/documents/277603/apf-policymakers-guide.pdf.

deactivated this website in October 2015 following an investigation by the New York Attorney General. Although the site 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."[7]

58. *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.[8]

59. 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." This website was still available online and available to consumers after May 21, 2011.

60. Endo distributed a pamphlet to consumers with the Endo logo entitled *Living with Someone with Chronic Pain*, which counseled: "Most health care providers who treat people

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[7] Attorney General of the State of New York, *In the Matter of Purdue Pharma L.P.*, Assurance No.: 15-151 (August 19, 2015).

[8] *Id.*

with pain agree that most people do not develop an addiction problem." A similar statement appeared on the Endo website www.opana.com.

61. 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." This guide is still available online.

62. Janssen currently runs a website, *Prescriberesponsibly.com*, which claims that concerns about opioid addiction are "overestimated."

63. 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 March 2016, the FDA emphasized the "known serious risk[] of . . . addiction"—"even at recommended doses" —of all opioids."[9] That same month, 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

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[9] *FDA announces safety labeling changes and postmarket study requirements for extended-release and long-acting opioid analgesics,* FDA (Sep. 10, 2013); *see also FDA announces enhanced warnings for immediate-release opioid pain medications related to risks of misuse, abuse, addiction, overdose and death,* FDA (Mar. 22, 2016), https://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm491739.htm.

addiction).[10] The CDC also emphasized that "continuing opioid therapy for 3 months substantially increases risk for opioid use disorder."[11]

Overstating the efficacy of screening tools

64. 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.

65. 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 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 falsely reassured doctors and patients that opioid addiction could be attributed to other prescribers who failed to rigorously manage and weed out problem patients.

66. Defendants conveyed these safe prescribing messages through in-person sales calls to doctors. Former Purdue sales representatives claimed, including, upon information and belief, based on their use elsewhere, to prescribers in the City, that doctors could screen out patients at high risk of addiction through urine tests and patient contracts, and that doctors could

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[10] CDC Guideline at 2.

[11] *Id.* at 21.

mitigate risk by prescribing only to trusted patients.[12]

67. 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.

68. 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 City prescribers.

69. For example, Purdue sponsored a 2011 CME program titled *Managing Patient's 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."

70. 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

[12] Allegations made upon information and belief in subsequent paragraphs of this Complaint are likewise based on Defendants' use of nationwide sales practices and evidence that statements or omissions were made, or practices used, elsewhere.

opioids.

71. 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, the City, attended these conferences.

72. 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.

73. 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.

74. The CDC Guideline confirms the falsity of Defendants' claims about the utility of patient screening and management strategies in managing addiction risk. The 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."[13]

B. DEFENDANTS FALSELY DESCRIBED ADDICTION AS PSEUDOADDICTION, AND DANGEROUSLY ENCOURAGED DOCTORS TO RESPOND BY PRESCRIBING MORE OPIOIDS.

75. Defendants deceptively advised doctors to ignore signs of addiction as the product of an unfounded condition it called pseudoaddiction. Pseudoaddiction was a concept invented to convey the idea 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 by adding fuel.

76. Purdue, through its unbranded imprint *Partners Against Pain*,[14] promoted pseudoaddiction through at least 2013 on its website.

77. The Federation of State Medical Boards ("FSMB"), a trade organization representing New Jersey's state medical board as well as others, finances opioid- and pain-

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[13] CDC Guideline at 28 (emphasis added).

[14] *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."

specific programs through grants from Purdue and other pharmaceutical manufacturers. 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."

78. *Responsible Opioid Prescribing* was sponsored by Purdue and other opioid manufacturers. 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.

79. 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.

80. 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.

81. Dr. Russell Portenoy, an ostensibly independent "key opinion leader" ("KOL") for Endo, Janssen, Cephalon, and Purdue popularized the concept and falsely claimed that pseudoaddiction is substantiated by scientific evidence.

82. The CDC Guideline rejects the concept of pseudoaddiction. The Guideline nowhere recommends that prescribers increase opioid doses if a patient is not experiencing pain relief. To the contrary, the 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,"[15] and that physicians should "reassess[] 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."[16]

C. DEFENDANTS OVERSTATED THE BENEFITS OF CHRONIC OPIOID THERAPY WHILE FAILING TO DISCLOSE THE LACK OF EVIDENCE SUPPORTING LONG-TERM USE

1. Mischaracterizing the benefits of long-term use

83. To convince prescribers and patients that opioids were appropriate to treat chronic pain, Defendants had to persuade them of a significant upside to long-term opioid use. But as the CDC Guideline makes clear, there is "*insufficient evidence* to determine the long-term benefits of opioid therapy for chronic pain."[17] 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)"[18] 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 opioids use longer than 12 weeks."[19] As a result, the CDC recommends that opioids

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[15] CDC Guideline at 13.

[16] *Id.* at 25.

[17] *Id.* at 10.

[18] *Id.* at 9.

[19] Letter from Janet Woodcock, M.D, Dir., Center for Drug Eval. and Research, to

be used not in the first instance and only after prescribers have exhausted alternative treatments.

84. Nevertheless, upon information and belief, Defendants touted the purported benefits of long-term opioid use, while falsely and misleadingly suggesting that these benefits were supported by scientific evidence.

85. Two prominent professional medical membership organizations, the American Pain Society ("APS") and the American Academy of Pain Medicine ("AAPM"), each received substantial funding from Purdue. Upon information and belief, 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*, that 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. Dr. Portenoy, a pain management specialist who received Purdue research grants and was a Purdue consultant, 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.

86. 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 Defendants in securing

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Andrew Kolodny, M.D. (Sept. 10, 2013).

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.

87. 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.

88. 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.

89. The AAPM/APS Guidelines are still available online, were reprinted in the *Journal of Pain*, have been a particularly effective channel of deception, 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.

90. 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]."[20] 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."[21] 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.

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

92. Both Actiq and Fentora are extremely powerful fentanyl-based IR opioids. Neither is approved for or has been shown to be safe or effective for chronic pain. Indeed, the

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[20] Jacques R. Caldwell, *et al.*, , *Treatment of Osteoarthritis Pain with Controlled Release Oxycodone or Fixed Combination Oxycodone Plus Acetaminophen Added to Nonsteroidal Antiinflammatory Drugs: A Double Blind, Randomized, Multicenter, Placebo Controlled Trial*, 266.4 Journal of Rheumatology 862-869 (1999).

[21] *Id.*

FDA expressly prohibited Cephalon from marketing Actiq for anything but cancer pain, and refused to approve Fentora for the treatment of chronic pain because of the potential harm, including the high risk of "serious and life-threatening adverse events" and abuse – which are greatest in non-cancer patients. The FDA also issued a Public Health Advisory in 2007 emphasizing that Fentora should only be used for cancer patients who are opioid-tolerant and should not be used for any other conditions, such as migraines, post-operative pain, or pain due to injury.

93. Despite this, Cephalon 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, Cephalon used CMEs, speaker programs, KOLs, journal supplements, and detailing by its sales representatives to give doctors and consumers the false impression that Actiq and Fentora are safe and effective for treating non-cancer pain.

94. For example: Cephalon paid to have a CME it sponsored, Opioid-Based Management of Persistent and Breakthrough Pain, published in a supplement of Pain Medicine News in 2009. The CME instructed doctors that "clinically, broad classification of pain syndromes as either cancer- or noncancer-related has limited utility" and recommended Actiq and Fentora for patients with chronic pain. The CME is still available online.

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

96. In December 2011, Cephalon widely disseminated a journal supplement entitled "Special Report: An Integrated Risk Evaluation and Mitigation Strategy for Fentanyl Buccal

Tablet (FENTORA) and Oral Transmucosal Fentanyl Citrate (ACTIQ)" to Anesthesiology News, Clinical Oncology News, and Pain Medicine News – three publications that are sent to thousands of anesthesiologists and other medical professionals. The Special Report openly promotes Fentora for "multiple causes of pain" – and not just cancer pain.

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

98. On 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.

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

99. Defendants also claimed—without evidence—that long-term opioid use would help patients resume their lives and jobs. On information and belief, sales representatives promoted the ability of opioids to improve patients' function and quality of life.

100. Defendants' and Defendant-sponsored materials that, upon information and believe, 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. 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.'" This guide was still available after May 21, 2011.

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 Cephalon, Endo and Purdue, taught that relief of pain by opioids, by itself, improved patients' function. The book remains for sale online.

d. Purdue and Cephalon 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.

101. Likewise, Defendants' claims that long-term use of opioids improves patient function and quality of life are unsupported by clinical evidence. 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.

102. As 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."[22] 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'

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[22] Andrea Rubinstein, *Are We Making Pain Patients Worse?*, Sonoma Med. (Fall 2009), http://www.nbcms.org/about-us/sonoma-City-medical-association/magazine/sonoma-medicine-are-we-making-pain-patients-worse?

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.

103. Assessing existing science, the CDC Guideline found that there was "[n]o evidence show[ing] a long-term benefit of opioids in pain and function versus no opioids for chronic pain with outcomes examined at least 1 year later"[23] and advised that "there is no good evidence that opioids improve pain or function with long-term use."[24] The FDA and other federal agencies have made this clear for years.[25] The CDC also noted that the risks of addiction and death "can cause distress and inability to fulfill major role obligations."[26] 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

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[23] CDC Guideline at 15.

[24] *Id.* at 20.

[25] 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), *available at* (rejecting claims that Actavisthe 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 Defendants on the FDA website.

[26] CDC Guideline at 2.

clearer and significant."[27] According to 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]."[28]

Omitting or mischaracterizing adverse effects of opioids

104. In materials Defendants produced, sponsored, or controlled, 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.

105. In addition to failing to disclose in promotional materials the risks of addiction, abuse, overdose, and respiratory depression, Defendants routinely ignored the risks of hyperalgesia, a "known serious risk associated with chronic opioid analgesic therapy,"[29] 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-

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[27] *Id* at 18.

[28] *See* n. 3, *supra*.

[29] *See* n. 19, *supra*.

traumatic stress disorder and anxiety also can accompany chronic pain symptoms).

106. Purdue and Cephalon 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).[30] This publication also warned that risks of NSAIDs increase if "taken for more than a period of months," with no corresponding warning about opioids.

107. Purdue also sponsored APF's *Exit Wounds* (2009), a book aimed at veterans. This book 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.

108. 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 taught that NSAIDs and other drugs, but not opioids, are unsafe at high doses.

109. 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). 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

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

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].)

110. 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 that 22% of patients in opioid trials dropped out before the study began because of the "intolerable effects" of opioids.[31]

111. Again, Defendants' misrepresentations were effective. A study of 7.8 million doctor visits nationwide between 2000 and 2010 found that opioid prescriptions increased from 11.3% to 19.6% of visits while NSAID and acetaminophen prescriptions fell from 38% to 29%. The CDC reports that the quantity of opioids dispensed per capita trebled from 1999 to 2015.

D. DEFENDANTS CONTINUED TO TELL DOCTORS THAT OPIOIDS COULD BE TAKEN IN EVER-HIGHER DOSES WITHOUT DISCLOSING THEIR GREATER RISKS

112. Defendants falsely claimed to prescribers and consumers that opioids could be taken in ever-increasing strengths to obtain pain relief, 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. Defendants needed to generate this comfort level among doctors and patients to ensure patients were maintained on the drugs. Further, as described in more detail in Section

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[31] Meredith Noble M, *et al.*, *Long-term opioid managementTerm Opioid Management for chronic noncancer painChronic Noncancer Pain (Review)*, Cochrane Database of Systematic Reviews, Issue 1, 11 (2010.).

E, Purdue encouraged doctors to prescribe higher doses, rather than prescribe OxyContin more frequently than twice-a-day—despite knowing that OxyContin frequently did not provide 12 hours of relief.

113. Purdue-sponsored publications and CMEs available in New Jersey also misleadingly suggested that higher opioid doses carried no added risk.

114. Through 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.

115. *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. This publication is still available online.[32]

116. 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.

117. 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."

118. 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

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[32] *See* n. 6, *supra.*

when I really need it?" The response is, "The dose can be increased. . . . You won't 'run out' of pain relief."

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

120. 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.[33] 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.

121. 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."[34] That is why the CDC advises

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[33] Kate M. Dunn, *et al.*, *Opioid Prescriptions for Chronic Pain and Overdose: A Cohort Study*, 152(2) Annals of Internal Med. 85-92 (Jan. 19, 2010). Most overdoses were medically serious and 12% were fatal.

[34] CDC Guideline at 19. The 2016 CDC Guideline reinforces earlier findings announced by the FDA. In 2013, the FDA acknowledged "that the available data do suggest a relationship between increasing opioid dose and risk of certain adverse events." For example, the FDA noted

doctors to "avoid increasing doses" above 90 mg MED.[35]

E. PURDUE MISLEADINGLY PROMOTED OXYCONTIN AS SUPPLYING 12 HOURS OF PAIN RELIEF WHEN PURDUE KNEW THAT, FOR MANY PATIENTS, IT DID NOT.

122. 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. While OxyContin's FDA-approved label directs 12 hour dosing, Purdue sought that dosing frequency in order to maintain a competitive advantage over more frequently dosed opioids. Yet Purdue has gone well beyond the label's instructions to take OxyContin every 12 hours by affirmatively claiming, in their general marketing and upon information and belief, to prescribers in the City, that OxyContin lasts for 12 hours, promoting 12-hour dosing as a key advantage of OxyContin, and by failing to disclose that OxyContin fails to provide 12 hours of pain relief to many patients.

123. 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, as discussed in Section D.

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that studies "appear to credibly suggest a positive association between high-dose opioid use and the risk of overdose and/or overdose mortality."

[35] CDC Guideline at 16.

124. 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.

125. 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."[36] 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 Newark.

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;

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[36] Harriet Ryan, "'*'You Want a Description of Hell?' OxyContin's 12-Hour Problem*," Los Angeles Times, May 5, 2016, http://www.latimes.com/projects/oxycontin-part1/.

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.[37]

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."[38]

F. PURDUE AND ENDO OVERSTATED THE EFFICACY OF ABUSE-DETERRENT OPIOID FORMULATIONS

132. By the mid-2000s, widespread addiction to and abuse of OxyContin had emerged in the public eye. Rather than acknowledge that these problems were the inevitable result of widespread prescribing of OxyContin for chronic pain, Purdue claimed that abuse and addiction resulted from diversion by abusers snorting or injecting the drugs. Purdue also brought to market

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[37] 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.

[38] CDC Guideline at 16.

an "abuse-deterrent" formulation of OxyContin but deceptively marketed it to doctors as a solution to the opioid epidemic.

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. Purdue sales representatives regularly used the so-called abuse-deterrent properties of Purdue's opioids as a primary selling point to differentiate those products from their competitors, including, upon information and belief, in the City. Specifically, Purdue detailers:

a. claimed that Purdue's ADF opioids *prevent* tampering and that its AD 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.

135. 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.

136. Purdue knew or should have known that "reformulated OxyContin is not better at

tamper resistance than the original OxyContin"[39] and is still regularly tampered with and abused. Websites and message boards used by drug abusers, such as bluelight.org and reddit, 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 OxyContin to be snorted or injected.

137. 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.

138. 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 the disadvantages of ADF OxyContin—reflecting the same pattern of tilting scientific research and literature to support the promotion of opioids discussed in Section IV.A.2.

139. The CDC Guideline confirms that "*[n]o* studies" support the notion that "abuse-

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[39] *In re OxyContin*, 1:04-md-01603-SHS, Docket No 613, Oct. 7, 2013 hr'g, Testimony of Dr. Mohan Rao, 1615:7-10.

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 nonoral routes."[40] 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."[41]

140. 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."[42] 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.

141. 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

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[40] CDC Guideline at 22. (emphasis added).

[41] Matthew Perrone, *Drugmakers Push Profitable, but Unproven, Opioid Solution*, Assoc. Press (Jan. 2, 2017), http://www.detroitnews.com/story/news/nation/2017/01/02/painkillers-drugmakers-addictive/96095558.

[42] Meeting Notice, Joint Meeting of the Drug Safety and Risk Management Advisory Committee and the Anesthetic and Analgesic Drug Products Advisory Committee; Notice of Meeting, May 25, 2015, 80 FR 30686.

evidence does not show that Purdue's ADF opioids are being abused in large numbers.

142. Generic versions of OxyContin, which became available in February 2011, threatened 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. As a result, Purdue extended its branded exclusivity for OxyContin until the patent protection on the abuse-deterrent coating expires.

143. Purdue's false and misleading marketing of the benefits of its ADF opioids preserved and expanded its sales by persuading doctors to write prescriptions for ADF opioids in the mistaken belief that they were safer. It also allowed prescribers to discount evidence of opioid addiction and abuse and attribute it to other, less safe opioids—*i.e.*, it allowed them to believe that while patients might abuse, become addicted to, or die from other, non-ADF opioids, Purdue's opioids did not carry that risk.

144. Endo has marketed Opana ER as tamper- or crush-resistant and less prone to misuse and abuse since at least May 21, 2011 even though: (1) the FDA rejected Endo's petition to approve Opana ER as abuse-deterrent in 2012; (2) the FDA warned in a 2013 letter that there was no evidence that Opana ER "would provide a reduction in oral, intranasal or intravenous abuse"; and (3) Endo's own studies, which it failed to disclose, showed that Opana ER could still be ground and chewed. Endo's advertisements for the 2012 reformulation of Opana ER falsely claimed that it was designed to be crush resistant, in a way that suggested it was more difficult to abuse. And since 2012, detailers for Endo have informed doctors, including, upon information and belief, doctors in the City, that Opana ER is harder to abuse. A consumer survey further

confirms several prescribers in the northeastern United States confirming that Endo sales representatives promoted Opana ER as "crush resistant."

145. 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. PURDUE AND ENDO ALSO ENGAGED IN OTHER UNLAWFUL, DECEPTIVE, AND UNFAIR CONDUCT BY FAILING TO REPORT SUSPICIOUS PRESCRIBING

146. Purdue deceptively and unfairly failed to report to New Jersey 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."[43]

147. As described in Section IV.A.1, 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

[43] Purdue, *Setting The Record Straight On OxyContin's FDA-Approved Label*, May 5, 2016, http://www.purduepharma.com/news-media/get-the-facts/setting-the-record-straight-on-oxycontins-fda-approved-label/; Purdue, *Setting The Record Straight On Our Anti-Diversion Programs*, July 11, 2016, http://www.purduepharma.com/news-media/get-the-facts/setting-the-record-straight-on-our-anti-diversion-programs/.

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.

148. 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.

149. 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 . . . ."[44] 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."[45] 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."[46]

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[44] Purdue website, *Opioids With Abuse-Deterrent Properties*, http://www.purduepharma.com/healthcare-professionals/responsible-use-of-opioids/opioids-with-abuse-deterrent-properties/.

[45] Purdue website, *Opioids Corporate Responsibility*, http://www.purduepharma.com/news-media/opioids-corporate-responsibility/.

[46] Purdue, *Setting The Record Straight On Our Anti-Diversion Programs*, July 11, 2016, http://www.purduepharma.com/news-media/get-the-facts/setting-the-record-straight-on-our-anti-diversion-programs/. Contrary to its public statements, Purdue seems to have worked behind the

150. 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. It aims to distance Purdue from its past conduct in deceptively marketing opioids, which gave rise to its 2007 criminal plea, and make its current marketing seem more trustworthy and truthful. In fact, Purdue has consistently failed to report suspicious prescribing it observed to authorities.

151. Purdue can track distribution and prescriptions of its opioids down to the retail and prescriber level. It has detailed data on opioid prescribing and sales and, through its extensive network of sales representatives, can observe signs of diversion.

152. Purdue identified those doctors – *internally*. Since at least 2002, Purdue 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 no longer were detailed, and sales representatives received no compensation tied to these providers' prescriptions.

153. Yet, Purdue failed to cut off these providers' opioid supply at the pharmacy

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scenes to push back against law enforcement.

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.

154. The same was true of prescribers. 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.

155. The NY AG 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.[47] Upon information and belief, similar practices occurred throughout New Jersey, including in Newark.

156. The NY AG has 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

[47] Attorney General of the State of New York, In the Matter of Purdue Pharma L.P., Assurance No.: 15-151, Assurance of Discontinuance Under Executive Law Section 63, Subdivision 15 at 5.

providers testified that they did not know about any policy or duty to report problematic conduct. The NY AG 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 scripts for Opana ER (although the subsequent criminal charges at issue did not involve Opana ER). Upon information and belief, Endo engaged in similar practices throughout New Jersey, including in Newark.

H. BY INCREASING OPIOID PRESCRIPTIONS AND USE, DEFENDANTS' DECEPTIVE MARKETING SCHEME FUELED THE OPIOID EPIDEMIC AND SIGNIFICANTLY HARMED NEWARK AND ITS CITIZENS

157. Defendants' misrepresentations prompted health care providers 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, Defendants have both benefited from and extended their prior misrepresentations, sustaining and expanding a market for their opioids.

158. Defendants' deceptive marketing substantially contributed to an explosion in the use of opioids. 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.

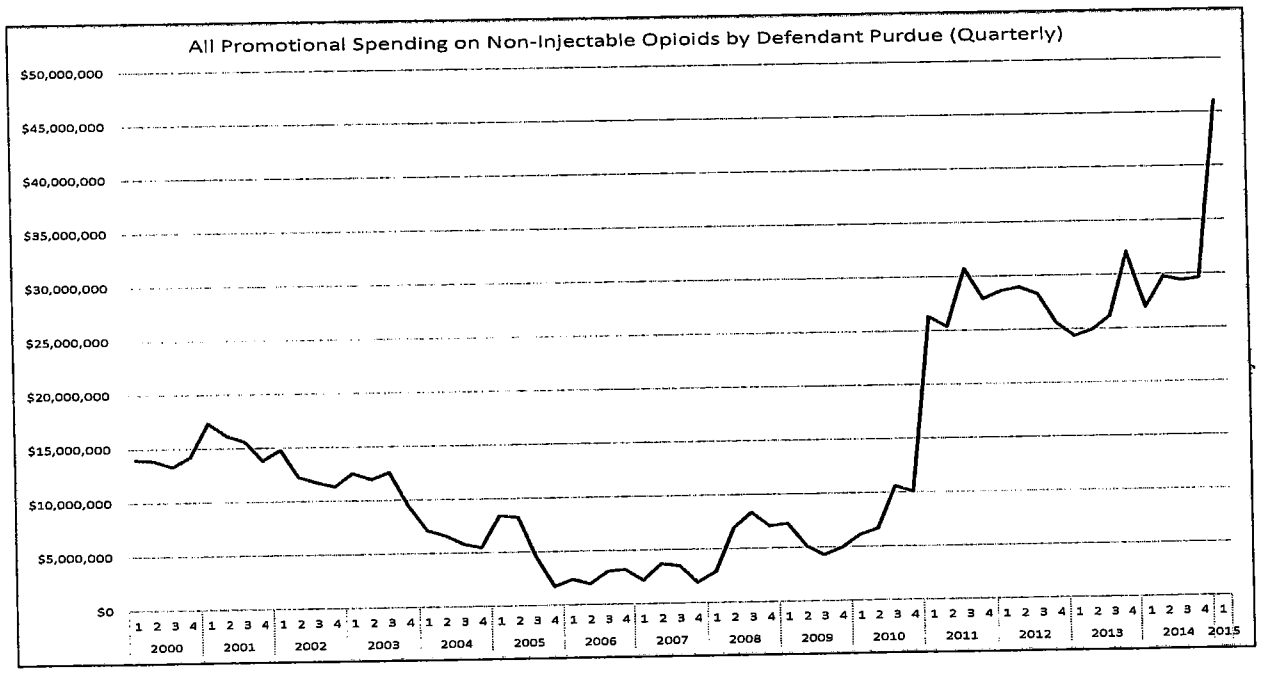
159. Both historically and currently, Purdue accounts for the lion's share of sales of brand name opioids. In 2013, there were 6 million prescriptions of OxyContin, resulting in $2.6

billion in sales—giving Purdue 44% of market value for ER/LA opioids, and 24% of the overall market (which includes widely prescribed generics). No other branded drug accounts for more than 3% of the ER/LA prescriptions annually.[48]

160. Overall sales of opioids in New Jersey have skyrocketed, and Newark is no exception.

161. The increase in opioid prescribing corresponds with Defendants' marketing push. As shown in the chart below, according to data obtained from a marketing research company, Purdue spent roughly $15 million per quarter in 2000. Its 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.

162. The largest component of this spending was attributable to sales representative



visits to individual prescribers, with total detailing expenditures rising from roughly $45 million annually in 2000 to more than $108 million in 2014.

163. Purdue devotes these resources to detailing—notwithstanding increasing efforts of hospitals and physician practice groups to restrict access—because it knows the effectiveness of in-person marketing. The effects of sales calls on prescribing behavior are well-documented in the literature, including in a 2009 study correlating the nearly 10-fold increase in OxyContin prescriptions between 1997 and 2002 to Purdue's doubling of its sales force and trebling of sales calls.

164. Not only Purdue, but also Cephalon, Endo and Janssen, devoted and continue to devote massive resources to direct sales contacts with doctors. In 2014 alone, Defendants spent $166 million on detailing branded opioids to doctors. This amount is twice as much as Defendants spent on detailing in 2000. The amount includes $108 million spent by Purdue, $34 million by Janssen, $13 million by Cephalon, and $10 million by Endo. Purdue, Janssen, and Cephalon made visits to doctors in Newark at which they promoted their opioids. Upon information and belief, Endo also detailed doctors in Newark and promoted its opioids during those visits.

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

166. Through third parties, Defendants also continue to obfuscate the manifest link between detailing and access to opioids. For example, the Purdue-funded Center for Lawful Access and Abuse Deterrence maintains a fact sheet on its website labeling as "myth" the notion that "[i]ncreased access to controlled substances is directly related to . . . aggressive marketing tactics to prescribers by pharmaceutical sales representatives."

167. The vast market for opioids is sustained today not only by Defendants' ongoing marketing, but also by their past, deception-fueled success in establishing opioids as a first-line treatment for chronic pain—through patients who believe they will not become addicted, addicts who demand more drugs, and health care providers who refill opioid prescriptions that maintain dependence and addiction in the belief they are doing the best for their patients or have no other option but to prescribe more opioids. Defendants' marketing of opioids as the answer to pain reinforces the psychological incentives for doctors to make their patients feel better—if they provide opioids, the patient is appeased; if they do not, they face a patient who feels underserved and may, with Defendants' encouragement, seek another doctor who will.

168. 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."[49]

169. 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 . . . .

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[49] "America's Addiction to Opioids: Heroin and Prescription Drug Abuse," *Senate Caucus on Int'l Narcotics Control*, hr'g, Testimony of Dr. Nora Volkow (May 14, 2014) http://www.drugcaucus.senate.gov/sites/default/files/Volkow%20Testimony.pdf.

[m]any of [whom] were even taught—incorrectly—that opioids are not addictive when prescribed for legitimate pain."[50]

170. 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,"[51] with particularly compelling data for extended release oxycodone—*i.e.*, OxyContin.

171. 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."[52]

172. 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. At least 1,901 people are reported to have died from opioid overdoses in New Jersey last year. Deaths involving heroin have more than doubled, and fentanyl-related deaths have risen 2,000%, since 2013.

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[50] *See* n.4, *supra*.

[51] Theodore J Cicero *et al.*, *Relationship Between Therapeutic Use and Abuse* of *Opioid Analgesics in Rural, Suburban, and Urban* Locations in the United States, 16.8 Pharmacoepidemiology and Drug Safety, 827-40 (2007).

[52] CDC, January 1, 2016 Morbidity and Mortality Weekly Report; Rudd, Rose A., et al. "Increases in drug and opioid overdose deaths—United States, 2000–2014." American Journal of Transplantation 16.4 (2016): 1323-1327.

173. Purdue's 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.

174. Overdose deaths are only one consequence. Opioid addiction and misuse also result in an increase in emergency room visits, emergency responses, and emergency medical technicians' administration of naloxone—the antidote to opioid overdose. Naloxone has been used more than 18,000 times in New Jersey since 2014.

175. 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.

176. There are also 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.

177. The deceptive marketing and overprescribing of opioids also had a significant detrimental impact on children. The overprescribing of opioids for chronic pain has given young children access to opioids, nearly all of which were prescribed for adults in their household. 11.8% of New Jersey high school students in 2013 reported having taken prescription drugs such as OxyContin, Percocet, Vicodin, codeine, Adderall, Ritalin, or Xanax at least once.

178. 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. In New Jersey, the incidence of NAS more than doubled between 2006 and 2013, from roughly 2.5 infants per 1,000 hospital births to 5.2 per 1,000, which would amount to 532 infants in 2013.

179. Children are also injured by the dislocation caused by opioid abuse and addiction.

180. Opioids now outpace other sources of addiction in demand for substance abuse

treatment. In Essex County, where roughly half of all admissions to substance abuse treatment centers occur in Newark, heroin and other opiates represent 49% of all admission, almost equaling the number of admissions for alcohol, cocaine, marijuana, and all other drugs combined.

181. 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.

182. 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 got them through friends or relatives, not from drug dealers or the internet. Often, patients on prescription opioids fail pill checks or other strategies recommended to monitor addiction, are discharged by their doctors, and then turn to heroin as an alternative.

183. Because heroin is cheaper than prescription painkillers, many prescription opioid addicts migrate to heroin. Roughly 80% of heroin users previously used prescription opioids. 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 New Jersey communities.

184. The City has incurred substantial expense to address the opioid epidemic created by Defendants' misconduct and to reimburse prescriptions paid for through its self-insured workers' compensation insurance.

I. ALTHOUGH DEFENDANTS KNEW THAT THEIR MARKETING OF OPIOIDS WAS FALSE AND MISLEADING, THEY FRAUDULENTLY CONCEALED THEIR MISCONDUCT

185. Defendants made, 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 Defendants of this, and likewise, Purdue and Cephalon paid hundreds of millions of dollars to address similar misconduct that occurred before 2008. 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 Defendants' misrepresentations.

186. Notwithstanding this knowledge, at all times relevant to this Complaint, Defendants took steps to avoid detection of and to fraudulently conceal their deceptive marketing and unlawful, unfair, and fraudulent conduct. 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. Purdue, Endo, Cephalon, and Janssen purposefully hid behind the assumed credibility of these sources and relied on them to establish the accuracy and integrity of Defendants' false and misleading messages about the risks and benefits of long-term opioid use for chronic pain. Purdue, Endo, Cephalon, and Janssen 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 it cited and offered them as evidence for propositions the studies did not support.

187. Purdue 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 Defendants' fraud and could not have acquired such knowledge earlier through the exercise of reasonable diligence.

CAUSES OF ACTION

COUNT I
N.J. Consumer Fraud Act – N.J. Stat. Ann. § 56:8-1 *et seq.*
(Against All Defendants)

188. Plaintiff incorporates the allegations within all prior paragraphs within this Complaint as if they were fully set forth herein.

189. Defendants violated New Jersey's Consumer Fraud Act, N.J. Stat. Ann. § 56:8-1 *et seq.*, because they engaged in unconscionable commercial practices, deception, fraud, false pretense, false promise, misrepresentation, or the knowing concealment, suppression, or omission of a material fact or facts in connection with the sale or advertisement of merchandise.

190. 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; and in falsely portraying their efforts or commitment to rein in the diversion and abuse of opioids, including in Newark, Defendants have engaged in misrepresentations and knowing omissions of material fact.

191. Specifically, misrepresentations and false pretenses 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 OxyContin provides a full 12 hours of pain relief; and

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

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

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

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

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

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

e. Defendants' claims regarding the benefits of chronic opioid therapy

lacked scientific support or were contrary to the scientific evidence;

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

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

h. Purdue and Endo failed to report suspicious prescribers.

193. Defendants' statements about the use of opioids to treat chronic pain were not supported by or were contrary to the scientific evidence, as confirmed by the CDC and FDA.

194. 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 City prescribers and consumers when taken in the context of the surrounding circumstances.

195. Defendants' acts and practices regarding prescribers and consumers as alleged in this Complaint are unconscionable commercial practices and are immoral, unethical, and offensive to established public policy, including:

- The policy, reflected in the City's and the State of New Jersey's efforts in this regard, to promote mental health and prevent substance abuse, and specifically, to curb the opioid epidemic in Newark;
- The policy reflected in N.J. Stat. Ann. § 24:6J-6, of supporting local opioid overdose prevention and response projects,
- The policy, reflected by the New Jersey Division of Consumer Affairs' guidelines' that patients be informed about opioids' side effects and drug interactions, receive the lowest dose and smallest quantity of opioids, that the CDC Guideline recommending non-opioid approaches such as physical therapy, be followed.
- The policy, reflected in New Jersey Administrative Code Title 13, Chpt. 45H and the creation of a Suspicious Activity Report ("SAR") portal to facilitate reports,of reporting suspicious orders to authorities;

196. Defendants' acts and practices as alleged constituted unfair competition. At all times relevant to this Complaint, Purdue promoted OxyContin as providing 12 hours of pain relief, and promoted abuse-deterrent formulations of its opioids as more difficult to abuse and less addictive, as means of maintaining a competitive advantage against other opioid pharmaceuticals. At all times relevant to this Complaint, Defendants promoted opioids as superior to competing products, such as NSAIDs, and exaggerated the risks of NSAIDs while ignoring risks of adverse effects of opioids.

197. The City is part of the broad class of persons that may avail themselves of a remedy under N.J. § 56:8-19.

198. The City has been injured as a direct and proximate result of Defendants' violations of the Consumer Fraud Act as alleged in this Complaint.

199. The City has suffered ascertainable loss of money or property as a result of Defendants acts and practices alleged in this Complaint.

200. Defendants are liable for three times the City's actual damages and reasonable attorneys' fees, filing fees, and reasonable costs of suit.

COUNT II
Public Nuisance
(Against All Defendants)

201. Plaintiff incorporates the allegations within all prior paragraphs within this Complaint as if they were fully set forth herein.

202. A public nuisance is an unreasonable interference with a right common to the general public, such as a condition dangerous to health, offensive to community moral standards, or unlawfully obstructing the public in the free use of public property.

203. Defendants' conduct significantly interfered, and continues to significantly interfere, with the public health and safety, the public peace, and the public comfort. Defendants' had control over their conduct in Newark and that conduct had an adverse effect on the public right. The public nuisance has significantly harmed any considerable number of the State's residents.

204. Defendants knew and should have known that their promotion of opioids was false and misleading and that their deceptive marketing scheme and other unlawful, unfair, and fraudulent actions would create or assist in the creation of a public nuisance.

205. Defendants have created or assisted in the creation of a condition that is injurious to public health, public safety, public peace, public comfort and public convenience, and offends the moral standards of communities throughout the State and significantly harmed any considerable number of the State's residents.

206. 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, and that harm outweighs any offsetting benefit.

207. 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 a considerable number of persons in Newark by their production, promotion, and marketing of opioids for use by residents of Newark.

208. Defendants' actions were, at the very least, a substantial factor in opioids becoming widely available and widely used, in deceiving healthcare professionals and patients about the risks and benefits of opioids for the treatment of chronic pain, and in the public health crisis that followed.

209. Defendants' conduct in creating and maintaining the public nuisance were neither fully regulated nor required by any federal or New Jersey law, and in fact were contrary to public policy and guidance from the FDA and CDC.

210. 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.

211. The City has been, and continues to be, directly and proximately injured by Defendants' actions in creating a public nuisance.

212. Plaintiff suffered special injuries distinguishable from those suffered by the general public.

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

Count III
Fraudulent and Negligent Misrepresentation
(Against All Defendants)

214. Plaintiff incorporates the allegations within all prior paragraphs within this Complaint as if they were fully set forth herein.

215. 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.

216. 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; and in falsely portraying their efforts or commitment to rein in the diversion and abuse of opioids, including in Newark, Defendants have engaged in misrepresentations and knowing omissions of material fact.

217. Specifically, misrepresentations or omissions 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 OxyContin provides a full 12 hours of pain relief; and

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

218. By engaging in the acts and practices alleged herein, Defendants omitted to state material facts that it had a duty to disclose by virtue of Defendants' other representations, including, but not limited to, the following:

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

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

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

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

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

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

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

h. Purdue and Endo failed to report suspicious prescribers.

219. Defendants' statements about the use of opioids to treat chronic pain were not supported by or were contrary to the scientific evidence, as confirmed by the CDC and FDA.

220. 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 City prescribers and consumers when taken in the context of the surrounding circumstances.

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

222. Defendants intended that the City and its residents would rely on their misrepresentations and omissions.

223. The City and its healthcare providers and residents reasonably relied upon Defendants' misrepresentations and omissions.

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

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

COUNT IV
Unjust Enrichment
(Against All Defendants)

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

227. As an expected and intended result of their conscious wrongdoing as set forth in this Complaint, Defendants have profited and benefited from opioid purchases made by the City.

228. In exchange for the opioid purchases, and at the time the City made these payments, the City expected that 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.

229. Defendants have been unjustly enriched at the expense of the City.

PRAYER FOR RELIEF

WHEREFORE, the City requests the following relief:

230. A finding that by the acts alleged herein, Defendants violated the New Jersey Consumer Fraud Act, N.J. Stat. Ann. § 56:8-1 *et seq.*;

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

232. An award of three times the City's actual damages under N.J. Stat. Ann. § 56:8-19;

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

234. For an order directing Purdue to abate and pay damages for the public nuisance;

235. For compensatory and punitive damages for Purdue's fraud and negligent misrepresentation;

236. For restitution or disgorgement of Purdue's 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;

237. For costs, filing fees, interest, and attorney's fees; and

238. For all other relief deemed just by the court.

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