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SUPERIOR COURT OF NEW JERSEY
CHANCERY DIVISION, ESSEX COUNTY
DOCKET NO. ESX-C-_____

CHRISTOPHER S. PORRINO, Attorney General of the State of New Jersey, and SHARON M. JOYCE, Acting Director of the New Jersey Division of Consumer Affairs,

Plaintiffs,

v.

PURDUE PHARMA, L.P.; PURDUE PHARMA INC.; THE PURDUE FREDERICK COMPANY; and XYZ CORPORATIONS 1-20,

Defendants.

Civil Action

**COMPLAINT FOR VIOLATION OF THE NEW JERSEY FALSE CLAIMS ACT, N.J.S.A. 2A:32C-1, ET SEQ., AS WELL AS OTHER CLAIMS**

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Plaintiffs Christopher S. Porrino, Attorney General of the State of New Jersey (the "Attorney General"), and Sharon M. Joyce, Acting Director of the New Jersey Division of Consumer Affairs (the "Director," and together with the Attorney General, "Plaintiffs"), with offices located at 124 Halsey Street, Newark, New Jersey, by way of Complaint state:

## I. PRELIMINARY STATEMENT

1. The State of New Jersey ("New Jersey" or "State") is in the grips of a long-building, now catastrophic public health crisis regarding the use of prescription opioid pain medications. Rampant opioid addiction, and the overdoses that are its consequence, are devastating New Jersey families and communities and straining the State's resources. At the root of this epidemic is the widespread overprescribing of opioids long-term to treat chronic pain conditions. Prescribing opioids for chronic pain is dangerous and, in many cases, improper, but it has become mainstream medical practice due to the fraudulent marketing efforts of pharmaceutical companies seeking an expanded market for their drugs. Chief among these is Purdue, which mounted a long-running—and hugely successful—campaign based on downplaying the addictive potential of opioids and overstating their efficacy at treating chronic pain. The State, through its Attorney General and the Director, brings this suit to hold Purdue accountable for its key role in the opioid epidemic and demand the company's contribution to the expensive solutions, including addiction treatment and prescriber education, that are necessary to abate the crisis.

2. Defendants Purdue Pharma, L.P., Purdue Pharma Inc. and The Purdue Frederick Company (collectively, "Defendants" or "Purdue") manufacture, market, and sell prescription opioid pain medications, including the brand-name drugs OxyContin, Butrans, and Hysingla ER. Although other brand-name opioids are available—along with widely prescribed generics like

oxycodone and hydrocodone—Purdue for 20 years has been the leading force in the prescription opioid market, both nationwide and in New Jersey.

3. Prescription opioids are narcotics. They are derived from and possess properties similar to opium and heroin, which is why they are regulated as controlled substances. Like heroin (which is also considered an opioid), prescription opioids work by binding to receptors on the spinal cord and brain, dampening the perception of pain. Opioids can create a euphoric high, which makes them addictive and, at higher doses, they cause respiratory depression that can be fatal. Most patients receiving more than a few weeks of opioid therapy will experience withdrawal symptoms—including severe anxiety, nausea, headaches, tremors, delirium, and pain—if opioids are delayed or discontinued. Depending on the length of use, these symptoms may persist for months, or even years, after a complete withdrawal from opioids. Finally, patients who use opioids continuously grow tolerant to the drugs' analgesic effects, requiring progressively higher doses to obtain the same levels of pain relief, and increasing the risks of withdrawal, addiction, and overdose.

4. Historically, these risks were well-recognized. Before the 1990s, opioids typically were used only to treat short-term acute pain (e.g., trauma and post-surgical pain) or for palliative (end-of-life) care because they were considered too addictive and debilitating for long-term use. This prevailing medical and popular understanding operated as a constraint on the market for prescription opioids.

5. As described in Section IV.A, beginning in the late 1990s, Purdue aggressively set out to change the perception of opioids to permit and encourage the use of these drugs not just for acute and palliative care, but also long-term, for chronic conditions like back pain, migraines, and arthritis. Purdue developed and then exploited the contentions that pain was

undertreated and pain treatment should be a higher priority of health care providers, which paved the way for increased prescribing of opioids for chronic pain. (As used in this Complaint, "chronic pain" means non-cancer pain lasting three months or longer.) Purdue then piggybacked on these initiatives to promote opioids generally, and its opioids in particular, as safe, effective, and appropriate for even long-term use to treat routine pain conditions.

6. Purdue spent hundreds of millions of dollars on an array of promotional activities and materials that falsely denied or minimized the risk of addiction and overstated the benefits of opioids. These activities, conducted nationally and in New Jersey since the late 1990s, have included (a) directly marketing Purdue opioids to prescribers through advertising and in-person sales calls; (b) generating a biased and methodologically defective body of scientific research, the purpose of which was to support, rather than objectively investigate, the use of opioids for chronic pain; and (c) indirectly marketing opioids to doctors and consumers through unbranded websites as well as "front groups" and key opinion leaders—Purdue-funded pain advocacy groups, professional societies, and individual physicians whose talks and publications gave the appearance of being independent and therefore credible but were, due to Purdue's influence, flawed and misleading. Purdue's indirect marketing pervaded even the continuing medical education ("CME") courses and treatment guidelines on which providers relied for expert guidance on prescribing opioids.

7. Purdue's massive marketing scheme, which occurred alongside similar, smaller-scale efforts of other opioid manufacturers, proved to be resoundingly successful at shifting the medical consensus regarding the use of opioids. They are now the most prescribed category of drugs, and upwards of 90% of prescription opioids are prescribed for chronic pain conditions.

Nationwide, nearly 62 million Americans received at least one opioid prescription last year. In New Jersey, there were 57 opioid prescriptions for every 100 residents in 2016.

8. In 2007, Purdue and three of its now-former executives pleaded guilty to federal criminal charges for certain deceptive conduct in the sale and marketing of opioids, and paid more than $600 million to resolve government enforcement actions. By then, however, the damage was done. 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.

9. As set forth in Section IV.B, from 2007 to this day, although Purdue has altered the precise messages that prompted its prosecution, the company persists in misrepresenting the risks and benefits of OxyContin and its other opioids. The company has failed to correct, and actually has built upon and continued to profit from, its prior misrepresentations and the platform of misunderstanding they created. Even more troublingly, the company has directed its deceptive marketing in pursuit of new markets: those who have not previously used these powerful drugs (also known as the "opioid naïve") and the elderly.

10. Since 2007, Purdue's marketing, nationwide and in New Jersey, has falsely and misleadingly presented the risks of opioids by (a) continuing to downplay the serious risk of addiction, including by claiming that signs of addiction merely reflect undertreated pain; (b) overstating the effectiveness of screening tools in preventing addiction, giving prescribers unwarranted confidence they can safely prescribe opioids; (c) denying or failing to disclose the dangers of opioids at higher doses, which increase the risk of addiction, overdose, and death; and (d) exaggerating the effectiveness of abuse-deterrent opioid formulations to prevent abuse and addiction. Purdue also has misrepresented the benefits of opioids, falsely claiming that long-term opioid therapy is appropriate and effective—and, in particular, will improve patients'

function and quality of life—without disclosing that there is no good evidence to support these claims. Purdue further has misleadingly promoted OxyContin as providing a full 12 hours of pain relief, when in fact the effect wears off well before 12 hours in many patients—causing patients to experience a "crash" and fueling a cycle of higher-dose prescribing (which Purdue expressly encouraged) and addiction.

11. Purdue has known that its longstanding and ongoing misrepresentations of the risks and benefits of opioids are not supported by or are directly contrary to the scientific evidence. Indeed, the falsity of its representations regarding the risks and functional benefits of opioids has been confirmed by the U.S. Food and Drug Administration (FDA) and the Centers for Disease Control (CDC), including in the CDC's 2016 Guideline for Prescribing Opioids for Chronic Pain ("2016 CDC Guideline"),[1] which exhaustively reviewed and re-affirmed the existing evidence on opioids.

12. As described in Section IV.D, Purdue's deceptive marketing has reaped the company massive revenues but has imposed catastrophic harms on the State and its citizens. By exaggerating the benefits of chronic opioid therapy, and downplaying its very serious risks, Purdue has maintained—and continues to profit handsomely from—the market that it largely created. Purdue is far and away the market leader in sales of branded opioids nationwide, and likewise sells the overwhelming majority of the branded opioids prescribed in New Jersey. According to the State's analysis, Purdue opioids account for 63% of the brand-name opioid prescriptions reimbursed through the State's Medicaid program, employee and retiree health plans, and workers' compensation programs. In 2015, Purdue reaped an estimated $3 billion in revenue, virtually all of it from the sale of opioids.

[1] Deborah Dowell et al., "CDC Guideline for Prescribing Opioids for Chronic Pain—United States, 2016," MMWR Recomm. Rep. 2016; 65 (No. RR-1):1–49 (Mar. 18, 2016).

13. Far from compassionately helping patients, the explosion in opioid prescribing and use—and in Purdue's 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 far outweigh the unproven and transient benefits."[2]

14. As a direct result of Purdue's marketing and its dangerously false message that opioids are not addictive but beneficial for chronic pain, New Jersey and the nation are now swept up in what the CDC has called a "national epidemic."[3] The increased volume of prescribing for chronic pain correlates directly to skyrocketing addiction, overdose, and death; booming secondary markets for diverted prescription opioids as well as heroin, to which many addicts cross over when prescription opioids prove too expensive or unavailable; and the devastating social and economic consequences of each of these problems. In October 2017, the federal government declared the opioid crisis a national public health emergency—the first such declaration under the Public Health Service Act not involving a natural disaster or infectious disease.

15. Sales of prescription opioids in the United States quadrupled between 1999 and 2015 and, correspondingly, opioid-related overdoses (including prescription opioids, heroin, and fentanyl) quadrupled as well. Nationwide, 91 people die each day from an opioid-related overdose, and more than 1,000 patients are treated in emergency departments for misusing prescription opioids. And far more Americans than those who die or are hospitalized are swept into battles with addiction and abuse that they will fight their entire lives. As many as one in

[2] Thomas R. Frieden & Debra Houry, "Reducing the Risks of Relief—The CDC Opioid-Prescribing Guideline," 374 New England Journal of Medicine 1501, 1503 (2016).

[3] CDC, "Examining the Growing Problems of Prescription Drug and Heroin Abuse" (Apr. 29, 2014), http://www.cdc.gov/washington/testimony/2014/t20140429.htm.

four patients who receive prescription opioids long-term for chronic pain in primary care settings struggles with addiction.

16. The opioid epidemic likewise has been catastrophic in New Jersey. In 2015, the last year for which full data are available, 1,173 people died of an opioid overdose—more people than died from guns and car accidents combined. Opioid-related trips to emergency departments in New Jersey doubled between 2005 and 2014, and the State currently meets little more than half of demand for substance abuse treatment—with opioids as the leading reason for treatment admissions. New Jersey also has seen a dramatic surge in neonatal abstinence syndrome—babies born into opioid addiction. And the rise in opioid addiction has led to a growing number of robberies, assaults, and thefts in New Jersey, which, in turn, has required law enforcement to devote increasing resources to this epidemic.

17. The health care costs associated with opioid overprescribing, addiction, and abuse are crushing. The State estimates that its Medicaid vendors have paid in excess of $150 million for opioids since 2008. The State has directly paid another $6 million under its Workers' Compensation Program since 2008 and $136 million under its employee and retiree health plans since 2012. Since 2008, New Jersey consumers—individuals, employers and private insurers—easily have paid hundreds of millions for opioid prescriptions. In addition to these costs, the State and private consumers have paid millions of dollars to treat addiction, overdose, and other injuries associated with opioid overprescribing and misuse.

18. While opioids are diverted through illicit prescribing and sales, it is the routine prescribing of opioids for medical use that fuels the opioid and heroin epidemic. Four out of every five heroin addicts used prescription opioids before crossing over to heroin.

19. Accordingly, New Jersey has undertaken an array of efforts to curb overprescribing and limit its effects. These include:

(a) establishing, and then mandating use of, a Prescription Monitoring Program to help providers determine what other opioids a patient has been prescribed;

(b) making prescription pads more difficult to counterfeit;

(c) publishing best practices for pharmacists for secure handling and dispensing of prescription drugs to reduce diversion;

(d) providing immunity from arrest and prosecution for a use or possession charge when a person seeks medical assistance for overdose;

(e) presenting the 2016 CDC Guideline to the State's Medicaid vendors and referring prescribers to the Guideline;

(f) setting a new, five-day limit on initial prescriptions of opioids for acute pain;

(g) providing funding and authority for health care providers to prescribe, and first responders to administer, overdose antidotes; and

(h) requiring insurers to cover 180 days of addiction treatment.

20. Yet, much more remains to be done. The cost and effort of remediating the opioid crisis require tremendous resources; Plaintiffs have brought this lawsuit in part because the burden of those costs should be shared by Purdue, which has cultivated the demand for opioids and profited from their use and abuse. Even today, at the height of the opioid epidemic, Purdue seeks to obscure its culpability for this crisis, as set forth in Section IV.E. Purdue distances itself from its past misconduct, and portrays itself as a responsible corporate citizen, by depicting the opioid epidemic as principally a problem of illicit drug diversion and abuse, not overprescribing and addiction; falsely promoting the safety of its abuse-deterrent formulations; and touting its efforts to rein in diversion, while failing to meaningfully investigate or report suspicious prescribing.

21. Purdue's deceptive conduct, which fomented and perpetuates the opioid crisis, has violated and continues to violate the New Jersey Consumer Fraud Act, N.J.S.A. 56:8-1 et seq.

("CFA"); the New Jersey False Claims Act, N.J.S.A. 2A:32C-1 et seq. ("FCA"); and the common-law prohibition against creation of a public nuisance.

22. To redress and punish Purdue's conduct, Plaintiffs seek an order requiring Purdue to cease its unlawful promotion of opioids, correct its misrepresentations, and abate the public nuisance its deceptive marketing has created. Plaintiffs further seek a judgment requiring Purdue to pay civil penalties, restitution, and damages; disgorge profits; and reimburse Plaintiffs' fees and costs.

## II. PARTIES

### A. Plaintiffs.

23. The Attorney General is charged with the responsibility of enforcing the CFA and all regulations promulgated thereunder, as well as the FCA. The Director is charged with the responsibility of administering the CFA on behalf of the Attorney General.

24. Under the CFA, the Attorney General may bring an action for injunctive relief, and the Court may order restitution, disgorgement, civil penalties, and fees and costs where, as here, it "appear[s] to the Attorney General that a person has engaged in, is engaging in, or is about to engage in any practice declared to be unlawful by this act." N.J.S.A. 56:8-8, 8-11, 8-13 and 8-19.

25. Under the FCA, the Attorney General may bring a civil action for treble damages, civil penalties, and costs where, as here, a person has caused false or fraudulent claims to be presented to the State or any agent or contractor working for the State. N.J.S.A. 2A-32C-1 through C-8.

26. The State also has standing parens patriae to protect the health and well-being, both physical and economic, of its residents and its municipalities. Opioid use and abuse have affected a substantial segment of the population of New Jersey.

### B. Defendants.

27. Purdue Pharma L.P. is a Delaware limited partnership. Purdue Pharma Inc. is a New York corporation that is the general partner of Purdue Pharma L.P. The Purdue Frederick Company is a New York corporation. Defendants operate as an integrated enterprise with its principal place of business at One Stamford Forum, 201 Tresser Boulevard, Stamford, Connecticut 06901.

28. Purdue manufactures, promotes, sells, and distributes the opioids OxyContin, MS Contin, Dilaudid, Dilaudid HP, Butrans, and Hysingla ER in the United States and New Jersey. OxyContin is Purdue's best-selling opioid. Purdue has generated sales estimated at more than $35 billion since it launched OxyContin in 1995. Purdue's annual revenues reportedly are about $3 billion, still mostly from OxyContin.

29. XYZ Corporations 1 through 20 are fictitious corporations meant to represent any additional business entities that have been involved in the conduct that gives rise to the Complaint but are unknown to Plaintiffs. As these defendants are identified, Plaintiffs shall amend the Complaint to include them.

## III. JURISDICTION AND VENUE

30. The Court has personal jurisdiction over Purdue because it has regularly transacted business in New Jersey, purposely directed business activities into New Jersey, maintained employees and business locations in New Jersey, and engaged in unlawful practices in New Jersey against New Jersey consumers.

31. The Purdue entities are registered to do business in New Jersey with Corporation Service Company as their registered agent located at Princeton South Corporate Center, Suite 160, 100 Charles Ewing Boulevard, Ewing, New Jersey 08628. Since 2001, Purdue Pharma L.P. has maintained a research laboratory in Cranbury, New Jersey, and before 2016, Purdue Pharma

L.P. manufactured pharmaceuticals—including opioids—through its subsidiary P.F. Laboratories, Inc. at a plant in Totowa, New Jersey.

32. Purdue has generated hundreds of millions of dollars of revenue through sales of its opioid pain medications in New Jersey. Purdue also has consistently maintained a sales force in the State. From 2007 to the present, at least [redacted] different Purdue sales representatives and sales managers have had a sales territory in or including New Jersey. In that period, Purdue's New Jersey sales force made more than [redacted] sales visits regarding OxyContin and other Purdue opioids to New Jersey health care providers.

33. As alleged herein, Purdue has deceptively and otherwise unlawfully marketed its opioids in New Jersey, through both conduct within the State and other business activities directed into the State. This conduct includes (a) directly conveying promotional messages to New Jersey health care providers through the sales force, and (b) funding, developing, influencing, adopting, and/or disseminating or making available publications regarding opioids—such as promotional materials, CME courses, and prescribing guidelines—to New Jersey health care providers and consumers.

34. Venue in this Court is proper, pursuant to Rule 4:3-2, because Plaintiffs' claims arose, in part, in Essex County and Purdue conducts business there. Among other things, Purdue has made thousands of sales visits regarding opioids to health care providers in Essex County. In addition, the New Jersey Division of Consumer Affairs has its principal office in Essex County.

## IV. GENERAL ALLEGATIONS COMMON TO ALL COUNTS

### A. From the Late 1990s to 2007, Purdue Engaged in a Campaign of Deception to Create and Sustain a Market for Its Opioids.

35. Beginning in 1996, Purdue presented OxyContin—and later its other opioids—as the solution to the problem of chronic pain. Through marketing that was as pervasive as it was

deceptive, Purdue convinced health care providers both that the risks of long-term opioid use were overblown and that the benefits, in reduced pain and improved function and quality of life, were proven. In fact, as the 2016 CDC Guideline confirmed, based on existing evidence, opioid use presents a "serious risk" of addiction, use for three months or more "substantially increases" that risk, and there never has been "good evidence that opioids improve pain or function with long-term use."[4]

36. From the start, Purdue knew its claims about long-term opioid use lacked scientific support. The FDA-approved labeling of Purdue's ER/LA opioids does not address long-term use (i.e., beyond 12 weeks). In the first OxyContin label and to this day, the only clinical study Purdue has relied upon for OxyContin's efficacy in adults is a two-week study of 133 patients. Other clinical trials on opioids' efficacy do not extend past 12 weeks. Yet, Purdue marketed OxyContin with the understanding and expectation that health care providers—believing the drug to be appropriate for long-term use—would prescribe it to their chronic pain patients over periods of months and even years.

37. The result of Purdue's sweeping marketing campaign 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. Purdue's marketing targeted generalists—primary care physicians, nurse practitioners, and physician assistants—who were both most likely to see patients with chronic pain conditions and least likely to have the training and experience to evaluate Purdue's marketing and patients' pain conditions. Its deceptive marketing created a cadre of doctors who looked for pain and treated it with opioids, and, as a result, an even broader cohort of patients who expected and required opioids. This laid

[4] 2016 CDC Guideline at 2, 20, 25.

the groundwork for today's epidemic of opioid abuse, injury, and death. Purdue skewed the medical and public understanding of opioids to minimize the drugs' risks and exaggerate their benefits—a distortion that Purdue failed to correct, and from which it continues to benefit. This early marketing also provided the base on which Purdue's more recent—and likewise deceptive—marketing was built.

38. To spread its false and misleading messages supporting chronic opioid therapy, Purdue marketed its opioids directly to health care providers and patients nationwide and in New Jersey. It did so principally through its sales force—sales representatives, also known as "detailers," who made in-person sales calls to prescribers in which they misleadingly portrayed opioids as safe, effective, and appropriate for the treatment of chronic pain.

39. This misinformation included, most prominently, deceptive statements about the risk of addiction. For example, as the United States Department of Justice (USDOJ) found in settling criminal charges against Purdue in 2007, sales representatives had "falsely told some health care providers that OxyContin had less euphoric effect, and less abuse potential than short-acting opioids."[5] Among the tactics Purdue used, according to USDOJ, was training sales personnel with false information that OxyContin—the first extended-release or long-acting ("ER/LA") opioid—had fewer "peak and trough" effects than short-acting opioids, also known as immediate release ("IR") opioids. USDOJ also found that Purdue sales representatives had falsely told prescribers that patients could discontinue low doses of OxyContin without experiencing withdrawal symptoms, and that OxyContin was more difficult to intravenously abuse than generic oxycodone.

[5] Press Release, U.S. Attorney's Office, Western District of Virginia, "The Purdue Frederick Company, Inc. and Top Executives Plead Guilty to Misbranding OxyContin, Will Pay Over $600 Million," at 3 (May 10, 2007).

40. In addition to making deceptive claims through its sales force, Purdue also widely advertised OxyContin, including in print ads in medical journals and in videos distributed directly to physicians. These ad campaigns, too, deceptively portrayed both the risks and benefits of chronic opioid therapy. For example, in 1998 and 2000, Purdue distributed to doctors thousands of copies of videos, titled "I Got My Life Back," which made the unsubstantiated claim that opioid addiction occurred in less than 1% of patients. In 2003, the FDA warned Purdue about ads that had run in the Journal of the American Medical Association, expressing concern that they would lead to ill-considered prescribing of OxyContin because the body of the ad text nowhere referred to the "serious, potentially fatal risks associated with OxyContin."[6] And a 2005 ad that ran in pain journals misleadingly implied long-term improvement in patients' pain, function and quality of life, touting OxyContin as an "around-the-clock analgesic . . . for an extended period of time" and featuring a man and a boy fishing under the tagline "There Can Be Life With Relief."

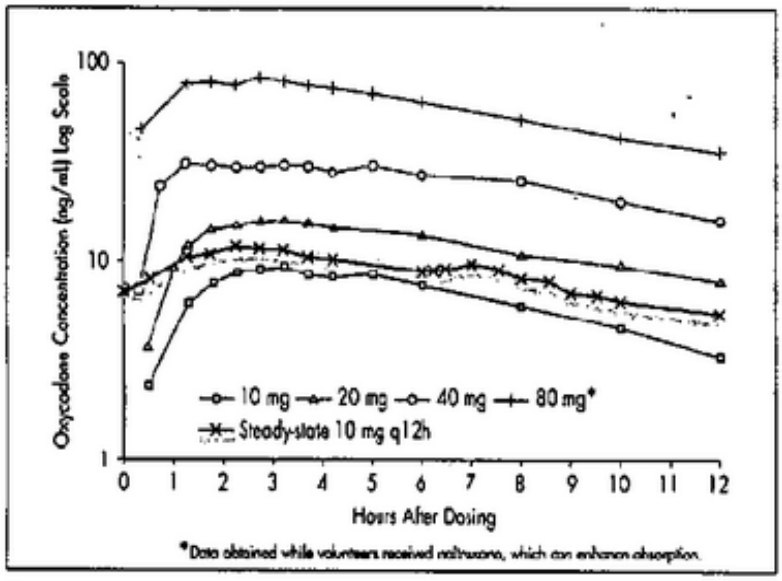
41. Purdue also falsely promoted OxyContin as effective for a full 12 hours and providing "steady state" relief, less likely than other opioids to create a cycle of crash and cravings that fuel addiction. As noted in Section IV.B.3, promoting OxyContin as a 12-hour drug was critical to establish the drug's market advantage over its 4- to 6-hour IR competitors and justify OxyContin's higher price. Purdue's advertising included the claim that OxyContin provides "Consistent Plasma Levels Over 12 Hours." That claim was accompanied by a chart, shown below, that depicted plasma levels on a logarithmic scale:

[6] Letter from Thomas Abrams, Director, FDA Division of Drug Marketing, Advertising and Communication, to Michael Friedman, Executive Vice President and Chief Operating Officer, Purdue Pharma L.P. (Jan. 17, 2003).

**For moderate to severe pain when a continuous, around-the-clock analgesic is needed for an extended period of time**

# Consistent Plasma Levels Over 12 Hours

**Plasma concentrations (ng/mL) over time of various dosage strengths**




- **OxyContin® 80 and 160 mg Tablets FOR USE ONLY IN OPIOID-TOLERANT PATIENTS requiring minimum daily oxycodone equivalent dosages of 160 mg and 320 mg, respectively. These tablet strengths may cause fatal respiratory depression when administered to patients not previously exposed to opioids**

*Steady state achieved within 24 to 36 hours*

42. This presentation obscured the steep decline in OxyContin's efficacy over 12 hours by depicting 10 milligrams in a way that it appeared to be half of 100 milligrams in the table's y-axis, making the absorption rate appear more steady or consistent over 12 hours. In fact, OxyContin works by releasing a greater proportion of oxycodone (about 40%) into the body upon administration followed by a steep decline over those hours.

43. Purdue communicated these deceptions through an extensive marketing campaign, including an expanded sales force compensated on the basis of increased sales; thousands of paid speakers and events for prescribers; pro-opioid websites designed for prescribers; giveaways of CDs, fishing hats, plush toys, and other items to prescribers; and patient coupons. These sales strategies coalesced behind a single message that opioids could be

safely prescribed and used, even long-term, without causing patients to become addicted, overdose, and die.

44. Purdue's claims regarding chronic opioid therapy were not supported by substantial scientific evidence, so the company set out to create the illusion that such support existed. Purdue buttressed its direct promotion of its opioids with an array of marketing approaches that bolstered the same deceptive messages by filtering them through seemingly independent and objective sources. Purdue recruited and paid physician speakers to present talks on opioids to their peers at lunch and dinner events. It funded biased research and sponsored CME courses that misleadingly portrayed the risks and benefits of chronic opioid therapy. It collaborated with professional associations and pain advocacy organizations, such as the American Pain Foundation, to develop and disseminate pro-opioid educational materials and guidelines for prescribing opioids. And it created "unbranded" websites and materials, copyrighted by Purdue but implied to be the work of separate organizations with names like Partners Against Pain, which echoed Purdue's branded marketing.

45. Among these tactics, all of which originated in the late 1990s and early 2000s, three stand out for their lasting influence on opioid prescribing nationwide and in New Jersey: Purdue's capture, for its own ends, of physicians' increased focus on pain treatment; Purdue's efforts to seed the scientific literature on chronic opioid therapy; and Purdue's corrupting influence on authoritative treatment guidelines issued by professional associations.

1. Purdue Used the Medical Community's Increased Focus on Pain as a Springboard for Its Deceptive Marketing.

46. As Purdue marketed OxyContin in the late 1990s, it both capitalized on and co-opted a movement in the medical community to make pain identification and treatment a priority for all patients. Purdue provided financial support to the organizations and people leading the

movement, and, in turn, they promoted the aggressive treatment of chronic pain, especially with opioids.

47. Purdue had already laid the groundwork for this strategy by financially supporting a cadre of researchers who spoke glowingly of the prospects for expanded use of opioids. Chief among these was Dr. Russell Portenoy, once dubbed the "King of Pain." While receiving Purdue funding and serving as a Purdue consultant, he wrote a seminal 1986 paper supporting chronic opioid therapy. Dr. Portenoy concluded—based on a retrospective review of just 38 patients—that "opioid maintenance therapy can be a safe, salutary and more humane alternative" to not treating patients with chronic pain.[7]

48. Beginning in 1995, the American Pain Society ("APS"), of which Dr. Portenoy later would become president, launched a national campaign to make pain a "vital sign"—an indicator doctors should monitor alongside blood pressure, temperature, heartbeat, and breathing. Purdue provided substantial funding to APS both to promote pain awareness generally and, on information and belief, to support the group's "Pain as the 5th Vital Sign" campaign. The Veterans Health Administration adopted this concept in its facilities nationwide in 1999, and "Pain as the 5th Vital Sign" spread from there to the private sector.

49. Coming on the heels of the APS campaign was the work of the Joint Commission on the Accreditation of Healthcare Organizations ("JCAHO"), which accredits hospitals across the United States. In 2001, JCAHO issued pain treatment standards. The JCAHO standards called for assessment of pain in all patients and in each physician-patient interaction, and made accreditation decisions contingent on institutions having policies in place to accomplish these goals.

[7] Russell K. Portenoy & Kathleen M. Foley, "Chronic use of opioid analgesics in non-malignant pain: report of 38 cases," 25(2) Pain 171-86 (May 1986).

50. JCAHO worked closely with Purdue to promote the pain standards. According to an investigation by the U.S. General Accounting Office, JCAHO licensed Purdue—alone—to distribute certain educational videos about how to comply with the new pain management standards. Purdue also sponsored various guides for implementing the JCAHO pain standards, such as "Pain Assessment and Management: An Organizational Approach." This book promoted the use of opioids, claiming that "[s]ome clinicians have inaccurate and exaggerated concerns about addiction, tolerance, respiratory depression, and other opioid side effects . . . despite the fact there is no evidence that addiction is a significant issue when persons are given opioids for pain control." (Emphasis added.) JCAHO distributed the book to hospital officials and physicians nationwide at a series of Purdue-sponsored "leadership summits" on pain management.

51. Both the APS "Pain as the 5th Vital Sign" campaign and the JCAHO pain standards have been widely integrated into medical practice. Although the JCAHO pain standards strictly applied only to pain management in hospitals, they influenced the entire medical profession through hospital-based residency training. Numerous New Jersey health care providers interviewed by the State—including many who were unaware of Purdue's involvement—credit these initiatives for "swinging the pendulum" toward overprescribing of opioids.

2. Purdue Seeded the Science Regarding the Efficacy and Risks of Opioids with Flawed and Biased Research.

52. Rather than rigorously test the safety and efficacy of opioids for long-term use, Purdue created scientific support for its marketing claims by sponsoring studies that were methodologically flawed, biased, and drew inappropriate conclusions from prior evidence. It then published studies with favorable outcomes and suppressed the problematic ones. The result

was a body of literature whose primary purpose was to support the use of opioids for chronic pain, but was passed off as legitimate scientific research. Subsequent studies then cited—and continue to cite—this research to insidious effect: the body of evidence on which physicians rely to prescribe opioids now fully incorporates Purdue's skewed science.

53. For example, Purdue-sponsored studies, and Purdue marketing materials that cited them, regularly made claims that the risk of psychological dependence or addiction is low absent a history of substance abuse. One such study, published in the journal Pain in 2003 and widely referenced since (with nearly 600 citations in Google Scholar),[8] ignored previous Purdue-commissioned research showing addiction rates between 8% and 13%—far higher than Purdue acknowledged was possible in its mainstream marketing.

54. Purdue relegated those earlier studies to less-prominent headache journals, where it knew they would be less widely read.[9] Instead, to support the claim that OxyContin rarely was addictive, the Pain article reached back to a 1980 letter to the editor—not an article, but a letter—in the New England Journal of Medicine.

55. That letter, J. Porter & H. Jick, "Addiction Rare in Patients Treated with Narcotics," 302(2) New England Journal of Medicine 123 (1980) ("Porter-Jick Letter"), is reproduced in full below:

[8] C. Peter N. Watson et al., "Controlled-release oxycodone relieves neuropathic pain: a randomized controlled trial in painful diabetic neuropathy," 105 Pain 71 (2003).

[9] Lawrence Robbins, "Long-Acting Opioids for Severe Chronic Daily Headache," 10(2) Headache Quarterly 135 (1999); Lawrence Robbins, "Works in Progress: Oxycodone CR, a Long-Acting Opioid, for Severe Chronic Daily Headache," 19 Headache Quarterly 305 (1999).

## ADDICTION RARE IN PATIENTS TREATED WITH NARCOTICS

*To the Editor:* Recently, we examined our current files to determine the incidence of narcotic addiction in 39,946 hospitalized medical patients[1] who were monitored consecutively. Although there were 11,882 patients who received at least one narcotic preparation, there were only four cases of reasonably well documented addiction in patients who had no history of addiction. The addiction was considered major in only one instance. The drugs implicated were meperidine in two patients,[2] Percodan in one, and hydromorphone in one. We conclude that despite widespread use of narcotic drugs in hospitals, the development of addiction is rare in medical patients with no history of addiction.

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1. Jick H, Miettinen OS, Shapiro S, Lewis GP, Siskind Y, Slone D. Comprehensive drug surveillance. JAMA. 1970; 213:1455-60.
2. Miller RR, Jick H. Clinical effects of meperidine in hospitalized medical patients. J Clin Pharmacol. 1978; 18:180-8.

56. The Porter-Jick Letter does not reflect any study, but simply describes a review of the charts of hospitalized patients who had received opioids. The Porter-Jick Letter notes that the review found almost no references to signs of addiction, though there is no indication that staff were instructed to assess or document signs of addiction. And because the opioids were administered in a hospital, there was no risk of patients taking more or higher doses than were prescribed.

57. The Porter-Jick Letter has become a mainstay in scientific literature, with more than 1,000 citations in Google Scholar. Purdue, for example, has cited it in support of Purdue's patently false marketing claim that "less than 1%" of opioid patients become addicted, most prominently in its 1998 "I Got My Life Back" video. Yet Purdue failed to disclose both the nature of the citation (a letter, not a study) and any of its serious limitations. Dr. Jick later

complained that drug companies "pushing out new pain drugs" had misused the Letter—citing it to conclude that their opioids were not addictive, even though "that's not in any shape or form what we suggested in our letter."[10] In June 2017, the New England Journal of Medicine, citing a new analysis of the Porter-Jick Letter's citation history, added this editor's note to its online version of the Letter: "For reasons of public health, readers should be aware that this letter has been 'heavily and uncritically cited' as evidence that addiction is rare with opioid therapy."

58. Purdue published other research supporting chronic opioid therapy that was just as flawed as the 2003 Pain article. One such Purdue-sponsored study, which featured two Purdue authors and appeared in the Journal of Rheumatology in 1999, misleadingly suggested that OxyContin was safe and effective as a long-term treatment for osteoarthritis.[11] Patients were given OxyContin only for 30 days, only 106 of the 167 patients continued the study after their appropriate dose was determined, and most who left did so due to ineffective pain control or side effects from the drug. While acknowledging the short-term nature of the trial, the authors still drew the unsupported conclusion 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 longterm."

59. Another Purdue-authored study, published in the Clinical Journal of Pain in 1999, misleadingly implied that OxyContin was safe and effective as a long-term treatment of back

[10] National Public Radio, "Doctor Who Wrote 1980 Letter on Painkillers Regrets That It Fed The Opioid Crisis" (June 16, 2017), http://www.npr.org/sections/healthshots/2017/06/16/533060031/.

[11] 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," 26:4 Journal of Rheumatology 862-868 (1999).

pain.[12] This study, too, had a high dropout rate and, though it concerned a chronic condition, it followed patients on OxyContin only between four and seven days. The study was not set up to consider long-term risks, including the risk of addiction, but blithely concluded that "common opioid side effects can be expected to become less problematic for the patient as therapy continues."

3. Purdue Worked with Professional Associations to Create Treatment Guidelines that Overstated the Benefits and Understated the Risks of Opioids.

60. Treatment guidelines were particularly important to Purdue in securing acceptance for chronic opioid therapy. They are relied upon by doctors, especially general practitioners and family doctors who have no specific training in treating chronic pain. Treatment guidelines not only directly inform doctors' prescribing practices, but also are cited throughout the scientific literature and referenced by third-party payors in determining whether they should cover prescriptions. Purdue financed and collaborated with two groups, in particular, on guidelines that have been, and continue to be, broadly influential in New Jersey and nationwide.

a. AAPM/APS Guidelines

61. The American Academy of Pain Medicine (AAPM) and APS each received substantial funding from Purdue. [redacted]

62. In 1997, AAPM and APS issued a consensus statement, "The Use of Opioids for the Treatment of Chronic Pain," that endorsed using opioids to treat chronic pain and claimed

[12] Martin E. Hale et al., "Efficacy and Safety of Controlled-Release Versus Immediate-Release Oxycodone: Randomized, Double-Blind Evaluation in Patients with Chronic Back Pain," 15(3) Clinical Journal of Pain 179-183 (Sept. 1999).

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 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, though it lingers on the internet elsewhere.

63. AAPM and APS also issued a 2001 set of recommendations, titled "Definitions Related to the Use of Opioids for the Treatment of Pain," that advanced the unsubstantiated concept of "pseudoaddiction." The term, coined by Dr. Haddox in a 1989 journal article, reflects the idea that signs of addiction may actually be the manifestation of undertreated pain and will resolve once the pain is effectively treated—i.e., with more or higher doses of opioids.[13] The 2001 AAPM/APS recommendations claimed "clock-watch[ing]," "drug seeking," and "[e]ven such behaviors as illicit drug use and deception can occur in the patient's efforts to obtain [pain] relief."

64. The 2016 CDC Guideline rejects the concept of pseudoaddiction, explaining that "[p]atients who do not experience clinically meaningful pain relief early in treatment . . . are unlikely to experience pain relief with longer-term use" and that physicians should "reassess[] pain and function within 1 month" to decide whether to "minimize risks of long-term opioid use by discontinuing opioids" because the patient is "not receiving a clear benefit."[14]

65. In 2009, AAPM and APS issued comprehensive opioid prescribing guidelines ("2009 AAPM/APS Guidelines"), drafted by a 21-member panel, that promoted opioids as "safe and effective" for treating chronic pain. The panel made what it termed "strong

[13] David E. Weismann & J. David Haddox, "Opioid Pseudoaddiction—an Iatrogenic Syndrome," 36 Pain 363-366 (1989).

[14] 2016 CDC Guideline at 13, 25.

recommendations" despite "low quality evidence," and concluded that the risk of addiction is manageable for patients, even patients with a prior history of drug abuse.

66. Six of the panel members, including Dr. Portenoy, received financial backing from Purdue, and another eight received funding from other opioid manufacturers. 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, made to the sponsoring organizations and committee members.

67. The 2009 AAPM/APS Guidelines were reprinted in the Journal of Pain, were distributed by Purdue sales representatives to New Jersey prescribers, and have been relied upon by New Jersey prescribers in their practices. The guidelines 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, the guidelines have now been cited nearly 1,700 times in academic literature.

b. FSMB Guidelines

68. The Federation of State Medical Boards ("FSMB") is an association of the various state medical boards in the United States. The state boards that comprise the FSMB membership, including New Jersey's, have the power to license doctors, investigate complaints, and discipline physicians. The FSMB has financed opioid- and pain-specific programs through grants from pharmaceutical manufacturers, including more than $800,000 from Purdue between 2001 and 2008.

69. In 1998, the FSMB developed its Model Guidelines for the Use of Controlled Substances for the Treatment of Pain ("FSMB Guidelines"), which the FSMB acknowledged were produced "in collaboration with" pharmaceutical companies and allied groups such as the

APS.[15] The FSMB Guidelines described opioids as "essential" for treatment of chronic pain, including as a first-line option; failed to mention risks of respiratory depression and overdose; addressed addiction only to define the term as separate from physical dependence; and state that an "inadequate understanding" of addiction can lead to "inadequate pain control." Purdue sales representatives distributed the FSMB Guidelines to health care providers in New Jersey.

70. A 2004 iteration of the FSMB Guidelines and the 2007 book adapted from them, Responsible Opioid Prescribing, repeated the 1998 version's claims. The book also claimed that opioids would improve patients' function and endorsed the dangerous, now-discredited concept of pseudoaddiction, suggesting that signs of addiction may actually reflect undertreated pain that should be addressed with more opioids.

71. Responsible Opioid Prescribing was sponsored by Purdue, among other opioid manufacturers, and Purdue had editorial input into its contents. In particular, Purdue's David Haddox, the man who developed the term "pseudoaddiction," [redacted] pseudoaddiction was presented as an accepted medical concept.

72. Through at least 2015, 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 nationwide through state medical boards and non-profit organizations. The New Jersey Academy of Family Physicians purchased copies of the book and, on information and belief, distributed them to practitioners in the State. New Jersey prescribers interviewed by the State recalled receiving and reviewing the book.

[15] FSMB, "Position of the FSMB in Support of Adoption of Pain Management Guidelines" (1998), https://www.fsmb.org/Media/Default/PDF/FSMB/Advocacy/1998_grpol_Pain_ Management_Guidelines.pdf.

### B. From 2007 to the Present Day, Purdue's Marketing in New Jersey Has Continued to Misrepresent the Risks and Benefits of Opioids.

73. In 2007, Purdue entered into consent decrees with the federal government and numerous states to resolve investigations into its marketing of OxyContin. As reported by USDOJ, those investigations centered on misrepresentations that OxyContin was less addictive and had less abuse potential than IR opioids, and that patients taking OxyContin could discontinue the drug without withdrawal symptoms. Prospectively, the decrees required Purdue more generally to discontinue all deceptive marketing, including any misrepresentations regarding OxyContin's potential for abuse, addiction, or physical dependence, and to provide a fair balance of risk and benefit information as required by FDA regulations. However, the decrees left to Purdue's judgment what steps to take to affirmatively correct past misrepresentations.

74. Rather than correct its misrepresentations and truly reform its conduct, Purdue instead built upon the deceptive messaging that had established chronic opioid therapy as commonplace and reaped Purdue massive revenues. Since that time, and up to the present day, Purdue has both echoed the deceptions for which it was cited in 2007 and made diverse other misrepresentations. Purdue has continued to omit discussion of the serious risks of opioids and lack of evidence supporting long-term opioid use—thereby failing to correct its prior deceptions, to its benefit—and to affirmatively misrepresent the risks and benefits of opioids for the treatment of chronic pain.

75. Purdue has accomplished much of this through its New Jersey sales force, the messages they verbally conveyed to prescribers, and the materials they showed or distributed to prescribers. Since the launch of OxyContin, Purdue has relied heavily on its sales representatives to market its opioids directly to prescribers, and that practice continues. For

example, of the $167 million Purdue spent on promoting opioids nationwide in 2016, $156 million was spent on detailing. By establishing personal relationships with doctors, Purdue's sales representatives are able to disseminate their misrepresentations in targeted, one-on-one settings.

76. At least [redacted] different Purdue sales representatives (excluding supervisors) have operated in New Jersey since 2007. Purdue's goal has been—and remains—that each of those representatives make seven to eight in-person sales calls to prescribers per day. [redacted] Most of these prescribers were visited repeatedly—often monthly or even more frequently. Indeed, in that same period, Purdue sales representatives made in excess of [redacted] unique sales visits in New Jersey—more than [redacted] per year. A West Orange pain specialist, one of the State's top prescribers of OxyContin between 2007 and 2016, alone received more than [redacted] Purdue detailing visits in that period. Purdue assessed sales representatives' performance based on their ability to drive prescribing of the company's opioids; former Purdue detailers in New Jersey reported having sales quotas of 500-700 OxyContin prescriptions per month.

77. Purdue developed sophisticated plans to select prescribers for sales visits based on their prescribing habits. It purchased and closely analyzed prescription sales data that allowed the company to track prescribing of its opioids and those of its competitors. According to former Purdue employees in New Jersey, any prescribing of an opioid—whether Purdue's or a competitor's—could land a prescriber on a detailing target list. As in its earlier marketing, Purdue has targeted generalists—such as primary care physicians—who have less specialized knowledge with which to evaluate Purdue's marketing claims.

78. Purdue employed the same marketing tactics and messages in New Jersey as it did nationwide, using uniform marketing materials and national and regional sales training. Purdue carefully trained its sales representatives to deliver company-approved sales messages. The company exactingly directed and monitored its sales representatives—through detailed action plans, trainings, tests, scripts, role-plays, supervisor tag-alongs, and review of representatives' "call notes" from each visit—to ensure that individual detailers actually delivered the company's desired messages. Purdue likewise required its sales representatives to deploy sales aids reviewed, approved, and supplied by the company.

79. Through its sales force and deceptive promotional materials, Purdue has continued to misrepresent the risks and benefits of its opioids to New Jersey prescribers. Specifically, Purdue has continued, as described below, to (a) minimize and misrepresent the serious risk of addiction; (b) overstate the benefits of chronic opioid therapy, while failing to disclose the lack of evidence supporting long-term use; and (c) misleadingly promote OxyContin as providing 12 hours of pain relief.

1. Purdue Has Falsely Minimized or Failed to Disclose the Known, Serious Risk of Addiction.

80. To convince New Jersey prescribers and patients that opioids are safe, Purdue has continued to deceptively minimize and fail to disclose the risks of long-term opioid use, particularly the risk of addiction. Purdue sales representatives are trained to deflect questions about addiction into discussions of abuse, and to draw technical distinctions between dependence and addiction to allay prescribers' concerns about addiction risks. Purdue's misrepresentations and omissions, which are described below, have reinforced each other to create the dangerously misleading impressions that: (a) Purdue's ER/LA opioids present a reduced risk of addiction, and even patients who seem addicted may simply be physically dependent on the drug or have

undertreated pain that requires more opioids; (b) patients at greatest risk of addiction can be identified, allowing doctors to confidently prescribe opioids to all other patients and even prescribe to high-risk patients, provided they are closely managed; (c) physicians can prescribe steadily higher doses of opioids without added risk; and (d) the abuse-deterrent formulations of Purdue's opioids both prevent abuse and are inherently less addictive. Each of these misrepresentations has been debunked by the FDA and the CDC.

a. Omitting, trivializing, and mischaracterizing addiction risk

81. Purdue's sales representatives have regularly omitted from their sales conversations any discussion of the risk of addiction from long-term use of opioids. These omissions, which are false and misleading in their own right, rendered even seemingly truthful statements about opioids false and misleading, especially in light of Purdue's prior misrepresentations regarding the risk of addiction. In addition, by failing to correct this earlier misinformation, Purdue's representatives let stand the dangerous impression that patients who receive chronic opioid therapy for legitimate pain conditions are unlikely to become addicted.

82. The messages delivered by detailers and heard by prescribers were passed on to patients. Patients in substance abuse treatment whose addiction began with prescriptions for chronic pain often report that they were not warned of the risk they might become addicted. This is confirmed by national research: A 2015 survey of more than 1,000 opioid patients found that 4 out of 10 were not told opioids were potentially addictive.[16]

83. Where they have brought up the topic of addiction, Purdue's sales representatives have emphasized to New Jersey prescribers that Purdue's ER/LA opioids (OxyContin, Butrans,

[16] Hazelden Betty Ford Foundation, "Missed Questions, Missed Opportunities" (Jan. 27, 2016), http://www.hazeldenbettyford.org/about-us/news-and-media/press-release/doctors-missing-questions-that-could-prevent-opioid-addiction.

and Hysingla) provide a slow-onset, stable dose without "peaks and valleys"—encouraging prescribers to infer that these opioids are safer because they do not produce the euphoric high that fosters addiction. In a 2011 sales training document, Purdue acknowledged that the "fewer peaks and valleys" message seen in a review of sales representative call notes was "problematic"—confirming both that the statements were made and that they were false. This misrepresentation is particularly deceptive given that for many patients, OxyContin does not provide an even 12 hours of pain relief and will cause patients to experience a crash (or valley) hours before they are due to take their next pill, as described in Section IV.B.3.

84. Purdue sales representatives also have explained to New Jersey prescribers—including with visual aids—that signs of addiction may actually reflect undertreated pain that should be treated with higher doses. This message reflects the same unsubstantiated and misleading concept of "pseudoaddiction" that Purdue advanced in its earlier marketing. Purdue has consistently used this concept to suggest to prescribers that they should actually prescribe more or higher doses of opioids when presented with patients who exhibit drug-seeking behaviors. Similarly, sales representatives are trained to assuage prescribers' worry about addiction by distinguishing it from opioid dependence, which they describe as a normal, benign consequence of extended opioid use. As described by one former sales manager, an addict is a patient who uses the drug despite harm, but a patient who simply needs the drug to function in normal daily life is dependent.

85. Promotional materials and other publications Purdue has disseminated or made available in New Jersey have included similar, mutually reinforcing messages minimizing the risk of addiction.

86. In 2011, for example, Purdue published a pamphlet for prescribers and law enforcement that misleadingly depicted the signs of addiction. The pamphlet, Providing Relief, Preventing Abuse, shows graphic pictures of the stigmata of injecting or snorting opioids—skin popping, track marks, and perforated nasal septa. In fact, opioid addicts who resort to these extremes are uncommon; the far more typical reality is patients becoming addicted through oral use. These depictions deceptively reassure doctors that, as long as they do not observe those signs of misuse, they need not worry that their patients are abusing or addicted to opioids. The pamphlet also promoted the concept of pseudoaddiction. Purdue sales representatives distributed Providing Relief, Preventing Abuse to New Jersey prescribers.

87. Purdue has relied, in particular, on unbranded marketing—"educational" materials for prescribers that discussed pain or opioids generally, and not particular Purdue products—to disseminate misleading messages about the risk of addiction. These efforts included, most prominently, campaigns under the banners Partners Against Pain and In the Face of Pain.

88. Partners Against Pain is a Purdue marketing imprint consisting of both medical education resources, distributed to prescribers by the sales force, and a now-defunct website that, before Purdue shut it down in 2016, was styled as an "advocacy community" for better pain care. Partners Against Pain 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." Purdue sales representatives have widely shown and disseminated Partners Against Pain

materials to New Jersey prescribers and encouraged prescribers to use the Partners Against Pain website as a resource.

89. Through at least 2013, the Partners Against Pain website relied on and directed users to the 2001 guideline from AAPM and APS, which endorsed the concept of pseudoaddiction and claimed that patients who engage in drug-seeking behaviors may not be addicted but simply have undertreated pain.

90. Purdue sales representatives in New Jersey also distributed a Partners Against Pain document titled "Key Terms in Pain Management," which made similar claims about drug-seeking behaviors. The document claimed that "[p]seudoaddiction can be distinguished from true addiction in that the behaviors resolve when the pain is effectively treated," again suggesting that the solution to the behavior was to prescribe more opioids. Purdue included this document as part of a Partners Against Pain pamphlet, "Clinical Issues in Opioid Prescribing," which the company also made available to prescribers.

91. A Partners Against Pain "Pain Management Kit" that debuted in 2009 likewise advocated the pseudoaddiction concept, referring prescribers to the 2001 AAPM/APS "Definitions Related to the Use of Opioids for the Treatment of Pain." The kit also introduced another resource—a set of drug abuse screening tools, discussed in Section IV.B.1.b—by stating that "[b]ehaviors that are suggestive of drug abuse exist on a continuum, and pain-relief seeking behavior can be mistaken for drug-seeking behavior." A 2010 Purdue pamphlet billed as "A Training Guide for Healthcare Providers" makes the same claim.

92. Purdue also maintained a website for patients, caregivers, and prescribers, In the Face of Pain (www.inthefaceofpain.com), that downplayed the risks of chronic opioid therapy. In the Face of Pain, which Purdue deactivated in October 2015 following an investigation by the

New York Attorney General, was another example of "unbranded" marketing; although it featured the Purdue copyright at the bottom of each page, the site did not refer to Purdue products in particular and cultivated the "impression that it [was] neutral and unbiased."[17]

93. 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. As of 2015, while a document linked from the In the Face of Pain website briefly mentioned opioid abuse, the site itself did not—even once—mention the risk of addiction, a risk so significant that it requires a black box warning on all opioid drug labels. At the same time, the website contained testimonials from several dozen physician "advocates" speaking positively about opioids but failed to disclose that from 2008 to 2013, Purdue paid 11 of these advocates a total of $231,000.

94. Purdue also worked closely with allies, such as the American Pain Foundation (APF), to disseminate misleading, unbranded messages about the risks of opioids.

95. Purdue had a particularly close relationship with APF, which was highly dependent on pharmaceutical company funding and produced numerous publications touting the use of opioids to treat chronic pain. Purdue was APF's [redacted] donor, with donations totaling [redacted] between 1999 and 2012. As early as 2001, Purdue grant letters informed APF that the contributions reflected Purdue's effort to "strategically align our investments in nonprofit organizations that share our business interests," making clear that funding depended on APF continuing to support Purdue's objectives. Purdue also engaged APF as a paid consultant on various initiatives.

[17] In the Matter of Purdue Pharma, No. 15-151, Assurance of Discontinuance (signed Aug. 19, 2015).

96. Among the APF publications Purdue sponsored was Exit Wounds, a 2009 book written as a personal narrative of one veteran recovering from war injuries. Exit Wounds described opioids as the "'gold standard' of pain medications" and minimized the risk of addiction, emphasizing that physical dependence often is mistaken for addiction and claiming that "[l]ong experience with opioids shows that . . . people who are not predisposed to addiction are very unlikely to become addicted to opioid pain medications." With Purdue's financial support, APF promoted and distributed Exit Wounds to veterans throughout the country, including, on information and belief, veterans in New Jersey.

97. Purdue also sponsored APF's A Policymaker's Guide to Understanding Pain & Its Management, a 2011 publication that claimed pain generally had been "undertreated" due to "[m]isconceptions about opioid addiction" and asserted, without basis, that "less than 1 percent of children treated with opioids become addicted." In addition to mischaracterizing the risk of addiction, A Policymaker's Guide perpetuated the misleading concept of pseudoaddiction, stating that "[p]seudo-addiction describes patient behaviors that may occur when pain is undertreated" and that "[p]seudo-addiction can be distinguished from true addiction in that this behavior ceases when pain is effectively treated"—i.e., with more opioids. On information and belief, Purdue distributed or made A Policymaker's Guide available to New Jersey prescribers.

98. Purdue provided substantial funding to, and closely collaborated with, APF in creating A Policymaker's Guide. Purdue provided a grant for its development and distribution and kept abreast of the content of the guide as it was formulated. 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.

99. Purdue's claims regarding addiction are contrary to longstanding scientific evidence, and its failures to disclose the risk of addiction are material given both the magnitude of the risk and the grave consequences of addiction.

100. Studies have shown that at least 8-12%, and as many as 30% or even 40%, of long-term users of opioids experience problems with addiction. In requiring a new black-box warning on the labels of all IR opioids in March 2016, similar to the warning already required for ER/LA opioids, the FDA emphasized the known, "serious risks of misuse, abuse, [and] addiction . . . across opioid products."[18] That same month, after a "systematic review of the best available evidence" by a panel excluding experts with conflicts of interest, the CDC published its guideline for prescribing opioids for chronic pain.[19] The CDC found that "[o]pioid pain medication use presents serious risks, including overdose and opioid use disorder," an alternative diagnostic term for addiction.[20] The CDC also emphasized that "continuing opioid therapy for 3 months substantially increases risk for opioid use disorder."[21]

b. Overstating the efficacy of screening tools

101. Purdue has falsely instructed New Jersey prescribers and patients that addiction risk screening tools, patient contracts, urine drug screens, and similar strategies allow health care providers to reliably identify and safely prescribe opioids to patients, including patients predisposed to addiction.

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[18] FDA, "FDA announces enhanced warnings for immediate-release opioid pain medications related to risks of misuse, abuse, addiction, overdose and death" (Mar. 22, 2016), http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm491739.htm.

[19] 2016 CDC Guideline at 2.

[20] Id.

[21] Id. at 25.

102. Such misrepresentations make health care providers more comfortable prescribing opioids to their patients, and patients more comfortable starting on chronic opioid therapy. These misrepresentations were especially insidious because Purdue 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 were critical to assure doctors, who were beginning to see or hear about the rising tide of opioid addiction, that they could safely prescribe opioids in their own practices and that addiction was not unavoidable, but the result of other prescribers' failing to rigorously manage and weed out problem patients.

103. Purdue conveyed these messages in its in-person sales calls. A former Purdue sales representative in New Jersey acknowledged discussing with health care providers that they could screen out patients at high risk of addiction through urine tests and patient agreements. Many New Jersey prescribers report using screening tools to manage addiction risk.

104. Sales representatives in New Jersey had at their disposal the Partners Against Pain "Pain Management Kit," which contained several drug abuse screening tools they could show to prescribers. One of these is the "Opioid Risk Tool" created by prominent opioid advocate Dr. Lynn Webster, who received research funding from Purdue. It is a five question, one-minute screening tool that relies on patient self-reports (particularly unlikely given the sensitive topic and the nature of addiction) to purportedly allow doctors to manage the risk that their patients will become addicted to or abuse opioids. Sales representatives distributed the kit to prescribers in New Jersey.

105. Purdue also has promoted screening tools as a reliable means to manage addiction risk in CME and scientific conferences available to New Jersey prescribers. For example, Purdue sponsored a 2011 CME taught by Dr. Lynn Webster via webinar titled "Managing

Patient's Opioid Use: Balancing the Need and Risk." This presentation deceptively instructed prescribers that screening tools and urine tests prevented "overuse of prescriptions" and "overdose deaths." Purdue also funded a 2012 symposium called "Chronic Pain Management and Opioid Use: Easing Fears, Managing Risks, and Improving Outcomes," which taught doctors that, through the use of screening tools, more frequent refills, and other techniques, high-risk patients showing signs of addictive behavior could be safely treated with opioids.

106. The 2016 CDC Guideline confirms the lack of substantial scientific evidence to support Purdue's claims regarding the utility of screening tools and patient 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, patient agreements, urine drug testing, or pill counts—all widely believed by doctors, including doctors in New Jersey, to detect and deter abuse—"for improving outcomes related to overdose, addiction, abuse, or misuse."[22] As a result, the 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." (Emphasis added.)[23]

c. Failing to disclose increased risk of higher doses

107. Purdue has falsely claimed to New Jersey prescribers and consumers that opioids can be taken at ever-increasing doses for better pain relief, without disclosing that higher doses carry greater risk of addiction and overdose. Further, as described in more detail in Section IV.B.3, Purdue encouraged physicians to increase the dose of OxyContin rather than prescribe it

[22] 2016 CDC Guideline at 11.

[23] Id. at 28. These screening tools may serve different purposes: they can assist doctors in identifying diversion, and they can convey to patients the gravity of the risks of opioid use.

more frequently, despite knowing that higher doses posed greater risks and that OxyContin often did not provide 12 hours of pain relief.

108. The ability to escalate doses was critical to Purdue's efforts to market opioids for long-term use to treat chronic pain. Unless doctors felt comfortable prescribing increasingly higher doses of opioids to counter tolerance to the drugs' effects, they may not have chosen to initiate opioid therapy at all. Numerous Purdue marketing materials depict the seven OxyContin tablet strengths—in a line or even a series of steps—and instruct prescribers that they can titrate, i.e., increase the dose, "as clinical need dictates."

109. Purdue's sales representatives omitted from their sales conversations any discussion of increased risk from higher doses of opioids, despite knowing that dose escalation—"titrating up," in Purdue's parlance—was virtually inevitable. A key sales strategy was to persuade prescribers to convert patients from other pain relievers to the lowest dose of OxyContin, without discussing that the dose would need to be increased over time. One former Purdue sales representative in New Jersey recalled that she was uncomfortable with this tactic, because she knew the natural progression was higher and higher doses.

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

111. 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 what, in the patient's view, was a sufficient dose of opioids, the patient should find another doctor who would.

112. A Policymaker's Guide, the 2011 publication on which Purdue collaborated with APF, asserted that dose escalations—even unlimited ones—are "sometimes necessary," but did not disclose the risks from high doses of opioids.

113. Purdue also deceptively presented the risks of opioids in comparison to the risks presented by non-steroidal anti-inflammatory drugs ("NSAIDs" like Advil or Motrin) or acetaminophen (Tylenol). The company sponsored a 2013 CME titled "Overview of Management Options" that highlighted the evidence of adverse effects from high doses of NSAIDs but did not discuss the increased risk from using high doses of opioids. The CME was edited by Dr. Portenoy, who received research support, honoraria, and consulting fees from Purdue. Issued by the American Medical Association in 2013, the CME remains available from the AMA online. Purdue also sponsored a pain pamphlet for physician assistants that similarly emphasized the risk of liver damage from acetaminophen at higher doses, while omitting any comparable discussion of the risks of opioids at high doses.

114. Even where Purdue marketing pieces acknowledged that certain serious risks rose with the dose, they failed to disclose the increased risk of addiction. For example, a 2009 brochure for prescribers stated that "there is no defined maximum daily dose" and "[t]he ceiling to analgesic effectiveness is imposed only by side effects." Side effects were defined to include respiratory depression and various non-serious events such as constipation, but not addiction or opioid abuse.

115. There is no substantial scientific evidence that doses of opioids can be continuously titrated upward without significant added risk. On the contrary, patients receiving high doses of opioids as part of long-term opioid therapy are three to nine times more likely to suffer overdose from opioid-related causes than those on low doses. As compared to available alternative pain remedies, patients develop a tolerance to opioids' analgesic effects quicker than they develop a tolerance to opioids' depressive effects on respiration. Accordingly, the practice

of continuously escalating doses to match pain tolerance can, in fact, lead to overdose even where opioids are taken as recommended.

116. As confirmed by the CDC in its 2016 Guideline, the "[b]enefits of high-dose opioids for chronic pain are not established," while the risks for serious harms are clear and dose-dependent. More specifically, the CDC explains that "there is now an established body of scientific evidence showing that overdose risk is increased at higher opioid doses." The CDC also states that there are "increased risks for opioid use disorder, respiratory depression, and death at higher dosages."

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

118. Because of these risks, the 2016 CDC Guideline advises doctors to "avoid increasing doses" above 90 morphine milligram equivalents (MME) per day. Yet, many patients continue to receive dangerously high doses of opioids. Among New Jersey patients insured by Medicaid, for example, 52% of patients taking OxyContin or Hysingla between 2008 and the present ultimately were prescribed doses exceeding the CDC's recommended limit.

119. Escalation to dangerous doses is built into the OxyContin and Hysingla product lines. Of the seven available OxyContin tablet strengths, the three strongest—40 milligrams (120 MME), 60 milligrams (180 MME), and 80 milligrams (240 MME)—all exceed the CDC limit when taken (as directed) twice daily. Patients on the twice-daily 80 milligram dose receive

nearly three times the recommended ceiling of 90 MME. The two highest strengths of Hysingla—a once-a-day pill—provide 100 and 120 MME, also exceeding the CDC threshold.

d. Overstating the efficacy of "abuse-deterrent" properties

120. Since 2010, Purdue has deceptively marketed its "abuse-deterrent" opioids—a reformulated version of OxyContin, and Hysingla ER—to New Jersey prescribers in a manner falsely implying that these drugs can curb abuse and even addiction.

121. By the mid-2000s, rampant addiction to, and abuse of, OxyContin and other opioids had emerged in the public eye. Prescription opioid abuse takes several forms, the most common of which is oral abuse, which includes not only using the drugs without a prescription, but also swallowing higher or more frequent doses than prescribed. Rather than focus on the oral abuse associated with the widespread prescribing of OxyContin for chronic pain, Purdue claimed that abuse and addiction result from product diversion, with abusers snorting or injecting the drug. Purdue's proffered solution was a new coating and elements to make its opioids more difficult to crush or inject. Purdue's marketing of this abuse-deterrent formulation has misleadingly assured prescribers that they can prescribe Purdue's opioids without contributing to the epidemic of misuse and abuse.

122. The FDA approved the reformulated OxyContin in 2010. In its medical review of Purdue's application, however, the FDA found that "the tamper-resistant properties will have no effect on abuse by the oral route (the most common mode of abuse)" and that "[w]hile the reformulation is harder to crush or chew, possibly mitigating some accidental misuse, oxycodone HCl is still relatively easily extracted."[24] In 2013, Purdue persuaded the FDA to permit

[24] New Drug Application 22-272, OxyContin, Division Director Summary Review for Regulatory Action, at 7 (Dec. 30, 2009), https://www.accessdata.fda.gov/drugsatfda_docs/nda/2010/022272s000MedR.pdf.

reference to the abuse-deterrent properties in the OxyContin label. When Hysingla ER (extended-release hydrocodone) launched in 2014, the product included similar properties.

123. Purdue regularly cites its introduction of abuse-deterrent opioids as evidence of its commitment to addressing the opioid crisis, as described in Section IV.E. In fact, the reformulation, and the change in labeling, solved an important business problem for Purdue: how to keep the money flowing after April 2013, when OxyContin's patent was set to expire. Generic versions of OxyContin became available in February 2011, threatening to erode Purdue's share of the long-acting opioid market as well as the price Purdue could charge. However, Purdue convinced the FDA in April 2013 that original OxyContin should be removed from the market as unsafe because it lacked abuse-deterrent properties—meaning generic equivalents of the old formulation also could not be sold. Purdue thus secured brand exclusivity for OxyContin through at least 2017; successful patent challenges now have competitors petitioning the FDA for approval of generic versions.

124. Purdue uses the abuse-deterrent properties of its opioids as a primary selling point to differentiate its products from its competitors, including generic opioids. In delivering this sales message, Purdue sales representatives have falsely claimed or implied to New Jersey prescribers that Purdue's abuse-deterrent formulations (a) prevent tampering and that these products cannot be crushed or snorted; (b) prevent or reduce opioid abuse, diversion, and addiction overall; and (c) are safer than other opioids. Purdue's sales representatives also have either failed to disclose that the abuse-deterrent formulations do not impact the most common form of abuse—oral ingestion—or affirmatively misrepresented that most abuse is by non-oral means.

125. These statements and omissions are inconsistent with the FDA-approved labels for OxyContin and Hysingla ER, which indicate that their abuse-deterrent properties can be defeated, state that the drugs can be abused orally notwithstanding the abuse-deterrent properties, and do not indicate that the drugs prevent or reduce abuse, misuse, or diversion.

126. Purdue knew or should have known that its abuse-deterrent drugs still are regularly tampered with and abused. In online forums such as bluelight.org and Reddit, drug abusers discuss a variety of ways to tamper with OxyContin and Hysingla ER, including by grinding the pills, microwaving then freezing them, or dissolving them in soda or lemon juice. Indeed, a still-pending citizen petition submitted by another pharmaceutical firm in 2016 challenged Purdue's abuse-deterrent labeling based on the firm's ability to easily process OxyContin for snorting or injection. And a 2015 study by researchers at Washington University in St. Louis found that many addicts continued to abuse reformulated OxyContin. Of the survey respondents who continued to abuse the drug, most either continued with or switched to oral abuse, while about a third found various methods to continue snorting or injecting the drug.[25]

127. There remains no substantial scientific evidence that Purdue's abuse-deterrent opioids actually reduce opioid abuse. As the 2016 CDC Guideline states, "[n]o studies" support the notion that "abuse-deterrent technologies [are] a risk mitigation strategy for deterring or preventing abuse," and the technologies—even when they work—"do not prevent opioid abuse through oral intake, the most common route of opioid abuse, and can still be abused by nonoral routes."

[25] Theodore J. Cicero & Matthew J. Ellis, "Abuse-Deterrent Formulations and the Prescription Opioid Abuse Epidemic in the United States: Lessons Learned from OxyContin," 72(5) JAMA Psychiatry 424-430 (May 2015).

128. Because of their questionable benefits, any discussion of abuse-deterrent technologies has a high potential to mislead practitioners and create a false sense of security about prescribing opioids. In a 2014 survey of 1,000 primary care physicians, nearly half reported that they believed abuse-deterrent formulations of opioids are inherently less addictive.[26] One-third of the doctors in that same study had the mistaken impression that most prescription drug abuse is by means other than swallowing the pills as intended.

129. Purdue knew that its marketing should not go beyond the words "abuse-deterrent properties" to claim that OxyContin and Hysingla actually deter abuse. FDA policy on such representations is clear. In 2013, the FDA warned Purdue competitor Endo over advertising implying that the "crush resistant" property of its Opana ER opioid actually made the drug more difficult to abuse.

130. Notwithstanding these concerns, Purdue's sales representatives have made claims about abuse deterrence that go well beyond the drugs' labeling.

131. Purdue sales representatives have not simply discussed "abuse-deterrent properties," but have stated or implied that Purdue's abuse-deterrent formulations are more difficult to abuse and less likely to be diverted. One New Jersey prescriber recalled a Purdue representative telling her that the majority of OxyContin abuse happens through snorting or injecting; another was told that street use is usually non-oral; and several were told that reformulated OxyContin is rendered inactive if crushed, so a user would not be able to get high from it. Representatives made similar claims about Purdue's other oral opioid, Hysingla, claiming that Purdue studies find that abusers do not like this drug. Even more troublingly,

[26] Catherine S. Hwang et al., "Primary Care Physicians' Knowledge and Attitudes Regarding Prescription Opioid Abuse and Diversion," 32(4) Clinical Journal of Pain 279-284 (Apr. 2016).

Purdue representatives have stated or implied to New Jersey prescribers that opioids with abuse-deterrent formulations are "helping thwart addiction."

132. The recollections of New Jersey prescribers about such marketing claims are corroborated by data the State obtained from a market research and analytics company that performs promotional message tracking in the pharmaceutical industry. The data consist of verbatim messages from detailing activity (as well as electronic, meeting, and event promotional activity) to a sample of panelists—office-based physicians, hospital-based physicians, nurse practitioners, and physician assistants—broken out by region. New Jersey is in the Northeast Region. Each month, panelists report via online surveys on the promotional activity in which they participated that month. The panelists' responses are based on the panelists' perception of the main message of the promotion. The responses received by the research company are reported word-for-word as "verbatims." Verbatims show Northeast Region practitioners receiving messages from Purdue sales representatives that OxyContin and Hysingla ER are "tamper proof," are "tamper resistant to prevent drug abuse," "present little opportunity for abuse," and are not subject to being "crush[ed] and misuse[d]."

133. Purdue's deceptive marketing of the benefits of its abuse-deterrent formulations is particularly dangerous because it persuades doctors—who might otherwise curtail their opioid prescribing—to continue prescribing Purdue's opioids in the mistaken belief they are safer. It also allows prescribers and patients to discount evidence of opioid addiction and attribute it to other, less safe opioids—i.e., to believe that while patients might abuse or overdose on non-abuse deterrent opioids, Purdue's opioids did not carry that risk.

2. Purdue Has Grossly Overstated the Benefits of Chronic Opioid Therapy While Failing to Disclose the Lack of Evidence Supporting Long-term Use.

134. To convince New Jersey prescribers and patients that opioids should be used to treat chronic pain, despite the unavoidable risk of addiction, Purdue had to persuade them that there is a significant upside to long-term opioid use. But as the 2016 CDC Guideline makes clear, there is "insufficient evidence to determine long-term benefits of opioid therapy for chronic pain." (Emphasis added.) In fact, the CDC found that "[n]o evidence shows a long-term benefit of opioids in pain and function versus no opioids for chronic pain with outcomes examined at least 1 year later (with most placebo-controlled randomized trials ≤ 6 weeks in duration)" and that other treatments were more or equally beneficial and less harmful than long-term opioid use.[27] The FDA similarly has recognized the lack of evidence to support long-term opioid use, stating in 2013 that it was "not aware of adequate and well-controlled studies of opioids use longer than 12 weeks."[28]

135. On the contrary, the available evidence indicates opioids are not effective to treat chronic pain, and may worsen patients' health. A 2006 study of studies found that "[f]or functional outcomes, . . . other [non-addictive] analgesics were significantly more effective than were opioids."[29] Increasing duration of opioid use is strongly associated with an increasing prevalence of mental health conditions (depression, anxiety, post-traumatic stress disorder, or substance abuse), increased psychological distress, and greater health care utilization. Moreover,

[27] 2016 CDC Guideline at 15, 19.

[28] Letter from Janet Woodcock, M.D., Director, FDA Center for Drug Evaluation and Research, to Andrew Kolodny, M.D., President, Physicians for Responsible Opioid Prescribing, at 10 (Sept. 10, 2013).

[29] Andrea D. Furlan et al., "Opioids for chronic noncancer pain: a meta-analysis of effectiveness and side effects," 174(11) Canadian Medical Association Journal 1589-1594 (2006).

as reflected in the same study, efficacy trials do not typically include data on opioid addiction. In many cases, patients who may be more prone to addiction are pre-screened out of the study pool, which does not reflect how doctors actually prescribe the drugs.

136. As one pain specialist observed, "[O]pioids 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."[30] Studies of patients using opioids to treat lower back pain and migraine headaches, for example, consistently have shown that patients experienced deteriorating function over time, as measured by ability to return to work or physical activity, pain relief, rates of depression, and subjective quality-of-life measures. Analyses of workers' compensation claims have found that (a) workers who take opioids are almost four times more likely to reach costs over $100,000, owing to greater side effects and slower returns to work; (b) receiving an opioid for more than seven days increased patients' risk of being on work disability one year later; and (c) an opioid prescription as the first treatment for a workplace injury doubled the average length of the claim.

137. Purdue long has been aware of the disconnect between the academic literature, which assesses efficacy only as far out as 12 weeks, and the reality—which it helped create—that many patients use OxyContin and other opioids for months or years. For example, [redacted] such evidence did not exist.

[30] Andrea Rubenstein, "Are we making pain patients worse?," Sonoma Medicine (Fall 2009).

138. Nevertheless, building on its earlier marketing, Purdue has continued to tout the purported benefits of long-term opioid use, while falsely and misleadingly implying that these benefits are supported by scientific evidence. In their sales conversations with New Jersey prescribers, Purdue sales representatives do not disclose the lack of evidence supporting long-term use. And Purdue promotional materials likewise promote long-term use without disclosing the absence of long-term studies.

139. For example, the OxyContin "Conversion and Titration Guide," which sales representatives widely distributed in New Jersey, implies that use can continue safely for years. A 2007 version of that guide recommended that "the need for around-the-clock opioid therapy should be reassessed periodically (e.g., every 6 to 12 months) as appropriate for patients on chronic therapy," but did not disclose the absence of evidence supporting safety and efficacy of use for 6 to 12 months. The 2017 version of this guide omits the parenthetical "(eg, every 6 to 12 months)" and simply states that prescribers should "periodically reassess the continued need for opioid analgesics." The guide still conveys, however, that chronic opioid therapy is appropriate without disclosing the lack of evidence for use beyond 12 weeks, and without correcting the previous misinformation Purdue conveyed to prescribers.

140. Purdue specifically has claimed—also without evidence—that long-term opioid use will improve patients' daily function and quality of life. Purdue's sales representatives have delivered this message in their New Jersey sales visits.

141. Purdue and Purdue-sponsored materials distributed or available in New Jersey reinforce this message. The 2009 APF book Exit Wounds asserted unequivocally that "[w]hen used correctly, opioid pain medications increase a person's level of functioning" and that opioids "can go a long way toward improving your functioning in daily life." And the 2011 publication

A Policymaker's Guide erroneously claimed that "multiple clinical studies have shown that long-acting opioids, in particular, are effective in improving [d]aily function . . . [and] quality of life for people with chronic pain."

142. These claims of functional improvement were both unsubstantiated by and contrary to the scientific evidence at the time. The sole study the Guide cited for this claim expressly noted the absence of long-term studies and actually found that "[f]or functional outcomes, . . . other analgesics were significantly more effective than were opioids."[31] The FDA has made clear for years that opioid manufacturers should not make claims regarding functional improvement and ability to perform daily activities, warning Purdue competitors in public letters that such claims lacked substantial scientific evidence.

143. Most recently, the 2016 CDC Guideline approved by the FDA concluded that "there is no good evidence that opioids improve pain or function with long-term use." (Emphasis added.) The CDC reinforced this conclusion throughout the Guideline, finding that (a) "[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"; (b) "[a]lthough opioids can reduce pain during short-term use, the clinical evidence review found insufficient evidence to determine whether pain relief is sustained and whether function or quality of life improves with long-term opioid therapy"; and (c) "evidence is limited or insufficient for improved pain or function with long-term use of opioids for several chronic pain conditions for which opioids are commonly prescribed, such as low back pain, headache, and fibromyalgia."[32]

[31] Andrea D. Furlan et al., "Opioids for chronic noncancer pain: a meta-analysis of effectiveness and side effects," 174(11) Canadian Medical Association Journal 1589-1594 (2006).

[32] 2016 CDC Guideline at 12, 15, 18.

144. The CDC also noted that the risks of addiction and death "can cause distress and inability to fulfill major role obligations."[33] As a matter of common sense (and medical evidence), drugs that can kill patients or commit them to a life of addiction or recovery do not improve their function and quality of life. Purdue's claims that patients will experience functional improvement, in addition to lacking evidence, also ignore these very serious consequences.

3. Purdue Has Misleadingly Promoted OxyContin as Supplying 12 Hours of Pain Relief.

145. To convince New Jersey prescribers and patients to use OxyContin, Purdue has misleadingly promoted the drug as providing 12 continuous hours of pain relief with each dose. Purdue points to labeling that it sought from the FDA, and for which the company is legally responsible, directing 12-hour dosing. Purdue sought that dosing to maintain a competitive advantage over more-frequently dosed opioids, despite knowing that it was inadequate—and dangerous—for many patients. Moreover, Purdue has gone well beyond the label's instructions to take OxyContin every 12 hours by affirmatively claiming that OxyContin lasts for 12 hours and by failing to disclose that OxyContin does not provide 12 hours of pain relief to many patients. In reality, Purdue has known since OxyContin's launch that it does not last for 12 hours in many patients, a phenomenon known as "end of dose failure."

146. These misrepresentations, which Purdue has made since 1996 and continues to make through the present day, are particularly dangerous because the inadequate dosing helps fuel addiction, as laid out below. And Purdue has doubled down on both its misstatements and the resulting harm to patients by suggesting to prescribers that the solution to end-of-dose failure

[33] Id. at 20.

is not more-frequent dosing but higher doses—which themselves pose greater risks, as discussed in Section IV.B.1.c.

147. OxyContin has been FDA-approved for twice-daily—"Q12"—dosing since its debut in 1996. Yet it was a business decision that drove the company to submit OxyContin for approval with 12-hour rather than 8-hour dosing. Internal Purdue marketing documents indicate that 12-hour dosing was considered key to differentiating the drug from the competition—generic, short-acting opioids that require patients to wake in the middle of the night to take the next dose.

148. 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 the 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," the reason is that it was not in Purdue's business interest to conduct any such studies.

149. 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."[34] 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."[35]

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[34] Purdue Pharma L.P., "New Hope for Millions of Americans Suffering from Persistent Pain," PR Newswire (May 31, 1996).

[35] FDA response letter from Janet Woodcock, Director, Center for Drug Evaluation and Research, to Richard Blumenthal, Connecticut Attorney General (Sept. 8, 2008), at 5, http://www.purduepharma.com/wp-content/pdfs/fda_response_blumenthal_oxycontin.pdf.

150. 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. According to a 2016 Los Angeles Times investigation, Purdue's own early studies showed many patients asking for more medication before their next scheduled dose. In one clinical trial, a third of patients dropped out because the treatment was ineffective. Researchers changed the rules to allow patients to take supplemental short-acting opioids—"rescue medication"—in between OxyContin doses. In another study, most patients used rescue medication, and 95% resorted to it at least once. Prescribers, including prescribers in New Jersey, likewise have complained to Purdue sales representatives that OxyContin does not supply 12 hours of pain relief in a significant number of the prescribers' patients.

151. End-of-dose failure renders OxyContin even more dangerous because patients experience the early stages of psychological and physical withdrawal symptoms on a daily basis, followed by a euphoric rush when they take their next dose—leading to 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]

152. Purdue has held fast to 12-hour dosing not because it is true but 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 for a recommendation of more frequent

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

dosing in the label (e.g., every 8 hours) because 12-hour dosing was "a significant competitive advantage."[37]

153. 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. Yet, 12-hour dosing—without further explanation—has been and remains a principal feature of Purdue's marketing. According to multiple former Purdue employees in New Jersey, the company trained its sales force to explain to doctors that, if the Q12 dose didn't last the full 12 hours, the sales representative should encourage the doctor to increase the dose. The sales representatives confirmed that they did, in fact, deliver this message to prescribers in New Jersey. At least one former New Jersey sales representative stated that she never received any information from Purdue about the drug lasting less than twelve hours.

154. Moreover, Purdue sales representatives in New Jersey have gone even farther than promoting dosing, falsely stating in sales calls that a key feature of OxyContin was that it provided a full 12 hours of pain relief—in one representative's words, "truly a Q12." The verbatim sales message data obtained by the State likewise shows practitioners in the data set's Northeast Region (which includes New Jersey) receiving messages from Purdue representatives that OxyContin has "true 12 hour dosing," "[r]eliable every 12-hour dosing," "[e]very 12 hour dosing . . . for better pain control," and "effective round the clock pain control."

155. Twelve-hour dosing also is featured in most OxyContin promotional pieces. A 2012 version of the Conversion and Titration Guide, for example, contains the tag line: "Because each patient's treatment is personal / Individualize the dose / Q12 OxyContin Tablets." And a 2014 visual aid used by sales representatives repeatedly refers not merely to OxyContin,

[37] Letter from Kleinfeld, Kaplan & Becker, LLP, counsel for Purdue Pharma L.P., to FDA re Connecticut Citizen Petition, FDA Dkt. No. 2004P-0043, at 13 (Apr. 14, 2004).

but to "every 12-hour OxyContin" and "Every-12-Hour OxyContin Tablets." None of these pieces discloses that the pain relief from each 12-hour dose will last well short of 12 hours for many patients, thereby leaving prescribers and patients unprepared for end-of-dose failure and the craving for more opioids that it creates. This is both an affirmative misrepresentation and a material omission.

156. Purdue's promoted solution to end-of-dose failure—increasing the dose, rather than the frequency, of prescriptions—exacerbates the risks of addiction, overdose, and death. Because the pain relief still does not last 12 hours, taking higher doses simply means that patients will experience higher highs and lower lows, increasing their craving for their next pill.

157. The OxyContin label and the Conversion and Titration Guide expressly direct this approach, advising prescribers that they can increase the dosage to achieve adequate pain relief "as clinical need dictates, while maintaining every 12-hour dosing." Purdue's representatives offered this advice—to "titrate up"— in their sales calls to New Jersey physicians. But this advice was not accompanied by appropriate warnings regarding increased risk of addiction associated with increased doses, as discussed in Section IV.B.1.c.

158. As a result, health care providers routinely prescribe OxyContin in doses above the recommended daily limit. Based on a nationwide 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 2016 CDC Guideline urges prescribers to "avoid" or "carefully justify." Such doses are similarly prevalent in New Jersey. About 63% of OxyContin and Hysingla prescriptions covered by Medicaid in New Jersey in the last decade exceeded the CDC threshold.

### C. Purdue Targeted the Elderly and Opioid-Naïve Patients to Expand Market Share and Profits.

159. Part of Purdue's strategy to continue expanding its market share, and hence its revenue, has been to target two, overlapping markets in particular: the elderly, a demographic that has seen an explosion in opioid prescribing in recent years, and opioid-naïve patients—those who previously had not taken opioids.

160. Training materials and sales goals for Purdue's sales representatives, [redacted] include multiple references to Purdue's efforts to persuade doctors to start prescribing its ER/LA opioids to elderly patients.

161. Purdue trained its sales representatives to help doctors identify elderly patients who would fit Purdue's desired patient profile for beginning long-term opioid treatment. For example, according to training materials provided by one former detailer in New Jersey, Purdue sales representatives were taught to ask questions like: "Doc, can an elderly patient have chronic pain and not be on an opioid?" and "[Doctor,] do you have patients over the age of 65 who are being treated with an opioid that would meet OxyContin's indication[?]" [redacted] This practice increases patients' risk for addiction and overdose, since the risks are dose-dependent. As the CDC has explained, use of ER/LA opioids such as OxyContin, which are indicated only for round-the-clock use, tends to be associated with higher daily dosages than use of as-needed IR opioids.

162. When sales representatives reported that a doctor was reluctant to prescribe OxyContin, their managers gave them instructions for their next visit, specifically that they should keep the doctor focused on starting with low-dose OxyContin to allay the doctor's concerns. [redacted]

163. [redacted]

164. Purdue also focused heavily on marketing its opioids in New Jersey as medications that were covered by insurance plans, with a focus on educating physicians about Medicare Part D (prescription benefit) coverage for opioids. [redacted] A Purdue "Sales Performance Plan" provided by one former representative in New Jersey contained the goal to "[e]xpand my Hysingla and Butrans prescribers and loyalists," including by "[f]ocus[ing] on Med D coverage and elderly patients." Another Purdue training document provided by this representative suggested sharing the profile of "Pam," an elderly patient, then asking, "[D]oc, are you aware that 3 of your biggest Med D plans have added Butrans and it is now preferred?"

165. Purdue has targeted seniors for a reason—they are a growth sector. In 2016, fully one in three enrollees in Medicare Part D received at least one opioid prescription. And more than 500,000 enrollees nationwide were on a high dose of at least 120 MME—well above the 90 MME level the CDC recommends avoiding. These high doses underscore the eventuality that elderly patients will not simply remain on OxyContin 10 milligrams but will require escalating doses.

166. Purdue's targeting of elderly patients overlapped with Purdue's broad marketing push to persuade doctors to prescribe OxyContin to opioid-naïve patients—even when faced with reluctant practitioners.

167. A former Purdue sales representative in New Jersey expressed significant concern about the intense pressure Purdue asked her to put on doctors to convert opioid-naïve patients to OxyContin. If a doctor was not already prescribing opioids for patients deemed "appropriate" by Purdue, sales representatives were supposed to persuade the doctor to start those patients on a low dose of OxyContin.

168. The deliberate implication was that this low dose was safe. The same sales representative explained that she knew once a patient started on OxyContin for chronic pain, it was likely that the dose would need to be increased as the patient developed a tolerance for the drug over time. Her personal view was, "Why go down that road if there was something else that the doctor felt was safer that they could prescribe?" This sales representative stated that she had difficulty meeting her OxyContin quarterly sales quotas as a result of her reluctance to push doctors to convert opioid-naïve patients to OxyContin.

169. [redacted]

[redacted]

170. Purdue's decisions to target the elderly and opioid-naïve patients reflect, yet again, a business strategy that placed little, if any, value on the well-being and safety of consumers. An objective risk-benefit analysis of opioid use by either of these populations provides even less justification for initiating ER/LA opioid therapy than might arguably exist among patients who were already using ER/LA opioids.

171. Elderly patients taking opioids are at greater risk for fracture and hospitalization, and they have increased vulnerability to adverse drug effects such as respiratory depression, which Purdue acknowledges in its opioids' labels (but not in its marketing). A 2010 paper reported that elderly patients who used opioids had a significantly higher rate of death, heart attacks, and strokes than users of NSAIDs.[38]

172. Purdue's specific focus on opioid-naïve patients, meanwhile, is particularly disconcerting in light of the steady drumbeat of information over the past decade emphasizing, as the CDC summarized in 2016, that "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

[38] Kathleen W. Saunders et al., "Relationship of opioid use and dosage levels to fractures in older chronic pain patients," 2010(25) Journal of General Internal Medicine 310-315 (Jan. 2009).

pain]."[39] Opioid-naïve patients need never experience the serious consequences of chronic opioid therapy. Yet, through its marketing efforts, Purdue has sought to add them to its captive customer base of patients who will continue to require opioids as they become dependent and, perhaps, addicted.

### D. Purdue Has Caused Significant Harm to Public Health, Welfare, and Safety in New Jersey.

173. As a direct result of the Purdue-driven overprescribing of opioids, New Jersey and its citizens have experienced an epidemic of drug addiction, abuse, overdose, and other injuries, with their attendant societal costs. In addition, the State of New Jersey, through its State-funded health programs, has been forced to pay hundreds of millions of dollars for opioid prescriptions, attendant treatment, and other costs, even though many of these prescriptions were not medically necessary and would not have been written but for Purdue's fraudulent scheme. Consumers, private employers, and insurers have suffered similar financial impacts.

#### 1. Purdue's Deceptive Marketing Has Fueled the Opioid Epidemic, Resulting in Addiction, Overdose, and Other Injuries to New Jersey Citizens.

174. Purdue's misrepresentations have prompted New Jersey health care providers to prescribe, patients to take, and payors to cover opioids for the treatment of chronic pain. Through its marketing, Purdue set out to—and did—overcome barriers to widespread prescribing of opioids for chronic pain. The company's deceptive messages under-represented the risks of opioids, overstated their benefits, and expanded the perception of who was an "appropriate patient" for opioid use—successfully creating a self-sustaining opioid economy for Purdue.

[39] Thomas R. Frieden & Debra Howry, "Reducing the Risks of Relief—The CDC Opioid-Prescribing Guideline," 374 New England Journal of Medicine 1501, 1503 (Apr. 21, 2016) (article announcing 2016 CDC Guideline).

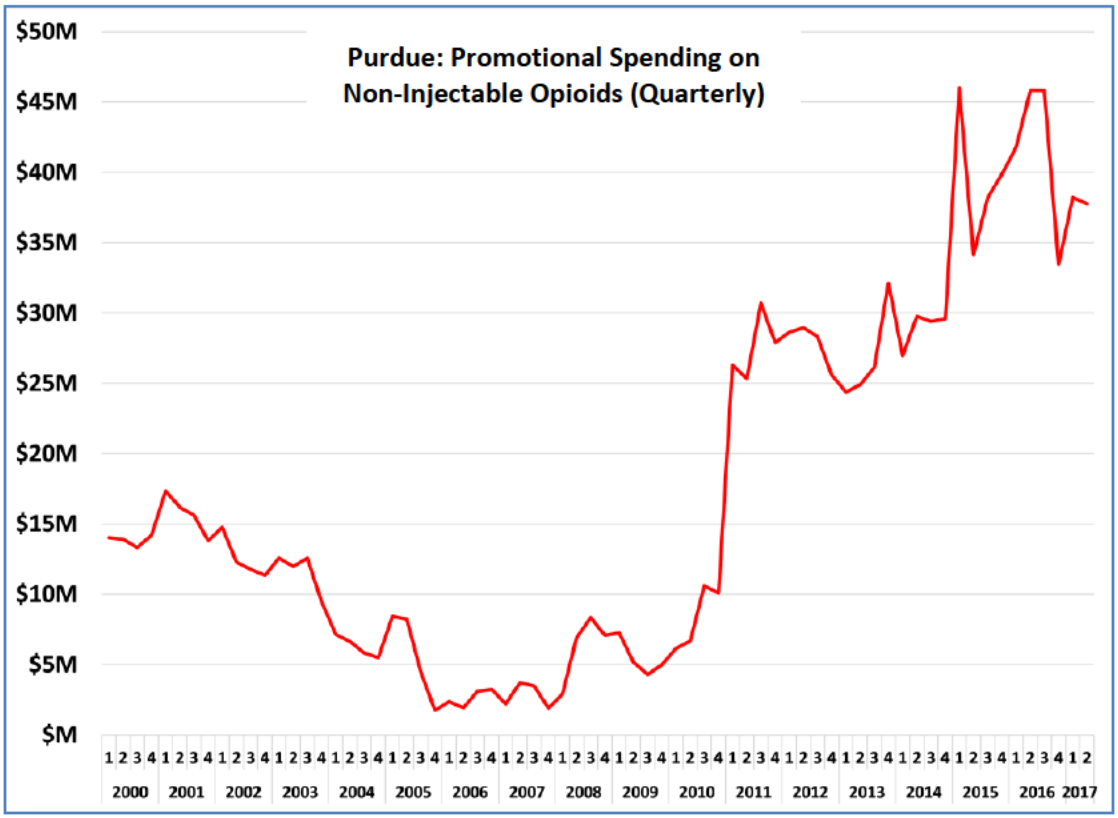
175. Purdue's deceptive marketing has directly contributed to an explosion in the use of opioids. In the United States, opioids are the most common treatment for chronic pain. As the CDC has reported, by 2012 health care providers were writing some 259 million opioid prescriptions annually—"enough for every adult in the United States to have a bottle of pills."[40]

176. Purdue accounts for the lion's share of sales of brand name opioids. Nationwide in 2013, there were 6 million prescriptions of OxyContin, resulting in $2.6 billion in sales—giving Purdue 44% of market value for all ER/LA opioids, and 24% of the overall opioid market (which includes widely prescribed generics). By comparison, no other branded drug accounted for more than 3% of ER/LA prescriptions annually. In New Jersey, from 2008 to the present, Purdue accounted for 73% of branded opioid prescriptions paid by the State's largest Medicaid provider and for 37% of those paid by the Workers' Compensation Program. Purdue opioids also accounted for 61% of the branded opioid prescriptions paid by the State's employee and retiree health plans between 2012 and the present.

177. Nationwide, opioid prescribing has quadrupled since 2000, a gigantic increase that corresponds to Purdue's equally massive marketing push. As depicted in the chart below, data obtained from a marketing research company show Purdue's spending nationally on opioid marketing stood at roughly $15 million per quarter in 2000. Its spending actually 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 the reformulated OxyContin, Purdue again kicked its marketing machine into overdrive. In 2011, Purdue's marketing spiked to more than $25 million per quarter, and by 2016, with the

[40] 2016 CDC Guideline at 1.

introduction of Hysingla, it soared to more than $40 million per quarter—$167 million annually, just on marketing opioids.




178. By far, the largest component of this spending was the cost of sales representatives, with total detailing expenditures nationwide rising from roughly $45 million annually in 2000 to $156 million in 2014.

179. Many physicians are unwilling to acknowledge the impact of detailing on their prescribing because of the uncomfortable conclusion that their medical judgment is influenced by pharmaceutical marketing. Yet, Purdue devotes enormous resources to detailing—notwithstanding increasing efforts of hospitals and physician practice groups to restrict access in recent years—because it knows that in-person marketing works. 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 with Purdue's

doubling of its sales force and trebling of sales calls.[41] The lockstep pattern between detailing and prescribing of Purdue's opioids continues to this day.

180. Purdue's aggressive marketing has affected even those physicians whom Purdue did not target or whose practices do not permit detailing. The vast new market for opioids is sustained today not only by Purdue's ongoing marketing, but also by its past, deception-fueled success in establishing opioids as a first-line treatment for chronic pain. As a consequence of commonplace opioid prescribing, many patients have come to believe they will not become addicted, addicts demand more drugs, and health care providers 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. Purdue's marketing of opioids as the best, first-choice answer to pain reinforces the psychological incentives for doctors who want to make their patients feel better—if they provide opioids, the patient is satisfied; if they do not, they face a patient who feels underserved and may, with Purdue's encouragement, seek another doctor who will.

181. As a result of Purdue's long-running and massively successful marketing campaign, opioids have become entrenched as a routine treatment for chronic pain conditions, despite their serious risks and the absence of evidence that they improve patients' pain and quality of life over the long term. As of 2010, an estimated 20% of patients presenting to physician offices with non-cancer pain symptoms or pain-related diagnoses (including acute and chronic pain) received an opioid prescription. Nationwide, opioid prescribing steadily increased through 2012. In New Jersey, while the State's years-long efforts to curb overprescribing have borne some fruit, prescribing rates—as measured in MME—stubbornly remained constant or

[41] Art Van Zee, "The Promotion and Marketing of OxyContin: Commercial Triumph, Public Health Tragedy," 99(2) American Journal of Public Health 221 (2009).

even increased in a majority of counties through 2015. The problem of overprescribing is particularly acute in six New Jersey counties—Atlantic, Burlington, Cape May, Cumberland, and Gloucester—all of which had prescribing rates ranked in the top 30% nationally in 2015.

182. The sharp increase in opioid use resulting from Purdue's marketing has led directly to a dramatic increase in opioid abuse, addiction, overdose, and death throughout the United States, including in New Jersey.

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

184. Scientific evidence demonstrates a close link between opioid prescriptions and opioid abuse. For example, a 2007 study found "a very strong correlation between therapeutic exposure to opioid analgesics, as measured by prescriptions filled, and their abuse," with particularly compelling data for extended release oxycodone—i.e., OxyContin.[42]

185. 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,

[42] 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 827-840 (Aug. 2007).

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."[43]

186. Nationwide, drug overdoses claimed the lives of more than 64,000 Americans in 2016. In recent years, two-thirds of all such deaths were attributable to opioids (including both prescription opioids and heroin). According to the CDC, between 1999 and 2015, more than 183,000 people in the United States died from prescription opioid-related overdoses alone—more Americans than died in the Vietnam, Iraq, and Afghanistan wars combined. In New Jersey, there were 1,587 drug overdose deaths overall in 2015, reflecting an 88% rise since just 2010. Although official statistics for 2016 still are being compiled, the number of overdoses last year is expected to exceed 2,000—a number that is larger than the population of many New Jersey towns. As reported by the New Jersey 101.5 FM radio station, the epidemic has gotten so bad that staff at the State's libraries—typically the most open buildings in their communities—are being instructed to watch out for users "overdosing inside . . . bathrooms or behind rows of books."[44]

187. According to national 2009 data analyzed by the National Institute on Drug Abuse, overdose deaths represent only the tip of the iceberg. For every overdose death that year, there were 9 abuse treatment admissions, 30 emergency department visits for opioid abuse or misuse, 118 people with abuse or addiction problems, and 795 non-medical users of opioids. In New Jersey, opioid-related emergency department visits doubled between 2005 and 2014 and rose another 13 percent in 2015. Emergency medical technicians have administered naloxone—

[43] CDC, Rose A. Rudd et al., "Increases in drug and opioid overdose deaths—United States, 2000–2014," Morbidity and Mortality Weekly Report (Jan. 1, 2016), https://www.cdc.gov/mmwr/preview/mmwrhtml/mm6450a3.htm.

[44] David Matthau, "Overdoses in NJ libraries—more signs of the opioid crisis," New Jersey 101.5 FM Radio (July 6, 2017), http://nj1015.com/overdoses-in-nj-libraries-more-signs-of-the-opioid-crisis/.

the emergency antidote to opioid overdoses—more than 18,000 times since its use was approved in New Jersey in 2014. According to a 2015 report by a national economics consulting firm, New Jersey's annual health care costs related to opioid abuse were estimated to exceed $683 million.

188. Rising opioid use, abuse, and addiction have had negative social and economic consequences far beyond overdoses and hospital visits. According to a 2016 study by a Princeton economist, unemployment increasingly is correlated with use of prescription pain medications. Nearly half of surveyed men not in the labor force said they took pain relievers daily, and two-thirds of them were on prescription medications—compared to just 20% of employed men who reported taking pain medications.[45] Worse still, many of those taking pain medications still said they experienced pain daily—an echo of the CDC's recent conclusion that "there is no good evidence that opioids improve pain or function with long-term use, and . . . complete relief of pain is unlikely." (Emphasis added.)[46]

189. 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 2016 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 are their counterparts who do not take opioids (14% and 9%, respectively). According to The Washington Post, secondary-

[45] Alan B. Krueger, "Where Have All the Workers Gone?," Princeton University and National Bureau of Economic Research (Oct. 4, 2016).

[46] 2016 CDC Guideline at 20.

effects medications—essentially, drugs to treat the effects of drugs—generated at least $4.6 billion in spending in 2015, on top of $9.57 billion in spending on opioids themselves.[47]

190. The potential market for treatment of opioid-induced constipation treatment—dubbed "OIC" in the industry—was so big that last year two companies bought a full minute of Super Bowl advertising to promote their OIC drug. Perversely, Purdue is looking to profit from both the sale of prescription opioids and drugs to treat the effects of their use. In sales visits to New Jersey prescribers, Purdue regularly pairs promotion of its opioids with promotion of its laxative product, Senokot. And in March of this year, the FDA approved Purdue's newest drug, Symproic, which the company is marketing specifically as a treatment for opioid-induced constipation.

191. The deceptive marketing and consequent overprescribing of opioids also have had a significant detrimental impact on young people in New Jersey. The overprescribing of opioids for chronic pain has given children access to opioids, nearly all of which were prescribed for adults in their household. In New Jersey, roughly one in four teenagers has abused prescription drugs, according to 2012 data.

192. Even infants have not been spared the impact of widespread opioid use and 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 and cry nonstop from the pain and stress of withdrawal, experience convulsions or tremors, have difficulty sleeping and feeding, and suffer from diarrhea, vomiting,

[47] Ariana Eunjang Cha, "The drug industry's answer to opioid addiction: More pills," The Washington Post (10/16/16), https://www.washingtonpost.com/national/the-drug-industrys-answer-to-opioid-addiction-more-pills/2016/10/15/181a529c-8ae4-11e6-bff0-d53f592f176e_story.html?.

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 neurological 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.

193. Nationwide, more than 21,732 infants in the United States were born with NAS in 2012, or about one every 25 minutes. According to an analysis by NJ.com, 6.4 of every 1,000 babies in New Jersey were born with NAS in 2014—more than double the 2008 figure. The problem is particularly acute in Atlantic, Cape May and Cumberland counties, where more than one out of every 50 babies in 2014 was born addicted to opioids.

194. Opioid addiction now outpaces other forms of addiction in demand for substance abuse treatment, and treatment providers are struggling to keep up. In 2016, prescription opioid and heroin abuse accounted for half of the substance abuse treatment admissions (including admissions for alcohol abuse) in New Jersey—more than 37,000 admissions—and accounted for the overwhelming majority of drug abuse admissions. Yet, the demand for treatment far outstrips the supply. The New Jersey Department of Human Services estimates that 37,000 New Jersey residents needed and wanted substance abuse treatment in 2016 but did not receive it.

195. Purdue's creation through false and misleading marketing of a virtually limitless opioid market has imposed significant burdens on the community at large. Purdue's success in extending the market for opioids to new patients and chronic conditions has created an abundance of drugs available for non-medical or criminal use and fueled a new wave of addiction, abuse, and injury. It has been estimated that 60% of the opioids that are abused come, directly or indirectly, through physicians' prescriptions.

196. Various studies report that as many as 80% of heroin addicts used prescription opioids before crossing over to heroin. In New Jersey, too, many of those who have overdosed started out on opioids with a prescription to treat chronic pain. Although prescribed opioids are prized among drug abusers because they are legal and predictable (i.e., the dose is clearly specified), recent years have seen a surge in prescription opioid abusers shifting to heroin because it is cheaper and easier to obtain than prescription opioids.

197. A recent, even more sinister 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, is now making its way into New Jersey communities through a booming trafficking network. Drug dealers are mixing fentanyl into heroin because it can be cheaply produced and creates an intense high. Patients who moved from prescription opioids to heroin may now find themselves graduated to heroin plus fentanyl. In 2015, 72% of heroin seized by law enforcement authorities in New Jersey was adulterated with fentanyl.

198. Fentanyl has been linked to an increasing number of the State's overdoses. Fentanyl was a factor in 417 New Jersey overdose deaths in 2015, and in 394 deaths in just the first six months of 2016. Fentanyl is 50 times more potent than heroin, and can quickly induce death in opioid-naïve users. And fentanyl abuse is often a game of Russian roulette, with users not knowing what mixture of fentanyl and heroin they are taking.

199. In addition to presenting heightened risks to persons addicted to opioids, the rise in the criminal market for opioids has burdened the State, as well as localities, with increased law enforcement costs.

200. Many patients who abuse or become addicted to opioids will lose their jobs, and some will lose their homes and their families. Some will get treatment, and fewer will

successfully complete it; many of those patients will relapse, returning to opioids or some other drug. Of those who continue to take opioids, some will overdose—some fatally, some not. Others will die prematurely from related causes—falls, traffic accidents, or assaults or from premature heart or neurological diseases—that hasten their death by 10 or 20 years.

201. In addition to the personal and familial burdens of opioid-related disability and death, such disability and death have diminished worker productivity. The CDC estimates the national cost of lost productivity associated with opioid use at approximately $40 billion annually.

2. Purdue's Deceptive Marketing Has Burdened the State of New Jersey with Direct Financial Costs.

202. The State has been damaged through the payment of false claims for chronic opioid therapy under (a) the State's Medicaid programs, (b) the State's employee and retiree health plans, and (c) the State's Workers' Compensation Program. The State has also been damaged by the payment of additional claims for drugs and medical services to treat conditions and injuries caused by chronic opioid use. These include treatments for neo-natal abstinence syndrome, addiction, and drug overdose.

a. The State's spending on opioids under comprehensive health care plans

203. Commensurate with Purdue's heavy promotion of opioids and the resultant, massive upswing in prescribing of opioids nationally and in New Jersey, the State has seen its own spending on opioids—through claims paid by its Medicaid and Workers' Compensation programs rise dramatically between 2008 and 2014, with particularly sharp increases, year-over-year, in 2011, 2012, and 2014.

(1) New Jersey Medicaid

204. The State provides comprehensive health care benefits, including prescription drug coverage, to low- and moderate-income residents through its Medicaid programs. Approximately 1.94 million New Jersey residents are enrolled in these publicly funded programs; the State funds prescription drug benefits for approximately 1.6 million of these enrollees. These programs are largely administered through five managed care organizations—Horizon NJ Health, United Health Care, Amerigroup, Wellcare, and Aetna (collectively "the Medicaid Contractors" or "MCOs")—which are paid a capitated rate, per beneficiary on a monthly basis, to provide the services covered under the State's Medicaid Plan.

205. Under the State's contract with the Medicaid Contractors, the Contractors are required to provide healthcare services and products to program beneficiaries "in accordance with medical necessity." "Medically necessary services" are defined as

> services or supplies necessary to prevent, evaluate, diagnose, correct, prevent the worsening of, alleviate, or cure a physical or mental illness or condition . . . The services provided . . . must be reflective of the level of services that can be **safely provided**, must be consistent with the diagnosis of the condition and **appropriate to the specific medical needs** of the enrollee and **not solely for the convenience of the enrollee or provider of service** and in accordance with standards of good medical practice and **generally recognized by the medical scientific community as effective** . . . Medically necessary services provided must be based on **peer-reviewed publications**, expert pediatric, psychiatric, and medical opinion, and medical/pediatric community acceptance. (Emphasis added.)

206. These services include opioids prescribed by providers as well as office visits for pain management (including toxicology screens) and treatments related to any adverse outcomes from chronic opioid therapy, such as overdose or addiction.

207. The Medicaid Contractors enlist health care providers ("Medicaid Providers")—including doctors and pharmacies—to provide services to New Jersey Medicaid beneficiaries. Among other things, these Medicaid Providers agree to comply with all State and federal

Medicaid requirements under a Provider Agreement that is "subject to the applicable material terms and conditions of the contract between the Contractor and the State and shall also be governed by and construed in accordance with all laws, regulations and contractual obligations incumbent upon the Contractor."

208. Opioids are only dispensed based on a licensed medical practitioner's prescription, which a practitioner will not write without first examining and diagnosing a patient. A Medicaid Provider submits a standardized form—the CMS 1500—to the Medicaid Contractor seeking reimbursement for such an office visit. By submitting a CMS 1500 form, the signatory certifies "that the services listed above were medically indicated and necessary to the health of this patient and were personally furnished by me or my employee under my personal direction." Pharmacies participating in Medicaid submit their requests for reimbursement of prescriptions electronically, using the NCPDP v.D.0 format.

209. The Medicaid Contractor verifies the validity of each claim and confirms compliance with program requirements. It submits a record of each payment—called an Encounter Report—to the State. The Encounter Report reflects the nature of the service provided and the Contractor's certification that the service was covered by the State Medicaid Plan and therefore medically necessary. The Encounter Reports are used to calculate and adjust, on a semi-annual basis, the capitated rates that the State pays its Medicaid Contractors. Where utilization rates or costs rise, the State's capitated rates rise, too.

210. A small percentage of the State's Medicaid recipients are enrolled in a fee-for-service plan. That plan is administered by Molina Medicaid Solutions. The only pertinent difference between the MCO plans and the fee-for-service plan is that the State reimburses

doctors and pharmacies directly for the cost of all medical services and drugs provided to Medicaid beneficiaries.

(2) The State Employee Health Plans

211. The State provides comprehensive health care benefits, including prescription drug coverage, to its current and retired employees and their dependents through two programs, the State Health Benefits Program and the School Employees' Health Benefits Program (collectively, the "Employee Health Plans"). Approximately 830,000 persons are enrolled in these plans. The Employee Health Plans are self-funded, meaning that the State bears the charges for all services and products used by beneficiaries.

212. The medical benefits provided to State employees are administered by two private companies: Horizon and Aetna. Employees are offered an array of plans, which are structured as preferred provider organizations ("PPOs") and health maintenance organizations ("HMOs"). The plans vary in terms of flexibility and cost (i.e., employee contributions, deductibles, and co-payments), but coverage under all plans is restricted to medically necessary care, which is defined by Horizon as a service or supply

- that is ordered by a doctor for the diagnosis or treatment of an illness or injury;
- **the prevailing opinion within the appropriate specialty** of the United States medical profession is that it is **safe and effective** for its intended use, and that its omission would adversely affect the person's medical condition;
- that it is the **most appropriate level** of service or supply considering the **potential benefits and harm** to the patient; **and**
- it is **known to be effective in improving health outcomes** (for new interventions, effectiveness is determined by **scientific evidence**; then, if necessary, by professional standards; then, if necessary, by expert opinion).

Aetna uses an equivalent definition, covering as "medically necessary" treatments that are "clinically appropriate," supported by "generally accepted standards of medical or dental

practice," supported by "credible scientific evidence," and cost-effective when compared to alternatives likely to produce the same result.

213. Such care includes not only opioids prescribed by providers, but office visits for pain management (including toxicology screens) and treatments related to any adverse outcomes from chronic opioid therapy, such as overdose or addiction.

214. The providers participating in the Employee Health Plans use the CMS 1500 when seeking payment for office visits, thereby certifying that the services provided were "medically indicated and necessary" to the health of the beneficiary. The claims are reviewed by the administrators, paid, and then forwarded to the State for reimbursement.

215. State employees' prescription drug benefits are administered by Express Scripts. Express Scripts covers all medically necessary and appropriate prescription drugs for plan participants. The terms of coverage are:

> [P]rescription drugs must meet federal Food and Drug Administration (FDA) approved indications and be **safe and effective for their intended** use . . . A prescription drug is medically necessary and appropriate if, as recommended by the treating practitioner and as determined by Express Scripts medical director or designee(s) it is **all of the following**:
>
> - A health intervention for the purpose of treating a medical condition;
> - The most **appropriate** intervention, considering potential **benefits and harms** to the patient;
> - **Known to be effective in improving health outcomes.** (For new interventions, effectiveness is determined by **scientific evidence**. For existing interventions, effectiveness is determined first by **scientific evidence**; then, if necessary, by professional standards; then, if necessary, by expert opinion);
> - **Cost effective** for the applicable condition, compared to alternative interventions, including no intervention. "Cost effective" does not mean lowest price.
>
> The fact that an attending practitioner prescribes, orders, recommends, or approves the intervention, or length of treatment time, does not make the intervention "medically necessary and appropriate." (Emphasis added.)

216. Pharmacists providing services for the Employee Health Plans use the NCPDP v.D.0 format to submit claims for prescription drugs to Express Scripts. Express Scripts pays the pharmacies for all prescriptions that comply with plan guidelines. The claims are then submitted to the State for reimbursement.

(3) The false claims against these State-funded comprehensive health benefits plans

217. Most long-term use of opioids to treat chronic pain is not medically necessary as defined by the State's comprehensive health benefits plans. As described above in Sections IV.A – IV.C, the long-term safety and efficacy of such use is not supported by substantial scientific evidence and is generally not the most appropriate treatment for moderate, chronic pain considering potential benefits and harms. Yet, Purdue undertook a systematic marketing campaign to encourage doctors to use opioids as the first line of treatment for chronic pain. In doing so, Purdue caused doctors and pharmacies to submit claims to its health plans that were false by:

(a) causing doctors to write prescriptions for chronic opioid therapy supported by Purdue's deceptive, false, and incomplete representations regarding the risks, benefits, and superiority of those drugs;

(b) causing doctors to certify that these prescriptions were "medically necessary" when, in fact, the prescriptions were not supported by substantial scientific evidence showing either that the risks associated with the drugs were outweighed by benefits or that the drugs were safe and effective for long-term, chronic use; and

(c) causing doctors to write opioid prescriptions when long-term opioid use renders patients dependent upon the continued and increased use of the drugs.

218. Alternatively, to the extent that chronic opioid therapy was considered "medically necessary" because it was consistent with the generally accepted professional and community standards that prevailed between the late 1990s and 2016, that medical consensus existed only because standards of practice had been re-written to conform to the false reality created by

Purdue's deceptive marketing. Purdue's marketing coopted and subverted every input that physicians rely upon in making prescribing decisions: medical literature, licensing board guidelines, insurers' formularies, and patient expectations.

219. For the majority of patients experiencing moderate chronic pain, long-term opioid use should not have been prescribed because it was neither necessary nor appropriate. As such, long-term opioid prescriptions would not have been eligible for reimbursement. The State would not have knowingly reimbursed claims for prescription drugs that were not eligible for coverage. For example, the State paid the following Medicaid and Employee Health claims:

(a) New Jersey Medicaid Patient A received 84 opioid prescriptions for chronic pain between December 2015 and July 2017, at a cost of $10,999 in claims paid by the State's Medicaid Contractor and subsequently presented to the State. These prescriptions were written by a doctor who received [redacted] visits from Purdue detailers over a period of [redacted] years.

(b) New Jersey Medicaid Patient B received 59 opioid prescriptions for chronic pain between January 2015 and May 2017, at a cost of $12,522 in claims paid by the State's Medicaid Contractor and subsequently presented to the State. These prescriptions were written by a doctor who received [redacted] visits from Purdue detailers over a period of [redacted] years.

(c) New Jersey Employee Health Patient E was diagnosed with unspecified back pain and chronic pain and received 37 opioid prescriptions between September 2014 and July 2017, at a cost of $16,311 in claims presented to and paid by the State. These prescriptions were written primarily by a doctor who received [redacted] visits from Purdue detailers over a period of [redacted] years.

(d) New Jersey Employee Health Patient F was diagnosed with lumbar radiculopathy and received 67 opioid prescriptions between January 2012 and July 2017, at a cost of $31,814 in claims presented to and paid by the State. These prescriptions were written primarily by a doctor who received [redacted] visits from Purdue detailers over a period of [redacted] years.

(e) New Jersey Employee Health Patient G was diagnosed with myalgia and myositis and received 57 opioid prescriptions between February 2012 and November 2016, at a cost of $10,061 in claims presented to and paid by the State. These prescriptions were written primarily by a doctor who received [redacted] visits from Purdue detailers over a period of [redacted] years.

(f) New Jersey Employee Health Patient H was diagnosed with spondylosis and received 35 opioid prescriptions between March 2014 and May 2017, at a cost of $43,599 in claims presented to and paid by the State. These prescriptions were written primarily by a doctor who received [redacted] visits from Purdue detailers over a period of [redacted] years.

220. Based on a preliminary review, the State's largest Medicaid MCO spent more than $109 million for over 2.9 million claims for opioid prescriptions submitted during the period January 2008 through June 2017. This includes approximately $37 million for Purdue opioids, as well as brand-name and generic opioids produced by other manufacturers. The State estimates that hundreds of thousands of claims were submitted during the same time period to the State's other Medicaid MCOs. The State estimates that a substantial percentage of these claims were false claims because they were for opioids prescribed for a period longer than 90 days and were prescribed: (a) at a strength of 90 MME or more; or (b) to treat moderate, rather than severe, pain; or (c) without exploration of alternative therapies like non-opioid medications and physical therapy.

221. Based on a preliminary review, the State spent more than $136 million for over 220,000 claims for opioid prescriptions submitted to the Employee Health Plans during the period January 2012 to August 2017. This includes approximately $80 million for Purdue opioids, as well as brand-name and generic opioids produced by other manufacturers. The State estimates that a substantial percentage of these claims were false claims because they were for opioids prescribed for a period longer than 90 days and were prescribed: (a) at a strength of 90 MME or more; or (b) to treat moderate, rather than severe, pain; or (c) without exploration of alternative therapies like non-opioid medications and physical therapy.

222. As a result of Purdue's deceptive marketing, New Jersey patients who used opioids long-term to treat chronic pain required additional services and supplies—in the form of office visits, toxicology screens, hospitalization for overdoses and infections, rehabilitation and

addiction-related therapy, and other treatments—necessitated by the adverse effects of opioids. These additional services and supplies caused the State to incur additional and consequential costs.

b. The State's spending under the Workers' Compensation Program

223. When a State employee is injured on the job, he or she may file a claim for workers' compensation; if the injury is deemed work-related, the State is responsible for paying its share of the employee's medical costs and lost wages. The State pays these claims through a self-funded program that is managed by Horizon Casualty Services ("HCS").

224. The State's Workers' Compensation Program has three overarching goals: to ensure prompt medical treatment for workers injured on the job; to maximize the likelihood that those workers can return to work; and to compensate workers for injuries that cannot be cured and wages lost during periods of disability.

225. The costs of opioid prescribing in the context of workers' compensation are substantial. In 2011, First Script, a national pharmacy managed care organization, prepared a Drug Trends Report outlining pharmaceutical trends identified in its workers' compensation book of business. In this report, First Script explained that short-acting and long-acting opioids represent the two most-prescribed drug classes within its workers' compensation program, representing 37% of its drug spending. The report also noted: "The nation's liberal consumption of narcotic pain relievers continues to gain recognition for its detrimental impact on injured workers—particularly those treated for chronic pain—and their employers."

(1) Medical and prescription drug benefits under Workers' Compensation

226. Horizon Casualty Services' provider agreement limits covered, or reimbursable, services and supplies to those that are: (a) causally linked to the worker's injury or condition, (b)

medically necessary, and (c) reasonable. Consistent with the goals of the program, services and supplies are also intended to yield "maximum medical improvement," which is achieved when "[t]he patient has reached maximal benefit from a curative treatment plan, or further medical treatment will not provide any improvement in the patient's current condition."

227. The State's Workers' Compensation Program covers all costs associated with treatment for workplace injuries and conditions. This coverage includes opioids, when prescribed by a doctor as medically necessary, and treatment related to any adverse outcomes from chronic opioid therapy, such as addiction treatment. Doctors submitting claims for services to Horizon Casualty Services use the CMS-1500 form.

228. Purdue caused doctors and pharmacies to submit, and the State to pay, claims to the State's Workers' Compensation program that were false by:

(a) causing doctors to write prescriptions for chronic opioid therapy supported by Purdue's deceptive, false, and incomplete representations regarding the risks, benefits, and superiority of those drugs;

(b) causing doctors to certify that these prescriptions and associated services were medically necessary, likely to improve functional capacity, or otherwise reasonably required, when, in fact, the prescriptions were not supported by substantial scientific evidence showing either that the risks associated with the drugs were outweighed by benefits or that the drugs were safe and effective for long-term, chronic use; and

(c) causing doctors to write subsequent prescriptions when long-term opioid use rendered patients dependent upon the continued and increased use of the drugs.

229. In the alternative, to the extent that chronic opioid therapy was considered "medically necessary" because it was consistent with the generally-accepted professional and community standards that prevailed between the late 1990s and 2016, Purdue engineered that medical consensus, causing doctors to believe that such long-term use of opioids to treat chronic pain was not simply permissible or appropriate but required.

230. As explained above, however, in many instances, the long-term use of opioids to treat moderate chronic pain is not medically necessary, reasonably required or appropriate because: (a) the risks do not materially exceed the benefits and (b) such use is not supported by substantial scientific evidence demonstrating that they improve physiological function or are otherwise safe and effective. In fact, the long-term use of opioids to treat chronic pain is antithetical to the purposes of Workers' Compensation: long-term use can cause hyperalgesia (increased sensitivity to pain) and cognitive impairment without improving physiological function.

231. In addition to these prescription costs, the State has paid for medical care and prescriptions necessitated by long-term opioid use and abuse including addiction treatment.

(2) Lost wages and disability

232. A growing body of research shows that long-term opioid use to treat chronic pain is associated with slower returns to work. The State has paid claims for lost wages attributable, in whole or in part, to opioid-related disability.

(3) The false claims against the State's Workers' Compensation fund

233. The following is a representative sample of claims submitted to the State's Workers' Compensation program:

(a) New Jersey Workers' Compensation Patient I was diagnosed with lumbago in October 2009. This patient received 191 opioid prescriptions between October 2009 and June 2017. The State has paid $64,242 for Patient I's medical care.

(b) New Jersey Workers' Compensation Patient J was diagnosed with a lumbar region sprain in April 2008. This patient received 150 opioid prescriptions between April 2008 and June 2017. The State has paid $15,176 for Patient J's medical care.

(c) New Jersey Workers' Compensation Patient K was diagnosed with a lumbar region sprain in February 2010. This patient received 132 opioid prescriptions. The State has paid $7,155 for Patient K's medical care.

(d) New Jersey Workers' Compensation Patient L received opioid prescriptions for chronic pain arising from a work-related injury. Patient L became addicted to opioids and consequently entered a 33-day residential rehabilitation treatment program for which the State paid an additional $68,700. While in this rehabilitation treatment program, Patient L claimed and the State paid $3,754 for lost wages.

234. As explained in Section IV.D.2.b.1, the State paid these prescription claims believing that they were medically necessary and therefore covered by the State's Workers' Compensation program. Long-term opioid use is generally neither necessary nor the most appropriate treatment for moderate chronic pain. Thus, these claims—and their attendant and consequential costs—were ineligible for payment.

235. Based on a preliminary review, the State spent more than $6 million for over 12,600 claims for opioid prescriptions submitted to the State's Workers' Compensation Program during the period January 2008 to August 2017. This includes approximately $886,000 for Purdue opioids, and $5.2 million for brand name and generic opioids produced by other manufacturers. The State estimates that a substantial percentage of these claims were false claims because they were for opioids prescribed for a period longer than 90 days and were prescribed: (a) at a strength of 90 MME or more; or (b) to treat moderate, rather than severe, pain; or (c) without exploration of alternative therapies like non-opioid medication and physical therapy.

c. Misrepresentations Regarding the Medical Necessity Were Material to the State's Decision to Pay These Claims

236. The fact that the State would pay for these ineligible prescriptions was both the foreseeable and intended consequence of Purdue's fraudulent marketing scheme. As described above, Purdue set out to change the medical and general consensus supporting chronic opioid therapy so that doctors would prescribe and so that government payors, such as the State, would pay for long-term prescriptions of opioids to treat chronic pain despite the absence of substantial

scientific evidence supporting chronic opioid therapy and the contrary evidence regarding the significant risks and limited benefits from long-term use of opioids.

237. Purdue's misrepresentations were material to and influenced the State's decisions to pay claims for opioids for chronic pain and, subsequently, to bear consequential costs in treating overdose, addiction, and other side effects of opioid use. But for the fraudulent and deceptive marketing campaign initiated by Purdue, the State would not have been presented with, or paid, claims for opioids to treat chronic, moderate pain.

238. As laid out above, Purdue's misrepresentations related to the State's requirement that medical treatments be medically necessary—a condition of coverage for any medical treatment under the State's comprehensive health plans and Workers' Compensation program. But for Purdue's fraudulent and deceptive marketing, prescribers would have more accurately understood the risks and benefits of long-term opioid use and would not have prescribed opioids as medically necessary or reasonably required to treat chronic pain. Misrepresentations as to, for example, whether patients were likely to become addicted to the drug, would be able to resume life activities, and would experience long-term relief were not minor or insubstantial matters, but went to the core of a prescriber's decision-making.

239. Since becoming aware of the growing use and abuse of opioids in New Jersey, the State has taken numerous steps to address the problem by educating prescribers and consumers about the risks and benefits of opioids, restricting prescribing, reducing the number of opioids pills in circulation, and increasing the coverage and availability of treatment for opioid overdose and addiction. The State's efforts include:

- launching, and then mandating use of, the Prescription Monitoring Program to help providers determine what other opioids a patient has been prescribed;
- launching the Project Medicine Drop initiative, designed to rid home medicine cabinets of unused opioids;

- publishing a set of best practices for pharmacists for the secure handling and dispensing of prescription drugs in order to reduce diversion;

- launching the "Know Addiction" public awareness campaign, which has distributed information and resources regarding the opioid epidemic, the risks of opioid use, abuse, and addiction, and the particular vulnerability of children, teens, and young adults to dangerous experimentation and misuse;

- setting a new, five-day supply limit on initial prescriptions of opioids for acute pain and authorizing doctors to prescribe only immediate release drugs in the lowest effective dose for this purpose;

- referring prescribers to the CDC Guideline;

- requiring insurers to cover addiction treatment for a period of 180 days—without delays or limits—when prescribed by a licensed provider; and

- passing legislation that provides funding and authority for health care providers to prescribe, and first responders to administer, overdose antidotes.

240. The State has taken concrete steps to limit the prescribing of long-term opioid use for chronic pain. The New Jersey Legislature passed legislation in February 2017 that requires practitioners to take certain affirmative steps before issuing an initial opioid prescription to treat chronic pain. The practitioner is required to prescribe the lowest effective dose and to disclose and discuss:

- risks of addiction and overdose even when the drug is taken precisely as prescribed;

- alternative therapies;

- the reasons why the prescription is necessary.

Before issuing a third refill prescription, practitioners are required to enter into a "pain management agreement" with patients which, among other things:

- documents a pain management plan;

- identifies other non-opioid medication and modes of treatment that are part of the pain treatment program;

- specifies measures that will be used to confirm proper prescription use, like toxicology screening and pill-counting.

Where opioid use is continuous and long-term, the practitioners must:

- assess the patient before issuing each renewal prescription;
- document the course of treatment, the patient's progress, and new information about the etiology of the pain every three months;
- assess whether the patient is experiencing problems associated with physical and psychological dependence and document the assessment;
- make periodic efforts to taper the dosage or otherwise reduce or discontinue opioid use; and
- refer the patient to a pain management or addiction specialist for independent evaluation or treatment.

241. The State Board of Medical Examiners' implementing regulations took effect in March 2017 and were consistent with the standards set forth in the 2016 CDC Guideline.

242. The State has also taken steps to limit its own coverage of long-term opioid use for chronic pain. The State presented the CDC Guideline to Medicaid vendors in April 2016. The State has also ratified coverage restrictions proposed by Express Scripts, applicable to the Employee Health Plans, for the purpose of monitoring and creating safer opioids utilization.

3. Purdue's Deceptive Marketing Has Caused Financial Injury to New Jersey Consumers.

243. Consumers, private employers, and insurers are paying costs similar to, but far greater than, the State for opioid prescriptions. These costs are paid out-of-pocket by individuals who are uninsured or who are insured through plans that require pharmacy co-payments; by employers that provide health insurance or self-fund health care coverage for their employees; and by insurance companies that provide managed care and traditional point-of-service plans to individuals, corporations, and political subdivisions. According to a 2015 report by a national economic consulting firm, New Jersey's annual health care costs related to opioid use and abuse were estimated to exceed $683 million, the majority of which is privately paid.

244. Because the State requires private employers and political subdivisions to provide workers' compensation to employees injured in the course of work, private employers and political subdivisions are incurring costs through their workers' compensation programs, too. According to a 2011 study by the National Council on Compensation Insurance ("NCCI"), approximately 38% of pharmacy costs in workers' compensation are for opioids and opioid combinations, amounting to approximately $1.4 billion in that year nationally.

### E. Purdue Knew that Its Marketing of Opioids Was False and Misleading, and the Company Fraudulently Concealed Its Misconduct.

245. Purdue made, promoted, and profited from its misrepresentations about the risks and benefits of opioids for chronic pain even though it knew that its 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 Purdue of this, and Purdue entered into settlements in the hundreds of millions of dollars to address similar misconduct that occurred before 2008. Purdue 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 Purdue's misrepresentations.

246. Notwithstanding this knowledge, at all times relevant to this Complaint, Purdue took steps to avoid detection of and to fraudulently conceal its deceptive marketing and unlawful and fraudulent conduct, and also to conceal or minimize questions or concerns raised by prescribers about addiction.

247. Purdue's 2007 settlement with the federal government included a Corporate Integrity Agreement ("CIA"). Section III of the Purdue CIA is entitled Corporate Integrity Obligations, which includes a statement of certain policies and procedures that Purdue agreed to implement and enforce. These policies and procedures include certain rules pertaining to the conduct of Purdue's sales force (the detailers). In particular, Section III(2)(c) requires Purdue to establish written procedures "governing the response to requests for information about . . . withdrawal, drug tolerance, drug addiction or drug abuse of Purdue's products."

248. Purdue has evaded its responsibility to provide information in response to prescriber requests for information by deflecting questions from prescribers about the risk of addiction. In response to such questions, Purdue sales representatives instead have focused on opioid dependence, speaking of it as a normal, benign consequence of opioid use; and opioid abuse, falsely suggesting that the company's "abuse-deterrent opioids" actually can curb misuse. These deflections misleadingly reassured doctors that they could safely prescribe Purdue's opioids long-term for chronic pain. According to a Purdue "Sales Representative Standards of Performance" document, which was revised March 3, 2008 and was still in use with Purdue detailers until at least July 2012, sales representatives were instructed to record "pertinent information [from the doctor visit] . . . in the free text call note box." Given the highly addictive properties of Purdue's opioids, and the specific wording of the Corporate Integrity Agreement, it is reasonable to expect that questions or concerns voiced by prescribers about addiction would be included in the call notes.

249. As part of the State's investigation, Purdue produced a total of [redacted]

[redacted] The conclusions are not mutually exclusive.

250. In fact, one former New Jersey sales representative specifically recalled her manager expressly instructing her not to include references to doctors expressing concern about addiction, the epidemic of opioid abuse, or the street value of OxyContin. She was told to keep her call notes generic to avoid raising any red flags that Purdue's headquarters would need to report in light of the Purdue CIA. Her manager told her that these kinds of hot-button topics could initiate an inquiry into the company's compliance with the CIA and would cause trouble. This former Purdue detailer described her call notes as "incomplete" and "a joke" because they did not accurately reflect the full scope of pertinent topics discussed during the visit—especially questions about addiction, which she recalled prescribers asking.

251. The State's review [redacted]

252. In addition, [redacted]

253. Purdue also disguised its 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 purposefully hid behind the assumed credibility of these sources and relied on them to establish the accuracy and integrity of Purdue's false and misleading messages about the risks and benefits of long-term opioid use for chronic pain. Purdue masked or never disclosed its role in shaping, editing, and approving the content of this information. Purdue also distorted the meaning or import of studies it cited and offered them as evidence for propositions the studies did not support.

254. Further, Purdue has failed to report to authorities illicit or suspicious prescribing of its opioids, even as it has publicly and repeatedly touted its "constructive role in the fight against opioid abuse" and "strong record of coordination with law enforcement."[48]

[48] Purdue Pharma L.P., "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 Pharma L.P., "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/.

255. Purdue's public stance long has been that patients who deliberately misuse opioids and the diversion of pills to illicit secondary channels—not overprescribing of OxyContin and other opioids for chronic pain—are to blame for widespread addiction and abuse. To address these issues, Purdue has funded various drug abuse prevention programs nationwide and in New Jersey, and, most notably, introduced abuse-deterrent opioids reformulated to make non-oral ingestion more difficult. Purdue also pumps out research, presented at conferences of addiction prevention professionals, stressing the importance of patient selection and touting the efficacy of its "abuse deterrent" opioids. Depicting the opioid crisis as a problem of misuse and diversion, and promoting its pills as solutions, 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.

256. 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 features in virtually all of Purdue's recent pronouncements in response to public scrutiny of opioid abuse.

257. Touting the benefits of opioids with abuse-deterrent formulations, 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 . . . ."[49] Purdue's statement on "Opioids Corporate Responsibility" likewise states that "[f]or many years, Purdue has committed

[49] Purdue Pharma L.P., "Opioids With Abuse-Deterrent Properties," http://www.purduepharma. com/healthcare-professionals/responsible-use-of-opioids/opioids-with-abuse-deterrent-properties/ (visited Oct. 17, 2017).

substantial resources to combat opioid abuse by partnering with . . . communities, law enforcement, and government."[50] 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."[51]

258. These public pronouncements create the misimpression that Purdue is proactively working with law enforcement and government authorities, nationwide and in New Jersey, to root out drug diversion, including the illicit prescribing that can lead to diversion. They aim to distance Purdue from its past, publicly admonished, conduct in deceptively marketing opioids, which gave rise to 2007 criminal pleas, and to make its current marketing seem more trustworthy and truthful. In fact, Purdue has consistently failed to report suspicious prescribing to authorities, despite having all the necessary tools—detailed prescribing data and the eyes and ears of its sales force—to observe such practices.

259. Since at least 2002, Purdue has maintained a database of health care providers suspected of inappropriately prescribing OxyContin or other opioids. According to Purdue, 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 volume. Purdue has said publicly that "[o]ur procedures help ensure that whenever we observe potential abuse or diversion activity, we discontinue our company's interaction with

[50] Purdue Pharma L.P., "Opioids Corporate Responsibility," http://www.purduepharma.com/news-media/opioids-corporate-responsibility/ (visited Oct. 17, 2017).

[51] Purdue Pharma L.P., "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/.

the prescriber or pharmacist and initiate an investigation."[52] According to Purdue, health care providers added to the database no longer are detailed, and sales representatives receive no compensation tied to these providers' prescription.

260. Yet, according to a 2016 investigation by the Los Angeles Times, Purdue failed to cut off these providers' opioid supply at the pharmacy level—meaning Purdue continued to generate sales revenue from their prescriptions—and failed to report these providers to state medical boards or law enforcement. In an interview with the Times, Purdue's former senior compliance officer acknowledged that in five years of investigating suspicious pharmacies, Purdue consistently failed to report suspicious dispensing or to stop supplies to the pharmacy, even where Purdue employees personally witnessed the diversion of its drugs. The same was true of prescribers. Despite its knowledge of illicit prescribing, Purdue did not report its suspicions, for example, until years after law enforcement shut down a Los Angeles clinic that Purdue's district manager described internally as "an organized drug ring" and that had prescribed more than 1.1 million OxyContin tablets. The New York Attorney General's settlement with Purdue specifically cited the company for failing to adequately address suspicious prescribing.

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

[52] Id.

## V. CAUSES OF ACTION

### COUNT ONE
### DECEPTIONS, MISREPRESENTATIONS, AND OMISSIONS OF MATERIAL FACTS VIOLATIONS OF THE CONSUMER FRAUD ACT, N.J.S.A. 56:8-2

262. Plaintiffs re-allege and incorporate by reference each of the allegations contained in the preceding paragraphs of this Complaint as though fully alleged herein.

263. The Consumer Fraud Act makes it unlawful for a business to engage in "deception, fraud, false pretense, false promise, misrepresentation, or the knowing concealment, suppression or omission of any material fact with intent that others may rely upon such concealment, suppression or omission" in connection with the sale or advertisement of pharmaceutical products. N.J.S.A. 56:8-1, 56:8-2.

264. The CFA defines "advertisement" as:

> . . . the attempt directly or indirectly by publication, dissemination, solicitation, indorsement or circulation or in any other way to induce directly or indirectly any person to enter or not enter into any obligation or acquire any title or interest in any merchandise or to increase the consumption thereof . . . .

N.J.S.A. 56:8-1(a).

265. The CFA defines "merchandise" as including "any objects, wares, goods, commodities, services or anything offered, directly or indirectly to the public for sale." N.J.S.A. 56:8-1(c).

266. The CFA defines "sale" as "any sale, rental or distribution, offer for sale, rental or distribution or attempt directly or indirectly to sell, rent or distribute." N.J.S.A. 56:8-1(e).

267. Purdue is a "person" as defined by the CFA and has advertised, offered for sale, and sold "merchandise" also as defined by the CFA.

268. Pharmaceutical manufacturers, like Purdue, are required to comply with the provisions of the CFA in their marketing, promotion, sale, and distribution of prescription drugs.

269. At all times relevant to this Complaint, Purdue violated N.J.S.A. 56:8-2 by engaging in the deceptive marketing and promotion of its products by:

(a) making and disseminating false or misleading statements about the use of opioids to treat chronic pain;

(b) causing false or misleading statements about opioids to be made or disseminated;

(c) making statements to promote the use of opioids to treat chronic pain that omitted or concealed material facts; and

(d) failing to correct prior misrepresentations and omissions about the risks and benefits of opioids.

270. Purdue's statements about the use of opioids to treat chronic pain were not supported by or were contrary to substantial scientific evidence, as confirmed by recent pronouncements of the CDC and FDA based on that evidence. Further, Purdue's material omissions, which were false and misleading in their own right, rendered even seemingly truthful statements about opioids false and misleading because they were incomplete. Finally, at the time it made or disseminated its false and misleading statements or caused these statements to be made or disseminated, Purdue knowingly failed to include material facts about the risks and benefits of long-term opioid use and intended that the recipients of its marketing messages would rely upon those omissions.

271. At all times relevant to this Complaint, Purdue violated N.J.S.A. 56:8-2 by making misrepresentations, including, but not limited to, the following:

(a) Claiming or implying that opioids would improve patients' function and quality of life;

(b) Mischaracterizing the risk of opioid addiction and abuse, including by stating or implying that "steady state" and abuse-deterrent properties meant the drugs were less likely to be addictive or abused, and that specific opioid drugs were less addictive or less likely to be abused than other opioids;

(c) Claiming or implying that addiction can be avoided or successfully managed through the use of screening and other tools;

(d) Promoting the misleading concept of pseudoaddiction and emphasizing the prevalence of dependence, thus concealing the true risk of addiction;

(e) Claiming or implying that increasing the dose of opioids (titrating up) poses no significant additional risk;

(f) Misleadingly depicting the safety profile of opioids by minimizing their risks and adverse effects while emphasizing the risks of competing products, including NSAIDs and acetaminophen; and

(g) Mischaracterizing OxyContin's onset of action and duration of efficacy to imply that the drug provides a full 12 hours of pain relief, when Purdue knew it does not.

272. By reason of Purdue's conduct, New Jersey consumers have suffered substantial injury as described above.

273. As a direct result of the foregoing deceptions, misrepresentations, and omissions of material fact, Purdue obtained income, profits and other benefits that it would not otherwise have obtained.

**WHEREFORE** Plaintiffs request an order: permanently enjoining Purdue from engaging in these deceptive acts and practices; directing the disgorgement of any money acquired or retained as a result of these practices; directing restitution of money Purdue acquired by virtue of these practices; directing payment of civil penalties against Purdue for each violation of the Consumer Fraud Act; and awarding attorneys' fees and costs to the State.

**COUNT TWO**
**UNCONSCIONABLE COMMERCIAL PRACTICES**
**VIOLATIONS OF THE CONSUMER FRAUD ACT, N.J.S.A. 56:8-2**

274. Plaintiffs re-allege and incorporate by reference each of the allegations contained in the preceding paragraphs of this Complaint as though fully alleged herein.

275. The Consumer Fraud Act makes it unlawful for a business to engage in any unconscionable commercial practice in connection with the sale or advertisement of pharmaceutical products. N.J.S.A. 56:8-2.

276. At all times relevant to this Complaint, Purdue violated N.J.S.A. 56:8-2 by engaging in the following unconscionable commercial practices:

(a) Engaging in deceptive, fraudulent, false, and misleading marketing that was unsupported by substantial scientific evidence to support its product claims in violation of 21 C.F.R. § 202.1(e);

(b) Engaging in a marketing campaign that failed, despite the known, serious risks of addiction and adverse effects posed by opioids, to present a fair balance of benefit and risk information in its promotion of opioids, in violation of FDA regulations, including 21 C.F.R. § 202.1(e);

(c) Promoting the purported advantages of opioids over other pain relief products, including but not limited to the risks and/or benefits of opioids in comparison to NSAIDs or acetaminophen, without substantial scientific evidence to support those claims, in violation of FDA regulations, including 21 C.F.R. § 202.1(e);

(d) Promoting high doses for extended periods of time, in contravention of longstanding public policy to avoid and minimize the risk of addiction and abuse of controlled substances;

(e) Targeting a vulnerable population—the elderly—for promotion of opioids to treat chronic pain in the face of the known, heightened risks of opioid use to that population, including risks of addiction, adverse effects, hospitalization, and death;

(f) Targeting opioid naïve patients and patients using IR or weaker (Schedule III) opioids for conversion to Purdue's ER/LA opioid products; and

(g) Using unbranded marketing, front groups, and key opinion leaders to evade FDA oversight and rules prohibiting deceptive marketing and to deceive prescribers and consumers regarding the impartiality of the information conveyed.

277. These acts or practices may be deemed unconscionable and unfair in that they offend public policy reflected in (a) federal law, which requires the truthful and balanced marketing of prescription drugs, 21 C.F.R. § 202.1(e); (b) the CFA, which protects consumers and competitors from deceptive marketing and to ensure an honest marketplace; and (c) State legislation and standards of practice related to controlled substances—including but not limited to the prescribing and dispensing standards set forth in N.J.A.C. 13:35-7.6—which seek to minimize the risk of addiction to and abuse of controlled substances.

278. These acts or practices were unconscionable because they unethically deprived prescribers of the information they needed to appropriately prescribe, or not prescribe, these dangerous drugs. Patients who use opioids can quickly become dependent and addicted, such that neither the patient nor the prescriber can avoid injury by simply stopping or choosing an alternate treatment.

279. By reason of Purdue's conduct, New Jersey consumers have suffered substantial injury, including but not limited to the financial costs, pain, and suffering associated with opioid addiction, injury, disability, overdose, and death.

280. As a direct result of the foregoing unconscionable acts and practices, Purdue obtained income, profits, and other benefits that it would not otherwise have obtained.

**WHEREFORE** Plaintiffs request an order: permanently enjoining Purdue from engaging in these unconscionable acts and practices; directing the disgorgement of any money acquired or retained as a result of these practices; directing restitution of money Purdue acquired by virtue of these unconscionable acts and practices; directing payment of civil penalties against Purdue for each unconscionable commercial practice; and awarding attorneys' fees and costs to the State.

**COUNT THREE**
**UNCONSCIONABLE COMMERCIAL PRACTICES TARGETING THE ELDERLY**
**VIOLATIONS OF THE CONSUMER FRAUD ACT, N.J.S.A. 56:8-2**

281. Plaintiffs re-allege and incorporate by reference each of the allegations contained in the preceding paragraphs of this Complaint as though fully alleged herein.

282. The CFA provides for additional penalties for pecuniary injury to a senior citizen.

283. At varying times, Purdue has targeted senior citizens as part of its strategy to continue expanding its market share in the sale of opioids, and, as such, its revenue.

284. Among other things, Purdue sales representatives have focused on the nursing home market and educating physicians about Medicare Part D coverage for opioids.

285. Elderly patients taking opioids are at a greater risk for fractures and hospitalization and have increased vulnerability to adverse drug effects, such as respiratory depression.

286. N.J.S.A. 56:8-14.3 provides: "In addition to any other penalty authorized by law, a person who violates the provisions of [the CFA] shall be subject to additional penalties as follows: A penalty of not more than $10,000 if the violation caused the victim of the violation pecuniary injury and the person knew or should have known that the victim is a senior citizen[;] or [a] penalty of not more than $30,000 if the violation was part of a scheme, plan, or course of conduct directed at senior citizens . . . in connection with sales or advertisements."

287. Each instance in which Purdue engaged in deceptive practices in connection with its marketing and sale of opioids to senior citizens falls within the scope of additional penalties provided by N.J.S.A. 56:8-14.3.

288. As a direct result of the foregoing deceptive and unconscionable acts and practices, Purdue obtained income, profits, and other benefits that it would not otherwise have obtained.

**WHEREFORE** Plaintiffs request an order: directing restitution of the amount of money Purdue acquired by virtue of these deceptive and unconscionable acts and practices; directing payment of the enhanced civil penalties authorized under N.J.S.A. 56:8-14.3 against Purdue for each deceptive and unconscionable commercial practice directed at senior citizens; and awarding attorneys' fees and costs to the State.

**COUNT FOUR**
**FALSE CLAIMS**
**VIOLATIONS OF THE NEW JERSEY FALSE CLAIMS ACT, N.J.S.A. 2A:32C-1**

289. Plaintiffs re-allege and incorporate herein by reference each of the allegations contained in the preceding paragraphs of this Complaint as though fully alleged herein.

290. A person is liable under the New Jersey False Claims Act, N.J.S.A. 2A:32C-3, when that person:

> (1) knowingly presents or causes to be presented to an employee, officer, or agent of the State, or to any contractor, grantee, or other recipient of State funds, a false or fraudulent claim for payment or approval;
>
> (2) knowingly makes, uses, or causes to be made or used, a false record or statement to get a false or fraudulent claim paid or approved by the State.

N.J.S.A. 2A:32C-2 defines a "claim" as:

> a request or demand, under a contract or otherwise, for money, property, or services that is made to any employee, officer, or agent of the State, or to any contractor, grantee, or other recipient if the State provides any portion of the money, property, or services requested or demanded, or if the State will reimburse the contractor, grantee, or other recipient for any portion of the money, property, or services requested or demanded.

291. Purdue's practices, as described in the Complaint, violated N.J.S.A. 2A:32C-3. Purdue, through its deceptive marketing of opioids for chronic pain, presented or caused to be presented false or fraudulent claims and knowingly used or caused to be used false statements to get false or fraudulent claims paid or approved by the State.

292. Purdue knew, deliberately ignored, or recklessly disregarded, at the time of making or disseminating these statements, or causing these statements to be made or disseminated, that such statements were untrue, false, misleading, or unsupported by substantial scientific evidence, and were made for the purpose of inducing the State, through its employees

and contractors, to pay for opioids for long-term treatment of chronic pain. In addition, Purdue knew or should have known that its marketing and promotional efforts created an untrue, false, and misleading impression about the risks, benefits, and superiority of opioids for chronic pain.

293. Purdue's scheme caused doctors and other prescribers to write prescriptions for opioids to treat chronic pain that were presented to the State's Medicaid, Employee Health, and Workers' Compensation plans for payment. Doctors, pharmacists, other health care providers, and/or other agents of the health plans and Workers' Compensation program expressly or impliedly certified to the State that opioids were medically necessary and reasonably required to treat chronic pain because they were influenced by the false and misleading statements disseminated by Purdue through the marketing campaign described in Sections IV.A and IV.B above. To the extent that such prescribing was considered customary or consistent with generally accepted medical standards, those standards were influenced and ultimately corrupted by Purdue's deceptive marketing as well.

294. Purdue knew or should have known that, as a natural consequence of its actions, governments such as the State would necessarily be paying for long-term prescriptions of opioids to treat chronic pain, which were dispensed as a consequence of Purdue's fraud. The misrepresentations Purdue made and caused to be made were material to the State's decisions to pay the costs of long-term opioid use because they falsely suggested that such treatment was medically necessary.

295. The State has paid millions of dollars for opioid prescriptions that were represented to the State as medically necessary. These prescriptions would not have been prescribed or covered and reimbursed by State insurance plans but for Defendants' deceptive, fraudulent, and unlawful marketing practices.

296. The State has paid and will continue to pay consequential health care costs necessitated by Purdue's deceptive, fraudulent, and unlawful marketing practices: drugs for persons dependent upon and addicted to opioids and treatment costs for those dealing with addiction, overdose, and other adverse effects.

**WHEREFORE** Plaintiffs request an order: enjoining Purdue from engaging in conduct that violates N.J.S.A. 2A-32C-3; requiring Purdue to pay the maximum civil penalty for each false or fraudulent claim Purdue caused to be presented to an official, employee, or contractor of the State for payment or approval; requiring Purdue to pay three times the amount of damages, including consequential damages, sustained by the State for each violation of this section; compelling Purdue to pay the cost of the suit, including attorneys' fees under N.J.S.A. 2A:32C-8; and awarding the State such other, further, and different relief as this Court may deem just.

**COUNT FIVE**
**PUBLIC NUISANCE**

297. Plaintiffs re-allege and incorporate herein by reference each of the allegations contained in the preceding paragraphs of this Complaint as though fully alleged herein.

298. Purdue, through the actions described in the Complaint, has created—or was a substantial factor in creating—a public nuisance by unreasonably interfering with a right common to the general public that harms the health, safety, peace, comfort, or convenience of the general community.

299. The State and its citizens have a public right to be free from the substantial injury to public health, safety, peace, comfort, and convenience that has resulted from Purdue's illegal and deceptive marketing of opioids for the treatment of chronic pain.

300. This injury to the public includes, but is not limited to (a) widespread dissemination of false and misleading information regarding the risks and benefits of opioids to

treat chronic pain; (b) a distortion of the medical standard of care for treating chronic pain, resulting in pervasive overprescribing of opioids and the failure to provide more appropriate pain treatment; (c) high rates of opioid abuse, injury, overdose, and death, and their impact on New Jersey families and communities; (d) increased health care costs for individuals, families, employers, and the State; (e) lost employee productivity resulting from the cumulative effects of long-term opioid use, addiction, and death; (f) the creation and maintenance of a secondary, criminal market for opioids; and (g) greater demand for emergency services and law enforcement paid for by the State at the ultimate cost of taxpayers.

301. At all times relevant to the Complaint, Purdue's marketing substantially and unreasonably interfered in the enjoyment of this public right by the State and its citizens. Purdue engaged in a pattern of conduct that (a) overstated the benefits of chronic opioid therapy, including by misrepresenting OxyContin's duration of efficacy and by failing to disclose the lack of evidence supporting long-term use of opioids; and (b) obscured or omitted the serious risk of addiction arising from such use. This conduct effected and maintained a shift in health care providers' willingness to prescribe opioids for chronic pain, resulting in a dramatic increase in opioid prescribing and the injuries described above.

302. At all times relevant to the Complaint, Purdue exercised control over the instrumentalities constituting the nuisance—i.e., its marketing as conveyed through sales representatives, other speakers, and publications, and its program to identify suspicious prescribing. As alleged herein, Purdue created, or was a substantial factor in creating, the nuisance through multiple vehicles, including (a) making in-person sales calls; (b) disseminating advertisements and publications; (c) sponsoring and creating flawed and biased scientific research and prescribing guidelines; and (d) sponsoring and collaborating with third parties to

disseminate false and misleading messages about opioids. To the extent Purdue worked through third parties, it adopted their statements as its own by disseminating their publications, and/or exercised control over them by financing, reviewing, editing, and approving their materials.

303. Purdue's actions were a substantial factor in creating the public nuisance by deceiving prescribers and patients about the risks and benefits of opioids and distorting the medical standard of care for treating chronic pain. Without Purdue's actions, opioid use would not have become so widespread, and the opioid epidemic that now exists in New Jersey would have been averted or would be much less severe.

304. The public nuisance was foreseeable to Purdue. As alleged herein, Purdue engaged in widespread promotion of opioids in which it misrepresented the risks and benefits of opioids to treat chronic pain. Purdue knew that there was no evidence showing a long-term benefit of opioids on pain and function, and that opioids carried serious risks of addiction, injury overdose, and death. Purdue was positioned to foresee not only a vastly expanded market for chronic opioid therapy as the likely result of Purdue's conduct, but also the widespread problems of opioid addiction and abuse that have, in fact, materialized. Purdue was on notice and aware of signs that the broader use of opioids was causing just the kinds of injuries described in this Complaint.

305. This public nuisance can be abated—in part—through health care provider and consumer education on appropriate prescribing, honest marketing of the risks and benefits of long-term opioid use, addiction treatment, disposal of unused opioids, and other means.

**WHEREFORE** Plaintiffs request an order: providing for abatement of the nuisance that Purdue created, or was a substantial factor in creating; enjoining Purdue from further conduct

contributing to the nuisance; and awarding damages to redress the consequential damages resulting from Purdue's creation of a public nuisance.

## VI. PRAYER FOR RELIEF

**WHEREFORE**, Plaintiffs respectfully request the Court enter judgment against Purdue:

(a) awarding judgment in its favor and against Purdue on each cause of action asserted in the Complaint;

(b) assessing treble damages for the payments made by or on behalf of the State for opioid prescriptions covered by the State's Medicaid, Employee Health and Workers' Compensation programs;

(c) assessing the maximum statutory civil penalties for each violation of the New Jersey False Claims Act;

(d) permanently enjoining Purdue from engaging in the deceptive and unconscionable acts and practices described in the Complaint;

(e) assessing maximum statutory civil penalties for each violation of the Consumer Fraud Act;

(f) requiring Purdue to disgorge all funds acquired and/or retained as a result of any acts or practices in violation of the CFA;

(g) requiring Purdue to restore to any affected person, whether or not named in this Complaint, any money acquired by means of any alleged practice herein to be unlawful and found to be unlawful, as authorized by the CFA;

(h) requiring Purdue to abate the public nuisance its conduct has created;

(i) directing Purdue to disgorge any money unjustly acquired by virtue of the conduct described in the Complaint;

(j) requiring Purdue to pay the costs of the suit, including attorneys' fees; and

(k) awarding such other, further, and different relief as this Court may deem just.

Dated: October ___, 2017
Newark, New Jersey

CHRISTOPHER S. PORRINO
ATTORNEY GENERAL OF NEW JERSEY
Attorney for Plaintiffs

By: _____

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## RULE 4:5-1 CERTIFICATION

I certify, to the best of my information and belief, that the matter in controversy in this action is not the subject of any other action pending in any other court of this State. I further certify, to the best of my information and belief, that the matter in controversy in this action is not the subject of a pending arbitration proceeding in this State, nor is any other action or arbitration proceeding contemplated.

Dated: October ___, 2017
Newark, New Jersey

CHRISTOPHER S. PORRINO
ATTORNEY GENERAL OF NEW JERSEY
Attorney for Plaintiffs

By: _____


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Deputy Attorney General, Assistant Chief
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**RULE 1:38-7(c) CERTIFICATION OF COMPLIANCE**

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 R. 1:38-7(b).

Dated: October ___, 2017
Newark, New Jersey

CHRISTOPHER S. PORRINO
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Attorney for Plaintiffs

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**DESIGNATION OF TRIAL COUNSEL**

Pursuant to R. 4:25-4, John E. Keefe, Jr. is hereby designated as trial counsel for the Plaintiffs in this action.

Dated: October ___, 2017
Newark, New Jersey

CHRISTOPHER S. PORRINO
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