THE STATE OF NEW HAMPSHIRE

MERRIMACK, SS SUPERIOR COURT

Docket No. _____

STATE OF NEW HAMPSHIRE

V.

PURDUE PHARMA, L.P.;
PURDUE PHARMA INC.; and
THE PURDUE FREDERICK COMPANY

COMPLAINT

NOW COMES the State of New Hampshire ("State"), by and through the Attorney General's Office, and complains as follows against the above-captioned Defendants.

CONTENTS

I. INTRODUCTION

1. 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 Hampshire.

2. 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.[1] Like

[1] Since 1970, opioids have been regulated under the Controlled Substances Act ("CSA"). Controlled substances are categorized in five schedules, ranked in order of their potential for abuse, with Schedule I the highest. The CSA imposes a hierarchy of restrictions on prescribing and dispensing drugs based on their medicinal value, likelihood of addiction or abuse, and safety. Opioids generally have been categorized as Schedule II or Schedule III drugs. Schedule II drugs have a high potential for abuse, have a currently accepted medical use, and may lead to severe psychological or physical dependence; Schedule III drugs are deemed to have a lower potential for abuse, but their abuse still may lead to moderate or low physical dependence or high

heroin, prescription opioids work by binding to receptors on the spinal cord and brain, dampening the perception of pain. Opioids also can create a euphoric high, which can make them addictive, and at higher doses, they can slow the user's breathing, causing potentially fatal respiratory depression. Further, 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 opioid use is delayed or discontinued. These symptoms may persist for months, or even years, after a complete withdrawal from opioids, depending on length of use. When using opioids continuously, patients grow tolerant to their analgesic effects—requiring progressively higher doses and increasing the risks of withdrawal, addiction, and overdose.

3. These adverse effects were well-recognized in the medical community. Before the 1990s, opioids typically were used only to treat short-term acute pain or for palliative (end-of-life) care because they were considered too addictive and debilitating for long-term use.[2] This prevailing understanding sharply limited the market for prescription opioids.

4. As Purdue developed OxyContin in the mid-1990s, it knew that to realize blockbuster profits, it needed to change the perception of opioids to permit and encourage the use of opioids not just for acute and palliative care, but also long-term for chronic conditions, like back pain, migraines, and arthritis. Purdue both fostered and capitalized upon the concepts 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. Purdue piggybacked on these initiatives to promote opioids generally, and its opioids in particular, as safe, effective, and appropriate for even long-term use for routine pain conditions. Specifically, Purdue

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psychological dependence. 21 U.S.C. § 812. OxyContin and Hysingla ER are Schedule II drugs; Butrans is a Schedule III drug.

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

misrepresented the risk of addiction as modest, manageable, and outweighed by the benefits of opioid use.

5. Purdue spent hundreds of millions of dollars on promotional activities and materials that falsely denied or trivialized the risk of addiction and overstated the benefits of opioids. These activities, conducted nationally and in New Hampshire, included directly marketing Purdue opioids to prescribers through advertising, websites, and in-person sales calls. Purdue also relied upon continuing medical education ("CME") treatment guidelines and other publications and programs by patient advocacy groups [redacted], professional associations, and physicians that were flawed and misleading, but seemed independent and therefore credible.

6. Purdue's marketing scheme, which occurred alongside similar, smaller-scale efforts of other opioid manufacturers, was resoundingly successful. Between 80% and 90% of opioids (measured by weight) used today are for chronic pain, [redacted]

7. Although Purdue and three of its executives pleaded guilty to federal criminal charges for deceptive conduct in 2007, and reached civil settlements with 26 states and the District of Columbia that same year,[3] 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. Numerous New Hampshire physicians interviewed by the State described absorbing, whether on the job, in residency, or in medical school, the twin

[3] New Hampshire did not enter a settlement with Purdue Pharma.

understandings that compassionate treatment of pain required prescribing opioids and that patients receiving opioids for legitimate pain conditions are unlikely to become addicted.

8. To this day, Purdue not only purposely benefits from its earlier misconduct, but persists in disseminating the same types of misleading messages that previously earned it censure. From 2011 to the present—the principal focus of this Complaint—Purdue maintained and expanded the market for its opioids in New Hampshire. First, Purdue continued to deceptively portray the risks and benefits of chronic opioid therapy, particularly the risk of addiction. Second, Purdue failed to correct, and thus was able to build upon and profit from, its prior misrepresentations. Purdue's current misrepresentations, which echo and rely upon its past deceptive marketing, allowed it to benefit from— and obligated it to correct— its past misconduct. Purdue also sought through its public presentations to distance itself from its past misconduct and to build confidence in its more recent marketing by falsely promoting the safety of its abuse-deterrent ("AD") formulations and its efforts to rein in the diversion and abuse of opioids, while privately failing to report suspicious prescribing, including in New Hampshire.

9. Specifically, both before and since 2011, Purdue has falsely and misleadingly: (1) continued to downplay the serious risk of addiction,[4] including by claiming that signs of addiction instead reflected undertreated pain; (2) overstated the effectiveness of screening tools in preventing addiction, giving prescribers unwarranted confidence they could safely prescribe opioids; (3) denied or failed to disclose the greater risks of opioids at higher doses; and (4) exaggerated the effectiveness of AD opioids to prevent abuse and addiction. As to benefits,

[4] Addiction is classified as a spectrum of "substance use disorders" that range from misuse and abuse of drugs to addiction. Patients suffer negative consequences wherever they fall on this spectrum. In this Complaint, "addiction" refers to the entire range of substance abuse disorders.

Purdue has (1) falsely claimed that chronic opioid therapy would improve patients' function and quality of life, even though there was—and still is—no good evidence to support these claims and significant evidence to the contrary; and (2) misleadingly promoted OxyContin as providing a full 12 hours of pain relief, when 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, addiction, and overdose.[5] By overstating the benefits of opioids, and understating their very serious risks, Purdue was able to rebalance the scale in favor of prescribing its opioids.

10. Purdue knew that its longstanding and ongoing misrepresentations of the risks and benefits of opioids were not supported by or were 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 and Prevention (CDC), including by the CDC in its 2016 *Guideline for Prescribing Opioids for Chronic Pain* ("2016 CDC Guideline"), which exhaustively reviewed the evidence on opioids.[6]

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[5] Opioids vary by duration. Long-acting or extended-release opioids ("ER/LA") purport to provide continuous opioid therapy for extended periods. Purdue's OxyContin, Hysingla ER, and Butrans are all long-acting opioids. In addition, opioids may be taken in short-acting formulations, also known as immediate release ("IR") opioids, which last approximately 4-6 hours. While it once was thought that ER/LA opioids were not as susceptible to abuse and addiction as short-acting ones, this view has been discredited. The FDA has required makers of ER/LA opioids to adopt "Risk Evaluation Mitigation Strategies" because the drugs present a "serious public health crisis of addiction, overdose, and death." FDA, Risk Evaluation and Mitigation Strategy (REMS) for Extended-Release and Long-Acting Opioids (Aug. 2014), *available at* http://www.fda.gov/Drugs/DrugSafety/InformationbyDrugClass/ucm163647.htm. In 1998, Purdue's OxyContin FDA label advised that it was less addictive than short-acting opioids, but this claim was removed by 2001. OxyContin's label now states, as do all labels of Schedule II ER/LA opioids, that the drug "exposes users to risks of addiction, abuse, and misuse, which can lead to overdose and death."

[6] As alleged herein, Purdue's marketing violates the prohibition in RSA 358-A:2 against deceptive acts or practices. Purdue also is governed by FDA rules requiring truthful marketing

11. Purdue's deceptive marketing, which drove prescribing not only of Purdue opioids but of opioids as a class, has opened the floodgates to opioid prescribing, use and abuse. Opioids are now among the most prescribed class of drugs. In 2015, health care providers wrote enough opioid prescriptions to medicate every American around the clock for three weeks. On an average day, more than 650,000 opioid prescriptions are dispensed in the U.S. In New Hampshire, in 2012, there were 72 opioid prescriptions for every 100 residents. From October 2014 to September 2015, between 12 and 15.3 million doses of narcotic pain relievers were dispensed in the state each quarter.

12. Purdue accounts for much of the prescribing of branded opioids in New Hampshire— [redacted]. In 2015, Purdue reaped an estimated $2.4 billion in revenue, virtually all of it from the sale of opioids.

13. Rather than compassionately helping patients, this explosion in opioid 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 [of opioids] far outweigh the unproven and transient benefits."[7] As one doctor stated: "This was an experiment on the population of the United States. It wasn't randomized, it wasn't controlled, and no data was collected until they started gathering death statistics."

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of prescription drugs. A drug company's branded marketing, which identifies and promotes a specific drug, must (a) be consistent with its label and supported by substantial scientific evidence; (b) not include false or misleading statements or material omissions; and (c) fairly balance the drug's benefits and risks. The regulatory framework governing the marketing of specific drugs reflects a public policy designed to ensure that drug companies, which are best suited to understand the properties and effects of their drugs, are responsible for providing prescribers with the information they need to accurately assess the risks and benefits of drugs for their patients. *See* 21 U.S.C. § 352(a); 21 C.F.R. §§ 1.21(a), 202.1(e)(3), 202.1(e)(6).

[7] Thomas R. Frieden et al., *Reducing the Risks of Relief — The CDC Opioid-Prescribing Guideline*, 374 New Eng. J. Med. 1501-04 (2016).

14. As a direct result of Purdue's marketing and its dangerously false message that opioids are not addictive but beneficial for chronic pain, the nation is now swept up in what the CDC called a "public health epidemic" and what the U.S. Surgeon General deemed an "urgent health crisis."[8] The increased volume of prescribing correlates directly to skyrocketing addiction, overdose, and death; secondary black markets for diverted prescription opioids as well as heroin and fentanyl; and the social and economic consequences of each of these problems.

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

16. The outcomes in New Hampshire are equally catastrophic— and getting worse. In 2016, the Deputy Administrator of the DEA called New Hampshire "ground zero" of the opioid epidemic. There were 438 fatal overdoses in the state in 2015, more than double the number in 2012. *Per capita*, New Hampshire is second in the nation in overdose deaths. Rates of substance abuse treatment admissions are up sharply, and based on interviews with addiction treatment providers, demand for help far exceeds their resources.

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[8] Daniel Sosin, *Examining the Growing Problems of Prescription Drug and Heroin Abuse,* CDC (Apr. 29, 2014), http://www.cdc.gov/washington/testimony/2014/t20140429.htm.; Vivek H. Murthy, *Letter from the Surgeon General* (July 27, 2017), http://turnthetiderx.org.

17. While opioids have been diverted through illicit prescribing and sales, it is the regular, legitimate prescribing of opioids that created and fueled this crisis. A study of 254 accidental opioid overdose deaths in Utah found that 92% of decedents had been receiving prescriptions from health care providers for chronic pain. Sales to patients who doctor shop (or visit multiple doctors to hide illicit or over-use) constitute roughly 1% of opioid volume— barely a rounding error.

18. Purdue's conduct has violated, and continues to violate, the Consumer Protection Act's prohibitions on deceptive acts and practices and unfair competition, RSA 358-A:2, as well as common-law prohibitions against unjust enrichment and creation of a public nuisance.

19. This Complaint arises from a multi-year investigation conducted by the New Hampshire Attorney General's Office, delayed by challenges to the Office's use of outside counsel to assist in its investigation since rejected by the New Hampshire Supreme Court. As part of that investigation, the Department interviewed physicians, addiction treatment specialists, and other health care providers statewide; took testimony from or interviewed former Purdue employees; obtained data from Medicaid, state health plans, and private insurers; reviewed hundreds of thousands of pages of documents; and gathered information from other state officials, the FDA, and the Drug Enforcement Administration ("DEA").

20. The State seeks an order requiring Purdue to cease its unlawful promotion of opioids, to correct its misrepresentations, and to abate the public nuisance its deceptive marketing has created. The State furthers seek a judgment requiring Purdue to pay civil penalties, restitution, disgorgement, and fees or costs permitted under law.

PARTIES

A. Plaintiff

21. The State of New Hampshire brings this action through its Attorney General's Office. Under the Consumer Protection Act, the Attorney General may bring an action in the name of the State for injunctive relief, restitution, and penalties where, as here, he "has reason to believe that trade or commerce declared unlawful by this chapter has been, is being or is about to be conducted" by any person, including partnerships and corporations. RSA 358-A:4, III; RSA 358-A:1, I.

22. 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 has affected a substantial segment of the population of New Hampshire.

B. Defendants

23. PURDUE PHARMA L.P. is a limited partnership organized under the laws of Delaware. PURDUE PHARMA INC. is a New York corporation with its principal place of business in Stamford, Connecticut, and THE PURDUE FREDERICK COMPANY is a Delaware corporation with its principal place of business at One Stamford Forum, 201 Tresser Boulevard, Stamford, CT, 06901-3431.

24. Purdue manufactures, promotes, sells, and distributes opioids such as OxyContin, MS Contin, Dilaudid, Dilaudid HP, Butrans, Hysingla ER, and Targiniq ER in the United States and New Hampshire. OxyContin is Purdue's best-selling opioid. Since 2009, Purdue's annual sales of OxyContin have fluctuated between $2 and $3 billion. [redacted]

III. JURISDICTION AND VENUE

25. The Court has subject matter jurisdiction over this action under RSA 491:7 and RSA 358-A:4.

26. The Court has personal jurisdiction over Defendants because they regularly transact business in New Hampshire, and the claims asserted herein arise from their business conducted in New Hampshire.

27. Venue in this Court is proper because Defendants are all non-residents. RSA 507:9; RSA 358-A:4, III(a).

IV. FACTUAL ALLEGATIONS

A. Purdue Engaged In a Long-Running Campaign of Deception to Create and Sustain a Market for Its Opioids.

28. Beginning in the late 1990s, 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.

29. The result was that by the mid-2000s, the medical community had abandoned its prior caution, and opioids were entrenched as an appropriate—and often the first—treatment for chronic pain conditions. Purdue not only marketed OxyContin for chronic pain conditions, but targeted primary care physicians (along with nurse practitioners and physician assistants), who were most likely to see patients with chronic pain conditions and least likely to have the training and experience to evaluate 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 the

groundwork for today's epidemic of opioid abuse, injury, and death. It skewed the medical and public understanding of opioids to minimize their risks and exaggerate their benefits—a distortion that Purdue failed to correct, and continues to benefit from. It also provided the base on which Purdue's equally deceptive post-2011 marketing was built.

30. 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 Hampshire. 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 chronic opioid therapy.

31. This misinformation included, most prominently, deceptive statements about the risk of addiction. For example, as the United States Department of Justice found in resolving 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."[9] Similarly, the sales force was taught, and passed on to health care providers, that opioids are not addictive when legitimately prescribed. [redacted] New Hampshire prescribers interviewed by the State recalled hearing then from Purdue detailers the messages that the drug was steady-state (for less euphoria), that the risk of addiction was low, and that pain patients would not become addicted.

[9] *United States v. The Purdue Frederick Company, Inc., et al.*, 1:07-cr-00029 (W.D. Va.), Criminal Information, at ¶ 24

32. Purdue also engaged in widespread advertising of OxyContin, including both print ads in medical journals and 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 thousands of copies of a video to doctors that made the unsubstantiated claim that opioid addiction occurred in less than 1% of patients. In 2003, the FDA warned Purdue about ads that ran 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."[10] And a 2005 ad that ran in the *Journal of Pain* 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 boy fishing under the tagline "There Can Be Life With Relief."

33. Purdue also falsely promoted OxyContin as if it were effective for a full 12 hours and provided "steady state" relief, less likely than other opioids to create a cycle of crash and cravings that fueled addiction and abuse. As noted in Section IV.B.3, Purdue's promotion of OxyContin as a 12-hour drug was critical to establish its market advantage over other competitors and justify its higher price. Its advertising included claims that OxyContin provides "Consistent Plasma Levels Over 12 Hours" and included a chart depicting plasma levels on a logarithmic scale. The chart, as shown below, minimized the steep decline in OxyContin's effectiveness over 12 hours by depicting 10 mg in a way that it appeared to be half of 100 mg in the table's y-axis, making the absorption rate appear more steady or consistent:

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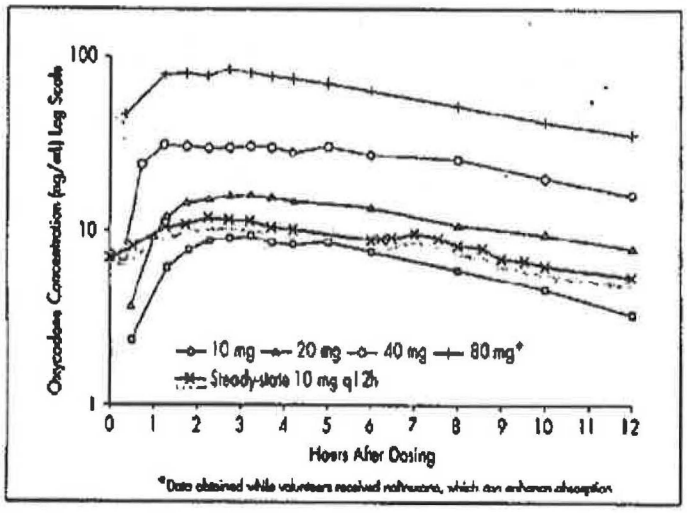
[10]Letter from Thomas Abrams to Michael Friedman, Executive Vice President and Chief Operating Officer, Purdue Pharma L.P. (Jan. 17, 2003)

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

34. 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, websites and coupons aimed at patients, and giveaways of CDs, fishing hats, and plush toys and other items.[11] 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.

35. Purdue's efforts to trivialize the risk of addiction were, and remain, at odds with the scientific evidence, as recently confirmed by the FDA and CDC. Studies have shown that at least 8-12%, and as many as 30% or even 40% of long-term users of opioids experience

[11] According to DEA, Purdue's use of branded promotional items was unprecedented among Schedule II opioids, and was an indicator of Purdue's aggressive and inappropriate marketing of OxyContin. GAO, *OxyContin Abuse and Diversion and Efforts to Address the Problem*, at 25 (Dec. 2003).

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 risk[] of . . . addiction"—"even at recommended doses of all opioids."[12] That same month, after a "systematic review of the best available evidence" by a panel excluding experts with conflicts of interest, the CDC also published guidelines ("2016 CDC Guideline") for prescribing opioids for chronic pain.[13] The CDC found that "[o]pioid pain medication use presents serious risks, including overdose and opioid use disorder" (a diagnostic term for addiction).[14] The CDC also emphasized that "continuing opioid therapy for 3 months substantially increases risk for opioid use disorder."[15] As confirmed by the CDC in its 2016 Guideline, there is "extensive evidence" of the "possible harms of opioids (including opioid use disorder [an alternative term for opioid addiction])."

36. Likewise, Purdue's claims that long-term use of opioids improves patient function and quality of life find no support in the literature, as also recently confirmed by the CDC. There were and are no controlled studies of the use of opioids beyond 16 weeks, and there is no evidence that opioids improve patients' pain and function long-term. On the contrary, the available evidence indicates opioids are not effective to treat chronic pain, and may worsen

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

[13] Deborah Dowell, M.D., Tamara H. Haegerich, PhD., and Roger Chou, M.D., *CDC Guideline for Prescribing Opioids for Chronic Pain – United States, 2016*, (Mar. 18, 2016) MMWR Recomm. Rep. 2016;65 (No. RR-1), at 2 ("2016 CDC Guideline").

[14] 2016 CDC Guideline at 2.

[15] *Id.* at 21.

patients' health. A 2006 study of studies found that "[f]or functional outcomes, . . . other [non-addictive] analgesics were significantly more effective than were opioids."[16] 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.

37. 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."[17] Studies of patients with lower back pain and migraine headaches, for example, have consistently shown that patients experienced deteriorating function over time, as measured by ability to return to work or physical activity, pain relief, rates of depression, and subjective quality-of-life measures. Analyses of workers' compensation claims have found that workers who take opioids are almost four times more likely to reach costs over $100,000, owing to greater side effects and slower returns to work; that receiving an opioid for more than seven days increased patients' risk of being on work disability one year later; and that an opioid prescription as the first treatment for a workplace injury doubled the average length of the claim.

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[16] Andrea D. Furlan, *Opioids for chronic noncancer pain: a meta-analysis of effectiveness and side effects*, 174(11) Can. Med. Ass'n J. 1589-94 (2006). This same study revealed that efficacy studies 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. This does not reflect how doctors actually prescribe the drugs, because even patients who have past or active substance use disorders tend to receive higher doses of opioids. Karen H. Seal, *Association of Mental Health Disorders With Prescription Opioids and High-Risk Opioids in US Veterans of Iraq and Afghanistan*, 307(9) J. Am. Med. Ass'n 940-47 (2012).

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

38. Assessing the state of the science, the CDC found in its 2016 Guideline that there was "[n]o evidence show[ing] a long-term benefit of opioids in pain and function versus no opioids for chronic pain with outcomes examined at least 1 year later (with most placebo-controlled randomized trials [less than or equal to] 6 weeks in duration)"[18] and advised that "there is no good evidence that opioids improve pain or function with long-term use."[19] The Guideline further acknowledged that "nonopioid pharmacologic therapies (including acetaminophen [and] [non-steroidal anti-inflammatory drugs ("NSAIDs")] . . .) are effective for chronic pain" and "are not generally associated with substance use disorder" or significant risk of fatal overdose.[20]

39. Thus, the CDC concluded that "[w]hile benefits for pain relief, function and quality of life with long-term opioid use for chronic pain are uncertain, risks associated with long-term opioid use are clearer and significant."[21] According to the CDC, "for the vast majority of patients, the known, serious, and too-often-fatal risks far outweigh the unproven and transient benefits [of opioids for chronic pain]."[22]

40. Because Purdue's claims regarding chronic opioid therapy had no scientific support, it created the illusion that they did. 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

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[18] 2016 CDC Guideline at 15.

[19] *Id.* at 20.

[20] *Id.* at 17-18.

[21] *Id.* at 18.

[22] *See* Thomas R. Frieden, M.D., M.P.H. and Debra Howry, M.D., M.P.H., *Reducing the Risks of Relief – The CDC Opioid-Prescribing Guideline*, New Eng. J. Med. (Apr. 21, 2016), at 1503 (article announcing 2016 CDC Guideline).

speakers to present talks on opioids to their peers at lunch and dinner events. It funded biased research and sponsored CME 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 ("APF"), 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, that echoed Purdue's branded marketing.

41. 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 Hampshire: Purdue's capture, for its own ends, of physicians' increased focus on pain treatment; its efforts to seed the scientific literature on chronic opioid therapy; and its 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.

42. As Purdue developed OxyContin in the mid-1990s, it was able to both foster and capitalize on a movement in the medical community to make pain treatment a priority for all patients. Early pro-opioid researchers such as Dr. Russell Portenoy, a pain management specialist who received Purdue research support and was a Purdue consultant, discounted the risk of addiction and, in Dr. Portenoy's words, advocated that "opioid maintenance therapy [could] be a safe, salutary and more humane alternative" to not treating patients with chronic pain.

43. In the late 1990s, the American Pain Society ("APS"), headed by Dr. Portenoy, pushed to make pain the "fifth vital sign"—an indicator doctors should monitor alongside blood pressure, temperature, heartbeat and breathing. APS, like Dr. Portenoy, received substantial funding from Purdue.

44. In 2001, the Joint Commission on the Accreditation of Healthcare Organizations ("JCAHO"), which accredits hospitals and other health care programs across the United States, issued pain treatment standards. These 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 this.

45. JCAHO licensed Purdue—alone—to distribute certain educational videos about how to comply with the new pain management standards and a book about pain management, which were also available for purchase from JCAHO's website. Purdue also funded and disseminated the publication *How to Meet the JCAHO Pain Standards*, which encourages discussing opioids in positive terms ("patient is not on opioids," not "patient denies opioid use") and identifies several pro-opioid pain advocacy groups as resources.

46. Both the "pain as the fifth vital sign" campaign and the JCAHO pain management standards have been widely integrated into medical practice. Numerous New Hampshire health care providers—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.

47. Rather than find a way to 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.

48. For example, Purdue-sponsored studies and marketing materials that cited them regularly made claims that "the risk of psychological dependence or addiction is low in the absence of a history of substance abuse." One such study, published in the journal *Pain* in 2003 and widely referenced since (with 584 citations in Google Scholar), ignored previous Purdue-commissioned research showing addiction rates between 8% and 13%—far higher than Purdue acknowledged was possible. Purdue relegated those earlier studies showing higher addiction rates to headache journals, where it knew they would be less widely read, particularly by primary care physicians and pain specialists, its primary audience. 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.

49. That letter, J. Porter & H. Jick, *Addiction Rare in Patients Treated with Narcotics*, 302(2) *New Eng. J. Med.* 123 (1980) ("Porter-Jick Letter"), is reproduced in full below. It does not reflect any study, but simply describes a review of the charts of hospitalized patients who had received opioids. The letter notes that the review found almost no references to signs of

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.

addiction, though there is no indication that caregivers were instructed to assess or document signs of addiction. Because the opioids were administered in a hospital, there was no risk of patients increasing their use.

50. The Porter-Jick Letter has become a mainstay in scientific literature, with 985 citations in Google Scholar. Purdue has referenced the letter in its own marketing brochures. Yet Purdue fails to disclose both the nature of the citation (a letter, not a study) and any of its serious limitations. In fact, Dr. Jick complains that the letter has been misused years later by drug companies "that were pushing out new pain drugs" and used his letter to conclude that their new opioids were not addictive, "[b]ut that's not in any shape or form what we suggested in our letter."

51. In the same vein, an analysis published in the New England Journal of Medicine ("NEJM") in June 2017 noted that citation of the Porter-Jick Letter significantly increased after the introduction of OxyContin and that three-quarters of the articles referencing the Letter cited it "as evidence that addiction was rare in patients treated with opioids."[23] The authors concluded: "We believe that this citation pattern contributed to the North American opioid crisis by helping to shape a narrative that allayed prescribers' concerns about the risk of addiction associated with long-term opioid therapy." In June, the NEJM took the unusual step of adding this note to its electronic copy 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."

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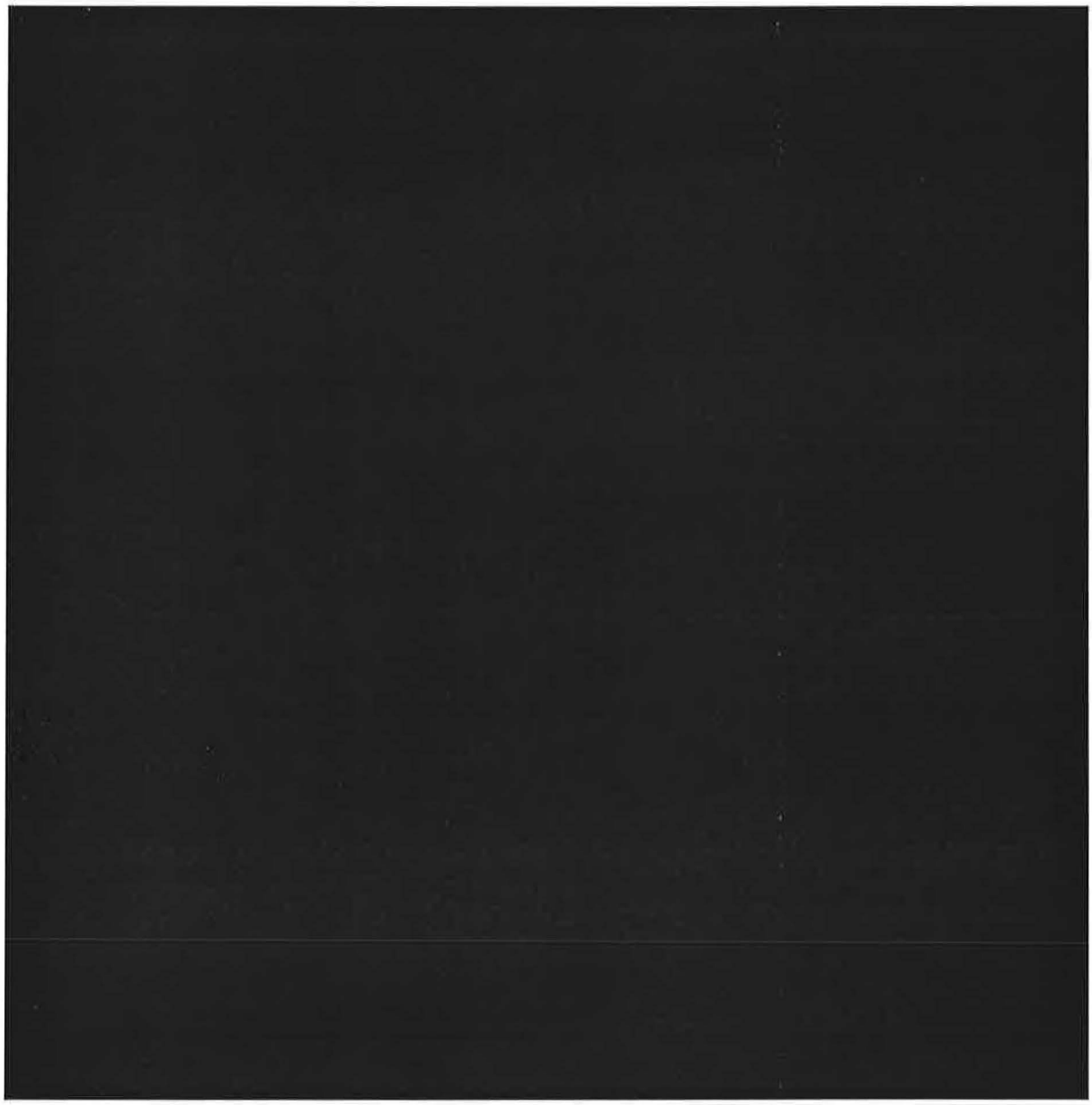
[23]Pamela TM Leung et al., *A 1980 Letter on the Risk of Opioid Addiction*. 376.22 New Eng. J. of Med., 2194-95 (2017).

52. Purdue's efforts to continue to develop science that would support its marketing efforts continued beyond this early foundation [redacted]



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

53. 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 are cited throughout the scientific literature and referenced by third-party payors in determining whether

they should cover treatments. Purdue financed and collaborated, in particular, with two groups on guidelines that have been, and continue to be, broadly influential in New Hampshire and nationwide.

a. *AAPM/APS Guidelines*

54. APS and the American Academy of Pain Medicine each received substantial funding from Purdue. From 2009 to 2012, APS received nearly $500,000; [redacted].

55. The societies issued a consensus statement in 1997, *The Use of Opioids for the Treatment of Chronic Pain*, that endorsed opioids to treat chronic pain and claimed that the risk that patients would become addicted to opioids was low. The co-author of the statement, Dr. 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.

56. AAPM and APS issued guidelines in 2009 ("AAPM/APS Guidelines") and continued to recommend the use of opioids to treat chronic pain. Six of the 21 panel members who drafted the AAPM/APS Guidelines, including Dr. Portenoy, received support from Purdue, and another 8 received support from other opioid manufacturers.

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

contributions that drug companies, including Purdue, made to the sponsoring organizations and committee members.

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

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

b. *FSMB Guidelines*

60. The Federation of State Medical Boards ("FSMB") is a trade organization representing the various state medical boards in the United States. The state boards that comprise the FSMB membership, including New Hampshire's, have the power to license doctors, investigate complaints, and discipline physicians. The FSMB finances opioid- and pain-specific programs through grants from Purdue and other pharmaceutical manufacturers.

61. In 1998, the FSMB developed *Model Guidelines for the Use of Controlled Substances for the Treatment of Pain* ("FSMB Guidelines"), which FSMB acknowledged were produced "in collaboration with pharmaceutical companies," including Purdue. 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, and addressed addiction only to state that "inadequate understandings" of addiction can lead to "inadequate pain control." They also warn that doctors would face discipline for inadequate treatment of pain.

62. A 2004 iteration of the FSMB Guidelines and the 2007 book adapted from them, *Responsible Opioid Prescribing*, repeat these same claims. The book also claimed that opioids would improve patients' function and advanced the dangerous, unsubstantiated concept of "pseudoaddiction"—the idea that signs of addiction, including shopping for doctors willing to newly write or refill prescriptions for opioids or seeking early refills, may actually reflect undertreated pain that should be addressed with more opioids.

63. The 2016 CDC Guideline rejects the concept of pseudoaddiction. The Guideline nowhere recommends that opioid doses be increased if a patient is not experiencing pain relief. To the contrary, the Guideline explains that "[p]atients who do not experience clinically meaningful pain relief early in treatment . . . are unlikely to experience pain relief with longer-term use," [24] and that physicians should "reassess[] pain and function within 1 month" in order to decide whether to "minimize risks of long-term opioid use by discontinuing opioids" because the patient is "not receiving a clear benefit."[25]

64. Another opioid manufacturer has repudiated the concept of pseudoaddiction. In finding that "[t]he pseudoaddiction concept has never been empirically validated and in fact has been abandoned by some of its proponents," the New York Attorney General, in its 2016 settlement with Endo Pharmaceuticals over deceptive marketing, reported that "Endo's Vice President for Pharmacovigilance and Risk Management testified . . . that he was not aware of any research validating the 'pseudoaddiction' concept" and acknowledged the difficulty in

[24] CDC Guideline at 13.

[25] *Id.* at 25.

distinguishing "between addiction and 'pseudoaddiction.'"[26] Consistent with this testimony, Endo agreed *not* to "use the term 'pseudoaddiction' in any training or marketing" in New York.

65. *Responsible Opioid Prescribing* was sponsored by Purdue, among other opioid manufacturers, [redacted].

66. The FSMB website describes 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 to state medical boards, including 4,100 in New Hampshire. Numerous New Hampshire prescribers interviewed by the State recalled receiving and reviewing the book, and several specifically cited it as a resource on which they relied.

B. From 2011 to the Present, Purdue's Marketing in New Hampshire Has Continued to Misrepresent the Risks and Benefits of Opioids.

67. From 2011 to the present, Purdue has built upon its deceptive marketing that established chronic opioid therapy as commonplace and reaped Purdue massive revenues from OxyContin and its other opioids. 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.

[26] Attorney General of the State of New York, *In the Matter of Endo Health Solutions Inc.*, Assurance No.: 15-228 (Mar. 1, 2016).

68. Purdue has accomplished much of this through its New Hampshire sales force and the publications they disseminated. Since the launch of OxyContin, Purdue has relied heavily on its sales representatives to market its opioids directly to prescribers, and that practice continues.

69. [redacted] By establishing personal relationships with doctors, Purdue's sales representatives are able to disseminate their misrepresentations in targeted, one-on-one settings that allows them to differentiate Purdue's opioids and to address individual prescribers' concerns about prescribing opioids for chronic pain.

70. Since the launch of OxyContin, Purdue's sales representatives have visited hundreds if not thousands of health care providers in New Hampshire. Purdue was the most frequent detailer of any opioid drug in New Hampshire and was responsible for *2 out of every 3* opioid detailing visits in the state. [redacted] Most of these prescribers were visited repeatedly; one prescriber recalled seeing representatives for Butrans several times per week.

71. [redacted]

72. [redacted]

[redacted]

73. Deploying in New Hampshire the same marketing tactics and messages it deploys nationwide, Purdue has used its sales force to continue to misrepresent the risks and benefits of its opioids. Specifically, from 2011 to the present Purdue has continued, as described below, to: (1) misrepresent the serious risk of addiction; (2) overstate the benefits of chronic opioid therapy, while failing to disclose the lack of evidence supporting long-term use; (3) misleadingly promote OxyContin as providing 12 hours of pain relief; and (4) misrepresent Purdue's role in addressing illicit or inappropriate prescribing.

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

74. To convince New Hampshire 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. These misrepresentations, which are described below, reinforced each other and created the dangerously misleading impressions that: (1) patients receiving opioid prescriptions for pain would not become addicted; (2) even patients who seemed addicted likely were not; they had undertreated pain and just needed more opioids; (3) patients at greatest risk of addiction could be identified, that all other patients could safely be prescribed opioids, and that even high risk patients could be prescribed opioids if closely

managed; (4) prescribers could increase opioid doses indefinitely without added risk; and (5) the abuse-deterrent formulations of Purdue's opioids both prevent abuse and overdose and are inherently less addictive. Each of these misrepresentations has been debunked by the FDA and CDC.

a. *Omitting, trivializing, and mischaracterizing addiction risk*

75. Based on interviews with New Hampshire prescribers and Purdue's former employees, 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.

76. Where they have brought up the topic of addiction, Purdue's sales representatives, reviving precisely the conduct underpinning the company's 2007 criminal plea, have emphasized to New Hampshire prescribers that ER/LA opioids (which include OxyContin, Butrans, and Hysingla ER) provide a slow-onset, stable dose without "peaks and valleys"—falsely implying 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 "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. Yet Purdue's sales force has continued to make this misrepresentation, which 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.

77. [redacted]

78. Purdue deceptively undermines evidence that opioids are addictive by suggesting or stating that the risk of addiction is not general, but limited to specific, high-risk patients. By appropriately screening patients, doctors can identify patients who are likely to become addicted, and safely prescribe to everyone else. This allows Purdue to discount general concerns or warnings regarding addiction, which can be set aside when prescribers were confident about their own patients. These assurances are false and unsafe, especially given that prescribers cannot accurately predict which patients at higher risk of addiction. *See* Section IV.B.1.b, *infra.*

79. [redacted]

80. Promotional materials and other publications Purdue has disseminated or made available in New Hampshire have included similar messages minimizing the risk of addiction.

81. Purdue, through its unbranded imprint *Partners Against Pain*,[27] promoted pseudoaddiction through at least 2013 on its website. [redacted] Based on interviews with prescribers, *Partners Against Pain* materials have been widely viewed and disseminated in New Hampshire and had [redacted]. Several prescribers specifically recalled visiting the website, downloading materials, or seeing *Partners Against Pain* brochures.

82. [redacted]

83. *Providing Relief, Preventing Abuse*, a pamphlet published by Purdue in 2011 [redacted] for prescribers and law enforcement shows pictures of the stigmata of injecting or snorting opioids—skin popping, track marks, and perforated nasal

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

septa—under the heading "Indications of Possible Drug Abuse." In fact, opioid addicts who resort to these extremes are uncommon; the far more typical reality is patients becoming dependent and addicted through oral use.[28] These depictions misleadingly reassure doctors that, as long as they do not observe those extreme signs, they need not worry that their patients are abusing or addicted to opioids. Purdue made *Providing Relief, Preventing Abuse* available to sales representatives to show or leave with prescribers, including, on information and belief, New Hampshire prescribers.

84. Purdue had a particularly close relationship with APF, which produced numerous publications that falsely and misleadingly portrayed the risks and benefits of opioids. Purdue was APF's second-biggest donor, with donations totaling [redacted]. [redacted] Purdue grant letters informed APF that Purdue's contributions reflected the company's effort to "strategically align its investments in nonprofit organizations that share [its] business interests," suggesting that funding depended on APF continuing to support Purdue's objectives.

[redacted]

[28] Purdue itself submitted briefing materials in October 2010 to a meeting of the FDA's Joint Meeting of the Anesthetic and Life Support Drugs Advisory Committee and the Drug Safety and Risk Management Advisory Committee in which it stated that OxyContin was used non-medically by injection only 4-17% of the time.

[redacted]

85. Purdue also sponsored *A Policymaker's Guide to Understanding Pain & Its Management*, a 2011 APF publication that claimed that pain generally had been "undertreated" due to "[m]isconceptions about opioid addiction" and asserted, without basis, that "less than 1% of children treated with opioids become addicted." *A Policymaker's Guide* also perpetuated the misleading concept of pseudoaddiction. At least one New Hampshire prescriber received it and it is still available online.[29]

86. Purdue provided substantial funding to and closely collaborated with APF in creating *A Policymaker's Guide.* Purdue provided a $26,000 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*.

87. Purdue also maintained a website, *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."[30]

88. *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

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[29] *See* http://s3.documentcloud.org/documents/277603/apf-policymakers-guide.pdf.

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

will treat their pain. While a document linked from the website briefly mentioned opioid abuse, the site itself did not—not once—mention the risk of addiction, a risk so significant that it requires a black -box warning on its 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, 11 of these advocates received a total of $231,000 in payments from Purdue.[31]

89. As laid out in Section IV.A.2, 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.

b. *Overstating the efficacy of screening tools*

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

91. Such misrepresentations make health care providers more comfortable prescribing opioids to their patients, and patients more comfortable starting 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

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

their own practices and that addiction was not unavoidable, but the result of other prescribers failing to rigorously manage and weed out problem patients.

92. Purdue conveyed these messages in its in-person sales calls. One former Purdue sales representative in New Hampshire acknowledged discussing with health care providers that they could screen out patients at high risk of addiction through urine tests and patient contracts. Prescribers reported being encouraged to use screening tools, and many prescribers said they used screening tools and patient opioid agreements to manage addiction risk.

93. [redacted] One of these is the "Opioid Risk Tool" created by prominent opioid advocate Dr. Lynn Webster[redacted]. It is a five question, one-minute screening tool that relies on patient self-reporting of a personal history of substance abuse, sexual abuse, or "psychological disease"— particularly unlikely given the sensitive topic and the nature of addiction—to purportedly allow doctors to manage the risk of opioid abuse and addiction.

94. Purdue also has promoted screening tools as a reliable means to manage addiction risk in CME and scientific conferences attended by or available to New Hampshire prescribers.

95. Purdue sponsored a 2011 CME taught by Dr. Lynn Webster titled *Managing Patient's Opioid Use: Balancing the Need and Risk.* This presentation deceptively instructed prescribers that screening tools, patient agreements, and urine tests prevented "overuse of prescriptions" and "overdose deaths." [redacted]

96. Purdue funded a 2012 CME program called *Chronic Pain Management and Opioid Use: Easing Fears, Managing Risks, and Improving Outcomes.* The presentation

deceptively instructed doctors that, through the use of screening tools, more frequent refills, and other techniques, high-risk patients showing signs of addictive behavior could be treated with opioids. At least one New Hampshire prescriber recalls reviewing this CME.

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

98. [redacted]

99. The 2016 CDC Guideline confirms the falsity of Purdue's claims about the utility of patient screening and management strategies in managing addiction risk. The Guideline notes that there are no studies assessing the effectiveness of risk mitigation strategies—such as screening tools or patient contracts—"for improving outcomes related to overdose, addiction, abuse, or misuse." The 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.)

c. *Failing to disclose increased risk of higher doses*

100. Purdue has falsely claimed to New Hampshire prescribers and consumers that opioids could be taken in ever-increasing strengths to obtain pain relief, without disclosing that higher doses increased the risk of addiction and overdose. Further, as described in more detail in Section IV.B.3, Purdue encouraged doctors to prescribe higher doses, rather than prescribe OxyContin more frequently than twice-a-day—despite knowing that OxyContin frequently did not provide 12 hours of relief.

101. [redacted] unless doctors felt comfortable prescribing increasingly high doses of opioids, they may not have maintained patients on the drugs.

102. These omissions were false and misleading in their own right and also failed to correct Purdue's earlier misinformation regarding higher doses, letting stand the dangerous impression that prescribers could increase the dose without added risk.

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

104. 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.

105. *A Policymaker's Guide,* the 2011 publication on which Purdue collaborated with APF, taught that dose escalations are "sometimes necessary," even unlimited ones, but did not disclose the risks from high dose opioids. This publication was distributed to at least one New Hampshire prescriber and is still available online.

106. Purdue sponsored a CME titled *Overview of Management Options* and issued by the American Medical Association ("AMA") in 2013. The CME was edited by Dr. Russell Portenoy, who received research support, honoraria, and consulting fees from Purdue. It misleadingly instructed physicians that NSAIDs (like ibuprofen) are unsafe at high doses (because of risks to patients' kidneys), but did not disclose risks from opioids at high doses.[32] This CME was presented online, was available nationwide, and was viewed by at least one New Hampshire prescriber. It was available online via the AMA through 2014.

107. These claims conflict with the scientific evidence. 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, scholars have suggested that tolerance to the respiratory depressive effects of opioids develops at a slower rate than tolerance to opioids' analgesic effects. Accordingly, the practice of continuously escalating doses to match pain tolerance can, in fact, lead to overdose even where opioids are taken as recommended.

108. 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 related to opioid

[32] While there is evidence of adverse effects from NSAIDs at higher doses, the CME was misleading in that it highlighted the risk from higher doses for one class of drugs, while omitting it for opioids.

therapy increase at higher opioid dose."[33] 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."[34] The CDC also states that "there is an increased risk for serious harms related to long-term opioid therapy that appears to be dose-dependent."[35] That is why the CDC advises doctors to "avoid increasing doses" above 90 morphine milligram equivalents per day.[36]

109. Among Medicaid patients in New Hampshire, nearly half of patients taking OxyContin from 2011-2015 were taking the equivalent of the CDC's maximum dose or higher. OxyContin's highest dose, 80 mg twice per day, is more than twice the CDC's recommended ceiling (and, as discussed in section IV.B.3, many patients take the drug more frequently).

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

110. By the mid-2000s, rampant addiction to and abuse of OxyContin had emerged in the public eye. Rather than acknowledge that these problems were the inevitable result of widespread prescribing of OxyContin for chronic pain, Purdue claimed that abuse and addiction resulted from diversion, with abusers snorting or injecting the drugs. Purdue proposed a solution in the form of a coating to make the drug more difficult to crush and added elements to make it unsuitable for injection.

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[33] CDC Guideline at 22.

[34] *Id.* at 24.

[35] *Id.* at 19. The 2016 CDC Guideline reinforces earlier findings announced by the FDA. In 2013, the FDA acknowledged "that the available data do suggest a relationship between increasing opioid dose and risk of certain adverse events." For example, the FDA noted that studies "appear to credibly suggest a positive association between high-dose opioid use and the risk of overdose and/or overdose mortality."

[36] *Id.* at 16.

111. This reformulated OxyContin was approved by the FDA in April 2010. However, the FDA noted that "the tamper-resistant properties will have no effect on abuse by the oral route (the most common mode of abuse)."[37] It was not until 2013 that the FDA, in response to a Citizen Petition filed by Purdue, permitted reference to the abuse-deterrent properties in the label. When Hysingla ER (extended-release hydrocodone) launched in 2014, the product included similar AD properties.

112. Purdue has engaged and continues to engage in deceptive marketing of its AD opioids—i.e., reformulated OxyContin and Hysingla ER. Purdue sales representatives regularly use the so-called abuse-deterrent properties of Purdue's opioids as a primary selling point to differentiate those products from their competitors. Specifically, Purdue detailers: (1) claim that Purdue's AD formulation *prevents* tampering and that its AD products cannot be crushed or snorted; (2) claim that Purdue's AD opioids *prevent or reduce* opioid abuse, diversion, and addiction; (3) assert or suggest that Purdue's AD opioids are "safer" than other opioids; and (4) fail to disclose that Purdue's AD opioids do not impact oral abuse or misuse and that its AD properties are and can be easily overcome.

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

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

114. Purdue knew and should have known that "reformulated OxyContin is not better at tamper resistance than the original OxyContin"[38] and is still regularly tampered with and abused. Websites and message boards used by drug abusers, such as bluelight.org and reddit, also report a variety of ways to tamper with OxyContin and Hysingla ER, including through grinding, microwaving then freezing, or drinking soda or fruit juice in which a tablet is dissolved. A publicly available Citizen Petition submitted to the FDA in 2016 by a drug manufacturing firm challenged Purdue's abuse-deterrent labeling based on the firm's ability to easily prepare OxyContin to be snorted or injected. The Attorney General's Office witnessed a demonstration of these methods.

115. [redacted] A 2015 non-Purdue study also shows that many opioid addicts are abusing Purdue's AD opioids through oral intake or by defeating the AD mechanism. Indeed, *one-third* of the patients in the study defeated the AD mechanism and were able to continue inhaling or injecting the drug. To the extent that the abuse of Purdue's AD opioids was reduced, those addicts simply shifted to other drugs such as heroin.

116. This conclusion was embedded, but misleadingly not acknowledged, in a 2013 article presented by Purdue employees based on review of data from poison control centers.[39] The authors' stated finding – that AD OxyContin can reduce abuse – ignores important negative findings. Data reported in the study reveals that abuse merely shifted to other drugs and that,

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

[39] Changes in oxycodone and heroin exposures in the National Poison Data System after introduction of extended-release oxycodone with abuse-deterrent characteristics

when the actual incidence of harmful exposures was calculated, there were *more* harmful exposures to opioids (including heroin) after the reformulation of OxyContin. Finally, the article highlights in a pull -out box that AD still preserves "analgesic benefit to patients," but does not present any data that supports this conclusion. In short, the article appears biased towards emphasizing advantages and ignoring disadvantages of AD OxyContin—reflecting the same pattern of tilting scientific research and literature to support the promotion of opioids discussed in Section IV.A.2.

117. The 2016 CDC Guideline confirms that "[n]o studies" support the notion that "abuse-deterrent technologies [are] a risk mitigation strategy for deterring or preventing abuse," noting that the technologies "do not prevent opioid abuse through oral intake, the most common route of opioid abuse, and can still be abused by nonoral routes." Tom Frieden, the Director of the CDC, has further reported that his staff could not find "any evidence showing the updated opioids [AD formulations] actually reduce rates of addiction, overdoses, or death."[40]

118. Purdue knew that promotion of AD opioids *as reducing abuse or addiction* was not supported by evidence. [redacted]

[40] Perrone, *Drugmakers push profitable, but unproven, opioid solution*, 12/15/16.

119. In 2015, claiming a need to further assess its data, Purdue abruptly withdrew a supplemental new drug application related to reformulated OxyContin one day before FDA staff were to release their assessment of the application. The staff review preceded a FDA advisory committee meeting related to new studies by Purdue "evaluating the misuse and/or abuse of reformulated OxyContin" and whether those studies "have demonstrated that the reformulated product has a meaningful impact on abuse."[41] The fact that such data has never been presented to the FDA gives rise to an inference that the data would not have supported claims that OxyContin's AD properties have not reduced abuse or misuse.

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

121. In New Hampshire, Purdue's sales representatives have made claims about abuse deterrence that go well beyond the drugs' labeling. Even before the 2013 changes to the OxyContin label, Purdue representatives in New Hampshire emphasized OxyContin's purported

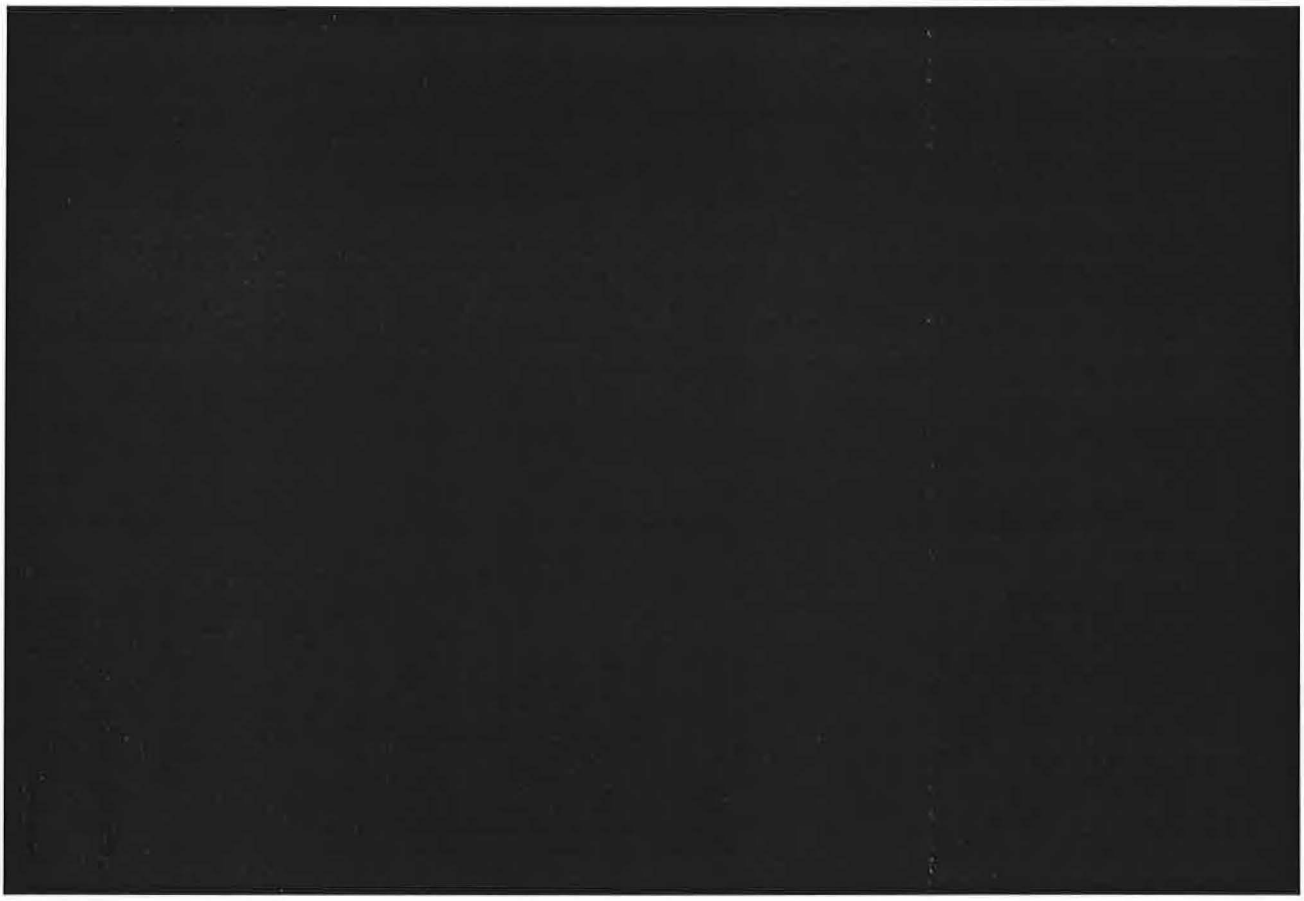
[41] Meeting Notice, Joint Meeting of the Drug Safety and Risk Management Advisory Committee and the Anesthetic and Analgesic Drug Products Advisory Committee; Notice of Meeting, May 25, 2015, 80 FR 30686.

AD properties to prescribers as a featured selling point. Both before and after the labeling changes, representatives stated or implied that reformulated OxyContin was difficult to abuse or divert, though there has been no approved language label or evidence supporting the claim that OxyContin is less likely to be diverted. A Bedford physician recalled being told by a Purdue sales representative OxyContin is "as impossible as can be to use in a non-oral formulation." And a Newport doctor described the abuse-deterrence message as "a hard sell"—"not subtext, but overt text." Representatives made the same claims about Hysingla ER. Purdue representatives also have stated or implied to New Hampshire prescribers that opioids with AD properties are less likely to be sought after and less addictive and did not disclose, despite their promotion of AD, that even AD formulations are subject to oral abuse, can be tampered with, and shift abuse to other opioids. Purdue also promoted its abuse-deterrence heavily to third party payors that covered New Hampshire patients.

122. The recollections of New Hampshire prescribers about such marketing claims are corroborated by data 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 to a sample of prescribers 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 for the 2011-2014 period show Purdue detailers in the Northeast emphasizing the "low" or "no" abuse potential of OxyContin. Given the consistency of sales messages, which are centrally controlled and directed, it is reasonable to infer that deceptive messages delivered to prescribers in the Northeast region were delivered to New Hampshire providers, as well.

123. As described in Section IV.C, *infra*, Purdue has claimed that its introduction of AD opioids reflects and furthers its commitment to help address the opioid crisis. However, Purdue's development and (misleading) promotion of AD opioids seems driven by Purdue's effort to preserve its profits, not to rein in opioid misuse. Generic versions of OxyContin, which became available in February 2011, threatened to erode Purdue's share of the long-acting opioid market and the price Purdue could charge. Through a Citizen Petition, Purdue was able to secure a determination by the FDA in April 2013 that original OxyContin should be removed from the market as unsafe (lacking AD properties), and thus non-AD generic copies could not be sold. As a result, Purdue extended its branded exclusivity for OxyContin for as long as the patent protection on the AD formulation coating remains in place.[42] [redacted]

[42] According to FDA's "Orange Book," the latest any patent for OxyContin expires is August 24, 2027.



124. Purdue's false and misleading marketing of the benefits of its AD formulation has preserved and expanded its sales of its opioids by persuading doctors who might have curtailed their prescribing to continue writing prescriptions of opioids and switch to Purdue's abuse-deterrent formulations in the mistaken belief that AD formulated opioids are safer. It also allowed prescribers to discount evidence of opioid addiction and abuse and attribute it to other, less safe opioids—*i.e.*, it allowed them to believe that while patients might abuse, become addicted to, or die from other, non-AD opioids, Purdue's opioids did not carry that risk.

125. [redacted]

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

126. To convince New Hampshire 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 the 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. The FDA, too, has recognized the lack of evidence to support long-term opioid use. In 2013, the FDA stated that it was "not aware of adequate and well-controlled studies of opioids use longer than 12 weeks." As a result, the CDC recommends that opioids be used not in the first instance and only after prescribers have exhausted alternative treatments.

127. Nevertheless, building on its earlier marketing, Purdue has continued to tout the purported benefits of long-term opioid use, while falsely and misleadingly suggesting that these benefits were supported by scientific evidence.

128. Based on interviews with former employees and New Hampshire prescribers, Purdue sales representatives regularly do not disclose in their sales conversations the lack of evidence supporting long-term use. One former Purdue sales representative in New Hampshire recalled that he "discussed use of the medication for as long as the patient was in pain," but he never raised with prescribers the fact that opioid clinical trials were limited to use lasting 12 to 16 weeks. Another former sales representative similarly acknowledged that she did not discuss with prescribers what evidence there was to support use beyond 12 to 16 weeks.

129. The OxyContin "Conversion and Titration Guide" distributed by sales representatives to New Hampshire prescribers likewise misleadingly promotes long-term use. A 2007 version of that guide recommended that "the need for 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 6-12 months. The 2012 version of this guide distributed in New Hampshire omits the parenthetical "(eg, every 6 to 12 months)," but it still conveys 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.

130. Purdue also has published misleading studies to enhance its view that opioids are effective long-term for chronic pain conditions. One study, promisingly titled *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, asserts that OxyContin is safe and effective for chronic pain condition osteoarthritis. The study, sponsored by Purdue, involved providing oxycodone for 30 days, and then randomizing participants and providing provide placebo, IR oxycodone with acetaminophen (like Percocet), or OxyContin. Only 107 of the 167 patients went on to the second phase of the study and most who withdrew left because of adverse events (nausea, vomiting, drowsiness, dizziness or headache) or ineffective treatment. Despite relating to a chronic condition, opioids were provided only short-term. The authors even acknowledge that the "results… should be confirmed in trials of longer duration to confirm the role of opioids in a chronic condition such as OA [osteoarthritis]."[43] Yet, the authors conclude, "This 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". This statement is not supported by the data – a substantial number of patients dropped out because of adverse effects, there was no reported data regarding addiction, and the study was not long-term. Like other Purdue studies, this one seems intentionally misleading.

131. Purdue recognized its own lack of competent evidence that opioids are appropriate and useful long-term [redacted]

[43] Smith, S. R., et al. "Comparative pain reduction of oral non-steroidal anti-inflammatory drugs and opioids for knee osteoarthritis: systematic analytic review." Osteoarthritis and cartilage 24.6 (2016): 962-972.

[redacted][44] The plan then identified the proposed title and authors for studies to support that message and target journals in which to publish these studies.

132. Purdue also has claimed--also without evidence--that long-term opioid use will improve patients' daily function and quality of life. Based on interviews with prescribers, Purdue's sales representatives have regularly delivered this message in their sales calls.

133. Purdue and Purdue-sponsored materials distributed or available in New Hampshire reinforce this message. The 2011 publication *A Policymaker's Guide* erroneously claimed that "multiple clinical studies have shown that opioids are effective in improving daily function and quality of life for chronic pain patients." A series of medical journal advertisements for OxyContin in 2012 presented "Pain Vignettes"—case studies featuring patients with pain conditions persisting over several months—that implied functional improvement. For example, one advertisement described a "writer with osteoarthritis of the hands" and implied that OxyContin would help him work more effectively.

134. These claims of functional improvement were both unsubstantiated by and contrary to the scientific evidence at the time. The FDA and other federal agencies have made this clear for years.[45] Most recently, the 2016 CDC Guideline concluded that "there is *no good*

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

evidence that opioids improve pain or function with long-term use."[46] (Emphasis added.) The CDC also noted that the risks of addiction and death "can cause distress and inability to fulfill major role obligations."[47] 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.

135. [redacted]

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

136. To convince New Hampshire prescribers and patients to use OxyContin, in particular, Purdue has misleadingly promoted the drug as providing 12 continuous hours of pain relief with each dose. In reality, OxyContin does not last for 12 hours in many patients, a fact Purdue has known since the product's launch. 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, despite knowing that it was inadequate for—and dangerous to—many patients, in order to maintain a competitive advantage over more-frequently dosed opioids. Yet Purdue has gone well beyond the label's instructions to take OxyContin every 12 hours by affirmatively claiming that OxyContin lasts for 12 hours and by failing to disclose that OxyContin fails to provide 12 hours of pain relief to many patients.

137. These misrepresentations, which Purdue has made since 1996 and continues to make through the present day, are particularly dangerous because the inadequate dosing helps

[46] CDC Guideline at 20.

[47] *Id.*

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

138. OxyContin has been FDA-approved for twice-daily—"Q12"—dosing frequency 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 and to promote OxyContin as providing 12 hours of pain relief. [redacted][48]

139. Under FDA guidelines for establishing dosing, Purdue merely had to show that OxyContin lasted for 12 hours for at least half of patients, and Purdue submitted a single study that cleared that bar. While the OxyContin label indicates that "[t]here are no well-controlled clinical studies evaluating the safety and efficacy with dosing more frequently than every 12 hours," the reason is that Purdue has not conducted any such studies.

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

[48] At the time of OxyContin's launch, the only ER/LA opioids available were morphine tablets or fentanyl patches, regarded as more powerful than necessary for moderate pain. Additional ER/LA opioids came on the market in 2006 with the introduction of Opana ER (oxymorphone); Nucynta ER (tapentadol) in 2011; and Zohydro ER (hydrocodone) in 2013.

approved such a marketing claim. To the contrary, the FDA found in 2008, in response to a Citizen Petition by the Connecticut Attorney General, that a "substantial number" of chronic pain patients taking OxyContin experienced "end of dose failure"—*i.e.,* little or no pain relief at the end of the dosing period.

141. As described in paragraph 33, Purdue also disseminated to prescribers a chart that was designed to demonstrate the constant release of OxyContin's active ingredient, through the end of the dosing period. However, Purdue manipulated that chart to compress the y-axis and show a less steep decline in OxyContin's effect.

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

143. End-of-dose failure renders OxyContin even more dangerous because patients begin to experience distressing psychological and physical withdrawal symptoms, followed by a euphoric rush with their next dose—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."[49] Many patients will exacerbate this cycle by taking their next dose ahead of

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

schedule or resorting to a rescue dose of another opioid, increasing the overall amount of opioids they are taking.

144. Purdue has remained committed 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 dosing in the label (*e.g.* every 8 hours) because 12-hour dosing was "a significant competitive advantage."

145. Without appropriate caveats, promotion of 12-hour dosing by itself is misleading because it implies that the pain relief supplied by each dose lasts 12 hours, which Purdue knew to be untrue for many, if not most, patients. FDA approval of OxyContin for Q12 dosing does not give Purdue license to misrepresent the duration of pain relief it provides to patients, which Purdue knew was not 12 hours; moreover, Purdue had a responsibility to correct its label to reflect appropriate dosing, to disclose to prescribers what it knew about OxyContin's actual duration, and not to promote more dangerous higher dosing, rather than increased frequency of use, just because of its marketing advantage.[50]

146. Yet, based on interviews with former Purdue employees and New Hampshire prescribers, 12-hour dosing—without further explanation—has been and remains a principal feature of Purdue's marketing. [redacted] Moreover, based on interviews with prescribers, Purdue sales representatives in

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

New Hampshire have gone even farther than promoting dosing, falsely stating in sales calls that OxyContin provides a full 12 hours of pain relief. [redacted]

147. [redacted]

148. According to the former regional sales manager, Purdue was aware of complaints by physicians, including physicians in New Hampshire, that OxyContin does not supply 12 hours of pain relief in some patients. Purdue also was aware of some physicians' practice of prescribing OxyContin more frequently than 12 hours—a common occurrence, according to interviews with New Hampshire prescribers.

149. Purdue's promoted solution to this problem is to increase the dose, rather than the frequency, of prescriptions, even though higher dosing carries its own risks—including increased danger of addiction, overdose, and death. It is like flying a plane higher, knowing that it will take longer to crash, rather than fueling more frequently to prevent the crash; in the context of OxyContin, it means that patients will experience higher highs and lower lows, increasing their craving for their next pill. Nationwide, based on an analysis by the *Los Angeles Times*, more than 52% of patients taking OxyContin longer than three months are on doses greater than 60 milligrams per day—which converts to the 90 milligrams of morphine equivalent that the 2016

CDC Guideline urges prescribers to "avoid" or "carefully justify." As noted above, an analysis of New Hampshire's own Medicaid data indicates 49% of OxyContin users were on this dangerous dose. Moreover, 41% of OxyContin prescriptions paid for by New Hampshire's Medicaid program were for more frequent than 12-hour dosing.

150. [redacted] According to interviews with prescribers and a former Purdue employee, Purdue's representatives offered this advice in their sales calls to New Hampshire 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.

C. Purdue Also Engaged In Other Unlawful and Fraudulent Conduct by Failing to Report Suspicious Prescribing.

151. Purdue has deceptively and unfairly failed to report to New Hampshire authorities illicit or suspicious prescribing of its opioids, even as it has publicly and repeatedly touted its "constructive role in the fight against opioid abuse," including its commitment to AD opioids and its "strong record of coordination with law enforcement."[51] Purdue went so far as to convert evidence of opioid abuse into a promotional opportunity. [redacted]

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

[redacted]

152. As described in Section IV.B.1, Purdue's public stance long has been that "bad apple" patients and drug diversion to illicit secondary channels—and not widespread prescribing of OxyContin and other opioids for chronic pain—are to blame for widespread addiction and abuse. To address the problems of illicit use and diversion, Purdue promotes its funding of various drug abuse and diversion prevention programs and introduction of AD opioids. This allows Purdue to present itself as a responsible corporate citizen while continuing to profit from the commonplace prescribing of its drugs, even at high doses for long-term use.

153. 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.

154. Touting the benefits of AD 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 . . . "[52] Purdue's statement on "Opioids Corporate Responsibility" likewise states that "[f]or many years, Purdue has committed substantial

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

resources to combat opioid abuse by partnering with . . . communities, law enforcement, and government."[53] 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."[54]

155. These public pronouncements create the misimpression that Purdue is proactively working with law enforcement and government authorities, nationwide and in New Hampshire, to root out drug diversion, including the illicit prescribing that can lead to diversion. It aims to distance Purdue from its past conduct in deceptively marketing opioids, which gave rise to its 2007 criminal plea, and make its current marketing seem more trustworthy and truthful. In fact, Purdue has consistently failed to report suspicious prescribing it observed to authorities, facilitating, rather than closely coordinating with law enforcement to stop, opioid diversion.

156. Purdue can track distribution and prescriptions of its opioids down to the retail and prescriber level. [redacted] Through its extensive network of sales representatives, Purdue also has a window into

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

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

the practices of countless doctors and can identify those whose waiting rooms are overcrowded, whose parking lots have numerous out-of-state vehicles, whose patients seem young and healthy or homeless—among other red flags of diversion. [redacted]

157. Purdue has identified those doctors— *internally*. 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 of the highest-strength pills (80 mg OxyContin pills or "80s," as they were known on the street, were a prime target for diversion).

158. 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 the prescriber or pharmacist and initiate an investigation."[55] 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.

159. Yet, Purdue failed to cut off these providers' opioid supply at the pharmacy level—meaning Purdue continued to generate sales revenue from their prescriptions—and failed to report these providers to state medical boards or law enforcement. Data Purdue possessed and concerns flagged by its own employees, wholesalers, and other sources identified hundreds of suspicious pharmacies each year. Yet, in an interview with the *Los Angeles Times*, which first

[55] Purdue, *Setting The Record Straight On Our Anti-Diversion Programs*, July 11, 2016, http://www.purduepharma.com/news-media/get-the-facts/setting-the-record-straight-on-our-anti-diversion-programs/.

reported this story, Purdue's former senior compliance officer acknowledged that in five years of investigating suspicious pharmacies, the company never stopped the supply of its opioids to a pharmacy, even where Purdue employees personally witnessed the diversion of its drugs, and regularly failed to report suspicious orders to the DEA.

160. 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 prescribed more than 1.1 million OxyContin tablets. Some of the pills diverted while Purdue stood by are alleged to have reached New Hampshire. The New York Attorney General's settlement with Purdue specifically cited the company for failing to adequately address suspicious prescribing.

161. [redacted]

162. Federal regulation requires manufacturers of controlled substances to monitor and report suspicious conduct. *See* 21 U.S.C. 823(e); 21 C.F.R. 1301.74(b). In fact, the DEA in 2006 and 2007 sent letters to manufacturers and wholesalers of opioids, including Purdue, reminding them of their legal "obligation to design and operate a system to disclose . . . suspicious orders of controlled substances," to inform the DEA "of suspicious orders when

discovered," and to "maintain effective controls against diversion" of controlled substances. Registrants' "responsibility does not end merely with the filing of a suspicious order report. Registrants must conduct an independent analysis of suspicious orders prior to completing a sale to determine whether the controlled substances are likely to be diverted from legitimate channels."

163. [redacted]

164. [redacted]

165. In New Hampshire, Purdue not only failed to share information on suspicious prescribing with DEA, but failed to conduct any investigations of prescribers. [redacted]

166. The failure to report or investigate suspicious prescribers did not reflect a lack of suspicious conduct. On information and belief, based on analyses of New Hampshire prescription data, there are at least 6 additional prescribers over the past 5 years whom Purdue could and should have investigated for suspicious prescribing based on Purdue's own criteria and data. These prescribers stood out from others based on either their overall volume of prescribing, the high numbers or ratios of 80 mg OxyContin prescribed, or both.

167. Only recently did Purdue provide information to the Board of Medicine about its internal database of suspicious prescribers, and only after the Board affirmatively requested it. In a September 2, 2016 letter to the Board, Purdue identified 13 health care providers who, it said, had been added to its internal no-call database over the years. According to Purdue, all 13 names were added to the list based on licensing actions brought by the Board or on media reports regarding potential misconduct—*i.e.*, none were added based on Purdue-initiated investigations.

D. By Increasing Opioid Prescriptions and Use, Purdue's Deceptive Marketing Scheme Has Fueled the Opioid Epidemic and Significantly Harmed New Hampshire and Its Citizens.

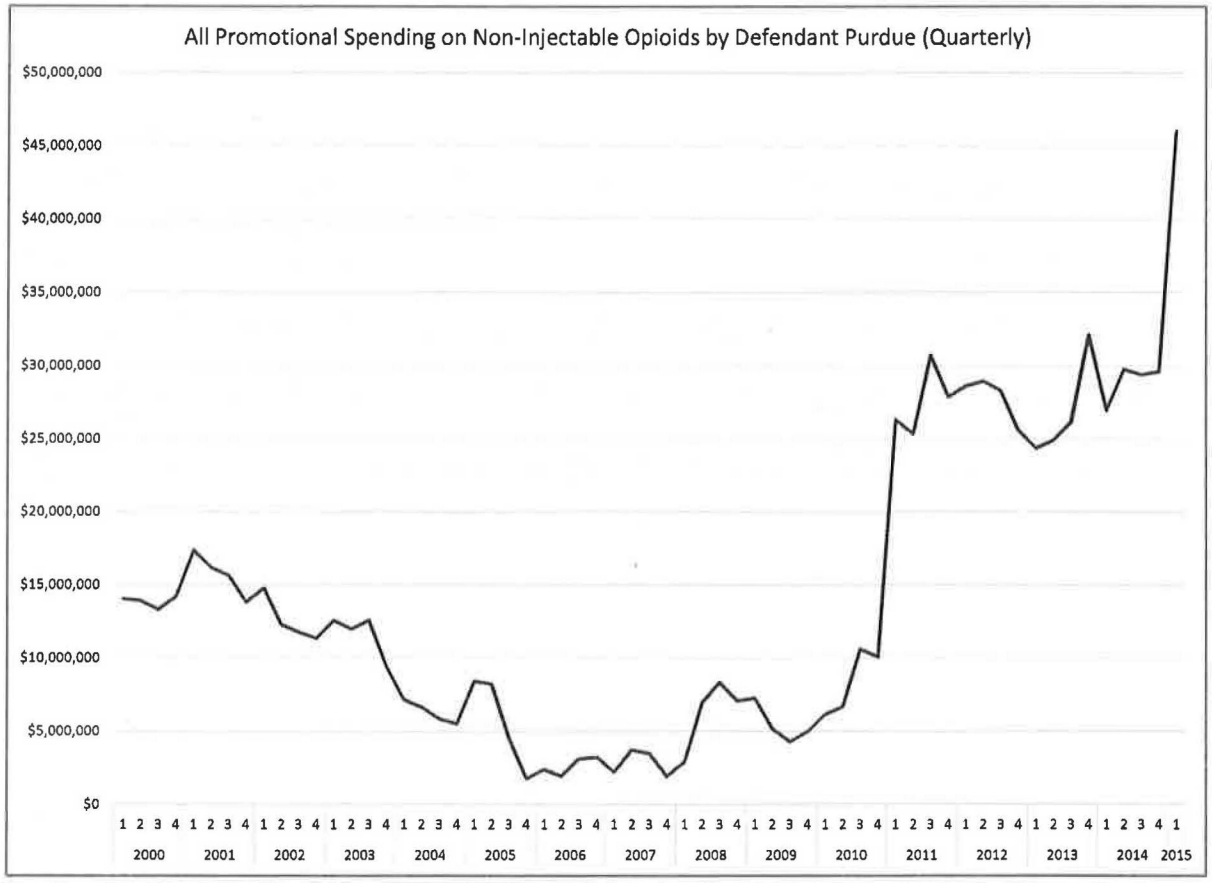
168. Purdue's misrepresentations have prompted New Hampshire health care providers to prescribe, patients to take, and payors to cover opioids for the treatment of chronic pain. Through its early marketing, it set out to—and did— overcome barriers to widespread

prescribing of opioids for chronic pain with deceptive messages about the risks and benefits of long-term opioid use. Through its continued deceptive marketing from 2011 to the present, it has both benefited from and built upon its prior misrepresentations, sustaining and expanding a market for its opioids.

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

170. Both historically and currently, Purdue accounts for the lion's share of sales of brand name opioids. [redacted] In New Hampshire for the period 2011-15, Purdue accounted for 43% of branded opioid prescription fills under Medicaid, 55% in the state employee health plan, and [redacted]. New Hampshire Medicaid spent $3.5 million on OxyContin from 2011-2015, with 7,886 prescriptions.

171. The increase in prescribing opioids corresponds with Purdue's marketing push. As shown in the chart below, according to data obtained from a marketing research company, Purdue's spending nationwide on marketing of opioids—including all of the drugs at issue here—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 reformulated



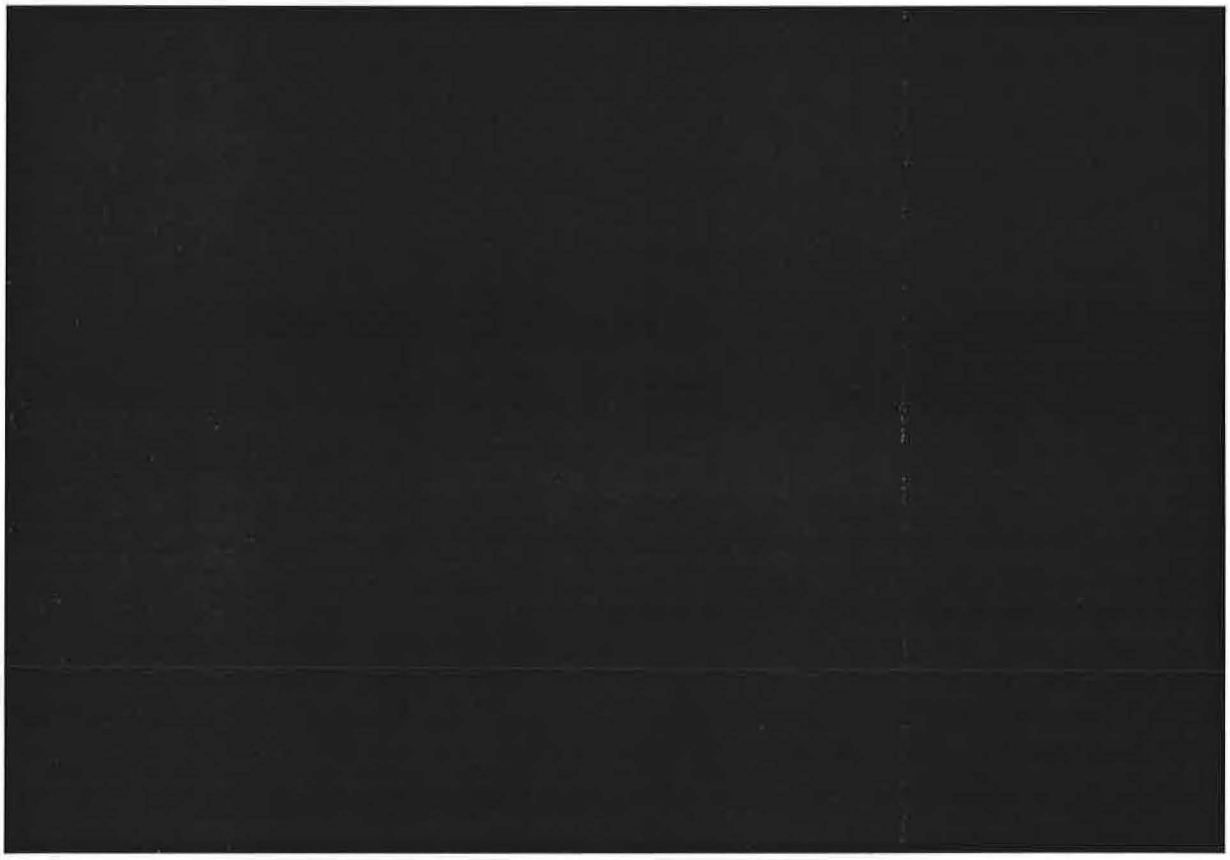
OxyContin, Purdue ramped up its marketing once again. In 2011, Purdue's marketing spiked to more than $25 million per quarter, and by the end of 2015, with the introduction of Hysingla ER, it soared to more than $40 million per quarter.

172. By far, the largest component of this spending was sales representative visits to individual prescribers, with total detailing expenditures rising from roughly $45 million annually in 2000 to more than $108 million in 2014. Purdue's marketing expenditures in New Hampshire are not available, but they can be expected to be consistent with the national data.

173. Purdue devotes these resources to detailing—notwithstanding increasing efforts of hospitals and physician practice groups to restrict access—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 to Purdue's doubling of its sales force and trebling of sales calls.

174. [redacted]



175. [redacted]

176. Physicians often are unwilling to acknowledge any impact of detailing on their prescribing, but some recognized its effect. According to one Carroll County doctor detailed by Purdue, "if they tell you about [the drug], the next time you see a patient, you think about it. It

imprints." She believed that the detailing caused her to prescribe Butrans because the drug was "fresh in her mind" when she saw a patient with pain. Another physician from Amherst, who also was detailed by Purdue, noted: "I ask myself if it affects my prescribing. You bet it does. If it didn't, they wouldn't do it."

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

178. Even physicians who assiduously avoid direct pharmaceutical marketing have been influenced through more subtle channels. One such physician interviewed by the State had decided on principle, years ago, to eliminate contact with sales representatives. In 2007, he began treating a patient with a rare disorder that caused inflammation and excruciating pain inside her eye. Because he had not prescribed opioids for chronic pain before, he educated himself by reading publications and taking CME. Among these were the Purdue-influenced book *Responsible Opioid Prescribing* and the Purdue-sponsored CMEs *Chronic Pain Management and Opioid Use: Easing Fears, Managing Risks, and Improving Outcomes* and *Overview of Management Options*—which collectively minimized the risk of addiction, suggested that patients at higher risk could be successfully managed, and implied that opioids were safe at high doses, as described in Section IV.B. Four years after he initiated chronic opioid therapy (with oxycodone and a fentanyl patch), the patient overdosed and died. That doctor has since vacated his medical license in resolution of disciplinary proceedings.

179. 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—through patients who believe they will not become addicted, addicts who demand more drugs, and health care providers who refill opioid prescriptions that maintain dependence and addiction in the belief they are doing the best for their patients or have no other option but to prescribe more opioids. Purdue's marketing of opioids as the answer to pain reinforces the psychological incentives for doctors who, like the ophthalmologist, 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.

180. 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 Hampshire. Young adults (ages 18-25), in particular, are using prescription painkillers non-medically at higher rates in New Hampshire than the rest of the nation.

181. Representing the NIH's National Institute of Drug Abuse in hearings before the Senate Caucus on International Narcotics Control in May 2014, Dr. Nora Volkow explained that "aggressive marketing by pharmaceutical companies" is "likely to have contributed to the severity of the current prescription drug abuse problem."

182. In August 2016, U.S. Surgeon General Vivek Murthy published an open letter to physicians nationwide, enlisting their help in combating this "urgent health crisis" and linking that crisis to deceptive marketing. He wrote that the push to aggressively treat pain, and the "devastating" results that followed, had "coincided with heavy marketing to doctors . . . . [m]any

of [whom] were even taught—incorrectly—that opioids are not addictive when prescribed for legitimate pain."[56]

183. 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.[57]

184. In a 2016 report, the CDC explained that "[o]pioid pain reliever prescribing has quadrupled since 1999 and has increased in parallel with [opioid] overdoses." Patients receiving opioid prescriptions for chronic pain account for the majority of overdoses. For these reasons, the CDC concluded that efforts to rein in the prescribing of opioids for chronic pain are critical "to reverse the epidemic of opioid drug overdose deaths and prevent opioid-related morbidity."[58]

185. Opioids are involved in 40% of all fatal drug overdoses, including overdoses due to illegal drugs. Drug poisonings now exceed motor vehicle accidents as a cause of death. According to the CDC, between 1999 and 2014, more than 165,000 people died in the United States from prescription-related overdoses. In New Hampshire, drug overdose deaths have spiked from 163 to 438 in 2015, and 91% of those deaths were opioid-related.

186. Overdose deaths represent only the tip of the iceberg. In New Hampshire, opioid- and heroin-related emergency department visits were 2,067 in 2015 and increased 26% in

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[56] *See* n.8, *supra*.

[57] Theodore J Cicero et al., *Relationship between therapeutic use and abuse of opioid analgesics in rural, suburban, and urban locations in the United States*. 16.8 Pharmacoepidemiology and drug safety, 827-40 (2007).

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

2016. There was a similar spike in emergency medical technicians' administration of naloxone—the emergency antidote to opioid overdose—with use rising from 1,050 in 2013 to 1,921 in 2015 and to 2,724 in 2015. In 2014, health care costs related to opioid abuse in New Hampshire exceeded $107 million.

187. Rising opioid use and abuse have had negative social and economic consequences far beyond overdoses. According to a 2016 study by a Princeton economist, unemployment increasingly is correlated with prescription painkiller use. Nearly half of surveyed men not in the labor force said they took painkillers daily, and two-thirds of them were on prescription medications—compared to just 20% of employed men who reported taking painkillers. Worse still, many of those taking painkillers still said they experienced pain daily.

188. There are also swelling costs from the growing universe of medications aimed at treating secondary effects of opioids—including not only addiction and overdose, but also side effects like constipation and sedation. According to a recent analysis by *The Washington Post*, working age women and men on opioids are much more likely to have four or more prescriptions from a physician (57% and 41%, respectively) than are their counterparts who do not take opioids (14% and 9%, respectively). These secondary-effects medications—essentially, drugs to treat the effects of opioids—generated at least $4.6 billion in spending in 2015, on top of $9.57 billion in spending on opioids themselves. In addition, there are also the costs of dispensing opioids— in office visits to obtain refills, count pills, or obtain toxicology screens to monitor potential abuse.

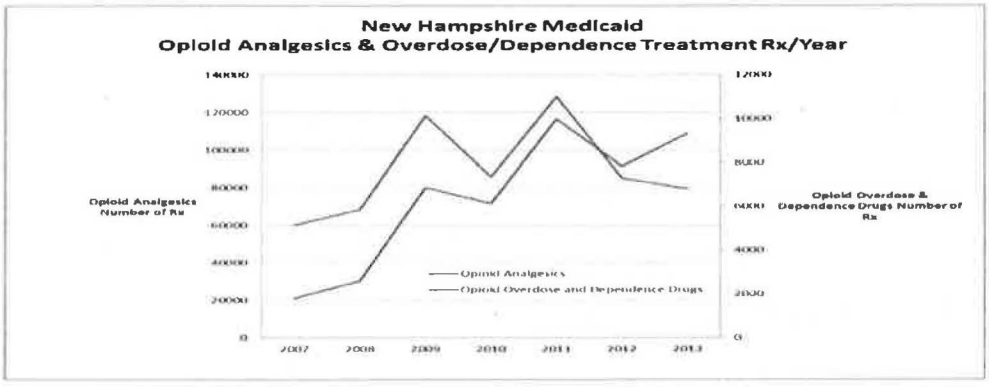
189. The deceptive marketing and overprescribing of opioids also have had a significant detrimental impact on children in New Hampshire. The overprescribing of opioids for chronic pain has given young children access to opioids, nearly all of which were prescribed

for adults in their household. In New Hampshire, roughly 1 in 5 teenagers has abused prescription drugs. Five children younger than 10 and 176 teenagers between the ages of 10 and 19 had opioid-related emergency room visits in New Hampshire in 2016.

190. Even infants have not been immune to the impact of opioid abuse. There has been a dramatic rise in the number of infants who are born addicted to opioids due to prenatal exposure and suffer from neonatal abstinence syndrome ("NAS," also known as neonatal opioid withdrawal syndrome, or "NOWS"). These infants painfully withdraw from the drug once they are born and cry nonstop from the pain and stress of withdrawal, experience convulsions or tremors, have difficulty sleeping and feeding, and suffer from diarrhea, vomiting, and low weight gain, among other serious symptoms. The long-term developmental effects are still unknown, though research in other states has indicated that these children are likely to suffer from continued, serious neurologic and cognitive impacts, including hyperactivity, attention deficit disorder, lack of impulse control, and a higher risk of future addiction. When untreated, NAS can be life-threatening. In 2009, more than 13,000 infants in the United States were born with NAS, or about one every hour. In New Hampshire, the number of infants born with NAS rose from just 21 in 2002 to 182 in 2009.Total births with drug exposure reached 504 in 2015, an increase of 37% from the previous year. In 2015, Memorial Hospital in North Conway reported that the percentage of pregnant women presenting with opioid dependence had skyrocketed, prompting the hospital to institute a coordinated treatment program to reduce NAS and treat the mothers' addiction. A similar program is in place at Dartmouth-Hitchcock Medical Center. Two Manchester hospitals reported that, between them, there were more than 100 babies born with NAS in 2016.

191. The number of children removed from homes with substance abuse problems went from 85 in 2010 to 329 in 2015—a 387% increase. "The opioid crisis is the biggest contributor when looking at what's changed," said one official. There are not only more children requiring assistance, but more children with complex needs who will not have a stable home to which to return. The City of Manchester referred more than 2,500 people to a student assistance program in 2016.

192. Opioids now outpace other sources of addiction in demand for substance abuse treatment. In New Hampshire, the percentage of individuals entering state-funded substance abuse treatment for oxycodone (the only prescription opioid reported) has sharply risen, while admissions for alcohol, cocaine, marijuana, and heroin have either decreased or remained stable. This data echoes the experience of treatment specialists interviewed by the State, who say that prescription opioid abuse is driving increased demand for addiction treatment. While state-funded treatment admissions related to other drugs have remained stable or fallen, oxycodone (the active ingredient in OxyContin) admissions have risen. From 2007-2013, the last years for which data are available, state Medicaid spending on drugs to counter overdose or addiction increased six-fold. These drugs were prescribed once per 36 opioid prescriptions in 2007 and once every 9 prescriptions in 2013.



193. Purdue's creation through false and misleading advertising 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.

194. Contrary to Purdue's misrepresentations, most of the illicit use stems from *prescribed* opioids. It has been estimated that 60% of the opioids that are abused come, directly or indirectly, through physicians' prescriptions. In 2011, 71% of people who abused prescription opioids got them through friends or relatives, not from drug dealers or the internet.

195. In New Hampshire, too, many of those who have overdosed started out on opioids with a prescription to treat their chronic pain. According to the state medical examiner's investigations of overdose deaths in 2014 and 2015, numerous decedents had a history of chronic pain and opioid use and abuse, were trying to reduce their use of OxyContin or address their addiction, and had or had recently filled opioid prescriptions.

196. Addiction treatment centers and specialists interviewed by the State likewise indicate that many of their patients—for one Nashua facility, up to 95%—started on legal opioid prescriptions. These observations comport with national studies indicating that opioids are the first drug of abuse by as many as 80% of heroin addicts. These patients are a diverse group, from professionals to the unemployed.

197. Those patients 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. One New Hampshire addiction treatment specialist,

for example, said her patients were not warned of the risks. She suggested that, to properly prepare patients, "this should be on the bottle -- 'could cause homelessness, incarceration, addiction.'"

198. In addition, because heroin is cheaper than prescription painkillers, many prescription opioid addicts migrate to heroin. According to addiction treatment centers interviewed by the State, while many patients became addicted to prescription opioids, most had crossed over to heroin before they sought treatment. Manchester police seized more than 27,000 grams of heroin in 2015, up from 1,314 in 2014.

199. 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 Hampshire communities through a booming trafficking network. Patients who traveled from prescription opioids to heroin may now find themselves graduated to heroin plus fentanyl. According to the DEA, agents previously saw heroin mixed with a little fentanyl; "[n]ow we're seeing fentanyl mixed with a little bit of heroin."[59] Fentanyl-related overdoses now far exceed those involving heroin alone. In 2011, the state medical examiner reported just 18 fentanyl-related fatalities; in 2015, that number ballooned to at least 261. 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.

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[59] Shawne K. Wickham, *Fentanyl Killing More People in NH Than Heroin*, N.H. Union Leader (Jan. 30, 2016), http://www.unionleader.com/apps/pbcs.dll/article?AID=/20160131/NEWS12/160139925/-1/mobile&template=mobileart.

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 disease that hastens their death by 10 or 20 years.

201. Although recovering addicts often are unwilling to discuss their histories, several shared their stories with the State. One, a Nashua lumberyard worker, injured his knee at age 21. A physician prescribed him the opioid Percocet. Despite a past that included recreational drug use, his doctor did not warn him about the risk of addiction. For years he was on and off various prescription opioids as he repeatedly reinjured his knee. He knew he was addicted when he started getting sick without the drugs. He ultimately turned to the streets for his pills, buying—and stealing—80 mg OxyContin tablets, fentanyl, and other opioids. As pills became harder to find, he turned to heroin.[60] At rock bottom, he was homeless, jobless, down to 100 pounds, and could not look himself in the mirror. After more than ten years on opioids, he eventually got clean through a Suboxone program. He wishes he knew more about what he was getting into with the first doctor, including the side effects, withdrawal, and risk of addiction. Having battled addiction to other drugs, he recalled that opioids had the heaviest toll.

202. Another recovered addict, now a treatment counselor in Nashua, injured his back as a teenager playing hockey. At the hospital, he was given morphine and Percocet to take home. He said he thought Percocet was safe because the doctor prescribed it. After successive

[60] 94% of patients in treatment for opioid addiction said they chose to use heroin because prescription opioids were more expensive and harder to obtain.

prescriptions ran out, he started stealing 80 mg OxyContin tablets from his grandfather, and later turned to buying them—and heroin—on the street. Despite dreams of playing college hockey, he took drugs instead of studying and never finished his degree. He lost jobs and relationships, overdosed several times, and spent time in detox, ultimately staying clean after time in an in-patient program arranged by his parents. He wishes that at the age of 16 he knew that he would throw away everything he had been taught to get the drugs.

E. Although Purdue Knew That Its Marketing Of Opioids Was False And Misleading, The Company Fraudulently Concealed Its Misconduct.

203. 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.

204. 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, unfair, and fraudulent conduct. Purdue 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.

205. 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.

V. CAUSES OF ACTION

COUNT ONE

CONSUMER FRAUD—DECEPTIVE AND UNFAIR ACTS AND PRACTICES

Violations of the Consumer Protection Act, RSA 358-A

206. The State realleges and incorporates by reference each of the allegations contained in the preceding paragraphs of this Complaint as though fully alleged herein.

207. The Consumer Protection Act makes it unlawful for a business to engage in "any unfair or deceptive act or practice in the conduct of any trade or commerce within this state." RSA 358-A:2.

208. Purdue's conduct as described in the Complaint violated RSA 358-A:2 because it was intended to and likely to deceive consumers and occurred, and continues to occur, in the course of Purdue's marketing activities within New Hampshire.

209. At all times relevant to this Complaint, Purdue violated RSA 358-A:2 by engaging in the following deceptive acts or practices:

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.

210. Purdue's statements about the use of opioids to treat chronic pain were not supported by or were contrary to the scientific evidence, as confirmed by the CDC and FDA based on that evidence.

211. Further, Purdue's omissions, which were false and misleading in their own right, rendered even seemingly truthful statements about opioids false and misleading.

212. At the time it made or disseminated its false and misleading statements or caused these statements to be made or disseminated, Purdue knew or recklessly disregarded that the statements were false or misleading and therefore likely to deceive the public. In addition, Purdue knew or recklessly disregarded that its false and misleading marketing, including its omissions, created a false or misleading impression of the risks and benefits of long-term opioid use.

213. At all times relevant to this Complaint, Purdue also violated RSA 358-A:2 by engaging in the following unfair acts or practices:

a. engaging in untrue, false, unsubstantiated, and misleading marketing in violation of 21 C.F.R. § 202.1(e);

b. promoting purported advantages of its opioids, including but not limited to decreased risk of abuse or addiction and 12-hour duration of pain relief, without substantial scientific evidence to support its claims, in violation of FDA regulations, including 21 C.F.R. § 202.1(e);

c. failing, 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);

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 and the standards of practice expressly stated in Med. 502.05, which mandates that prescriptions of opioids for chronic pain be "for the lowest effective dose for a limited duration";

e. frustrating prescribers' ability to ensure informed consent by accurately explaining the risk of addiction, overdose, and death and outlining the risks and benefits of opioid use, as required under the standards expressed in RSA 318-B:41 and Med. 502.05;

f. frustrating the public policy in favor of, and the State's efforts to reduce the overprescribing, overuse, misuse, and abuse of addictive prescription opioids, as reflected in the State's Prescription Drug Monitoring Program and Comprehensive Response to the opiate/opioid public health crisis;

g. failing to report its knowledge regarding suspicious prescribing in New Hampshire to law enforcement or the Board of Medicine.

214. These acts or practice were unfair in that they offend public policy, reflected in federal law, that requires the truthful and balanced marketing of prescription drugs, 21 C.F.R. § 202.1(e), and the monitoring and reporting of suspicious orders of controlled substances, 21 C.F.R. § 1301.74(b).

215. These acts or practices were unfair in that they offended the State's public policy, expressed in the Act itself, to protect consumers and competitors from deceptive marketing and to ensure an honest marketplace.

216. These acts or practices were unfair in that they offended public policy, reflected in state legislation and standards of practice, to minimize the risk of addiction to and abuse of controlled substances by limiting opioid prescriptions to the lowest effective dose for a limited time and requiring that patients be provided full information regarding the risks and benefits of

using opioids to treat chronic pain, *see* RSA 318-B:41; Med. 502.05, as well as the State's other efforts to prevent and address opioid abuse and addiction.

217. These acts or practices were unfair in that they immorally and 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 or addicted, such that neither the patient nor the prescriber could avoid injury by simply stopping or choosing an alternate treatment. Purdue also immorally and unethically withheld information from authorities that they could have used to reduce opioid abuse and diversion in New Hampshire.

218. These acts or practices were unfair in that Purdue made continuous misrepresentations in an ongoing effort to avoid enforceable obligations and obtain benefits by touting the use of opioids for chronic pain, twice-daily dosing of "12-hour" OxyContin, and the use of AD formulations as providing benefits Purdue knew they would not deliver. This course of conduct immorally and unscrupulously placed New Hampshire consumers in continuous peril and caused substantial injury.

219. These acts or practices were unfair in that they have resulted in a substantial injury to New Hampshire consumers that is not outweighed by any countervailing benefits to consumers or competition. Purdue's marketing has caused New Hampshire consumers to suffer opioid addiction, abuse, overdose, death, and associated economic loss, and there is no countervailing benefit of such unsubstantiated and unbalanced marketing. Further, Purdue's failure to report suspicious prescribing has resulted in continued illicit prescribing of opioids by physicians who could have been investigated by law enforcement or the Board of Medicine.

220. Purdue's conduct, as described in this Complaint, meets and exceeds a level of rascality that would raise an eyebrow of someone inured to the rough and tumble of the world of commerce.

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

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

223. Pursuant to RSA 358-A:4, III, the State requests an order permanently enjoining Purdue from engaging in these deceptive and unfair acts and practices.

224. Pursuant to RSA 358-A:4, III(a), the State requests an order directing restitution of money Purdue acquired by virtue of these deceptive and unfair acts and practices.

225. Pursuant to RSA 358-A:4, III(b), the State requests an order assessing a civil penalty of $10,000 against Purdue for each violation of the Consumer Protection Act.

226. Pursuant to RSA 358-A:6, IV, the State requests and order awarding to the State all legal costs and expenses.

COUNT TWO

CONSUMER FRAUD—UNFAIR COMPETITION

Violations of the Consumer Protection Act, RSA 358-A

227. The State realleges and incorporates by reference each of the allegations contained in the preceding paragraphs of this Complaint as though fully alleged herein.

228. The Consumer Protection Act makes it unlawful for a business to engage in "any unfair method of competition . . . in the conduct of any trade or commerce within this state." RSA 358-A:2. The Act specifies that one such unfair method of competition is "[r]epresenting

that goods or services have sponsorship, approval, characteristics, ingredients, uses, benefits, or quantities that they do not have."

229. Purdue's conduct as described in the Complaint violated RSA 358-A:2 because Purdue, by minimizing and misstating the risks of opioids and overstating their benefits, has represented, and continues to represent, that its opioids have characteristics and benefits they do not have in the course of Purdue's marketing activities within New Hampshire. In particular, Purdue has stated or implied that:

a. Twice-daily dosing of OxyContin provides 12 hours of pain relief with each dose, when Purdue knew or recklessly disregarded that for many patients the pain relief lasts well short of 12 hours; and

b. AD formulations of its opioids make the drugs less likely to be abused or less addictive, when no evidence exists for such statements;

230. At the time it made or disseminated these statements, Purdue knew or recklessly disregarded that there was no scientific evidence to support the statements or that available science contradicted the statements.

231. At all times relevant to this Complaint, Purdue promoted OxyContin as providing 12 hours of pain relief, and promoted AD formulations of its opioids as more difficult to abuse and less addictive, as means of maintaining a competitive advantage against other opioid pharmaceuticals.

232. By reason of Purdue's conduct, New Hampshire consumers have suffered substantial injury, including but not limited to pain and suffering from inappropriate dosing, opioid addiction, injury, overdose, death, and economic loss.

233. By reason of Purdue's conduct, its cities, towns, and counties have suffered substantial injury, including but not limited to costs associated with administering first responder services and support care for the families of individuals suffering drug overdoses.

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

235. Pursuant to RSA 358-A:4, III(a), the State requests an order permanently enjoining Purdue from engaging in unfair methods of competition as described herein.

236. Pursuant to RSA 358-A:4, III(a), the State requests an order directing restitution of money Purdue acquired by virtue of the unfair methods of competition described herein.

237. Pursuant to RSA 358-A:4, III(b), the State requests an order assessing a civil penalty of $10,000 against Purdue for each violation of the Consumer Protection Act.

238. Pursuant to RSA 358-A:6, IV, the State requests and order awarding to the State all legal costs and expenses.

COUNT THREE

FALSE CLAIMS

Violations of the Medicaid Fraud and False Claims Act, RSA 167:61-b

239. The State realleges and incorporates by reference each of the allegations contained in the preceding paragraphs of this Complaint as though fully alleged herein.

240. RSA 167:61-b is violated when any person:

> (a) Knowingly presents, or causes to be presented, to an officer or employee of the [New Hampshire] department [of Health and Human Services], a false or fraudulent claim for payment or approval.
> (b) 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 department.
> (c) Conspires to defraud the department by getting a false or fraudulent claim allowed or paid. . . .
>
> N.H. Rev. Stat. Ann. § 167:61-b(I).

241. RSA 167:61-b(V)(a) defines a claim as:

> any request or demand, whether under a contract or otherwise, for money or property that is made to an officer, employee, agent, or other representative of the department or to a contractor, grantee, or other person, if the department provides

> any portion of the money or property that is requested or demanded, or if the department will reimburse the contractor, grantee, or other recipient for any portion of the money or property that is requested or demanded.

242. Defendants' practices, as described in the Complaint, violated RSA 167:61-b. Defendants, through their 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 a false statement to get a false or fraudulent claim for payment approved by the State.

243. Defendants knew that the doctors, pharmacists, other health care providers, and/or agents of the State Medicaid program to whom they deceptively marketed prescription opioids had treated and would continue to treat New Hampshire Medicaid patients.

244. Defendants 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, or misleading and were made for the purpose of getting the State's Medicaid program to pay for opioids for long-term treatment of chronic pain. In addition, Defendants knew, deliberately ignored, or recklessly disregarded, that their marketing and promotional efforts created an untrue, false, and misleading impression about the risks, benefits, and superiority of opioids for chronic pain.

245. Defendants knew their false statements were material to healthcare providers' decision to prescribe opioids to New Hampshire Medicaid patients. Indeed, Defendants intended such statement to be material to encourage additional opioid prescriptions.

246. Defendants' scheme caused doctors to write prescriptions for opioids to treat chronic pain that were presented to the State's Medicaid program for payment. The State only covers the cost of prescription drugs that are medically necessary. Specifically, New Hampshire's rules governing the Medicaid program define "medically necessary" services as:

> health care services that a licensed health care provider, exercising prudent clinical judgment, would provide, in accordance with generally accepted standards of medical practice, to a recipient for the purpose of evaluating, diagnosing, preventing, or treating an acute or chronic illness, injury, disease, or its symptoms, and that are:
>
> > (1) Clinically appropriate in terms of type, frequency of use, extent, site, and duration, and consistent with the established diagnosis or treatment of the recipient's illness, injury, disease, or its symptoms;
> >
> > (2) Not primarily for the convenience of the recipient or the recipient's family, caregiver, or health care provider;
> >
> > (3) No more costly than other items or services which would produce equivalent diagnostic, therapeutic, or treatment results as related to the recipient's illness, injury, disease, or its symptoms; and
> >
> > (4) Not experimental, investigative, cosmetic, or duplicative in nature.

PART He-W 530.01(e). In addition, under He-W 570.09, practitioners or pharmacists must certify specific brand drugs as "brand necessary" or "brand medically necessary." Doctors, pharmacists, other health care provides, and/or agents of the State Medicaid program expressly or impliedly certified to the State that opioids were medically necessary to treat chronic pain because they were influenced by the false and misleading statements disseminated by Defendants about the risks, benefits, and superiority of opioids for chronic pain. Moreover, many of the prescriptions written by physicians or other health care providers and/or authorized by the State Medicaid program and submitted to the State were for uses that were misbranded and/or not otherwise approved by the FDA.

247. Defendants knew, deliberately ignored, or recklessly disregarded that, as a natural consequence of their 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 Defendants' fraud.

248. Defendants' misrepresentations and omissions were material because if the State had known of the false statements disseminated by Defendants and their third-party allies that doctors, pharmacists, and other health care providers or agents of the State Medicaid program, health plan, and workers' compensation program were relying on to certify and/or determine that opioids were medically necessary, the State would have undertaken efforts to avoid its payment of false claims and to rein in the harm from the inappropriate prescribing of opioids, as discussed *supra* at Section IV.D.

249. Alternatively, the misrepresentations were material because they would have a natural tendency to influence or be capable of influencing whether the costs of long-term prescriptions of opioids to treat chronic pain were paid by the State.

250. By virtue of the above-described acts, Defendants knowingly made, used or caused to be made or used false records and statements, and omitted material facts, to induce the State to approve and pay such false and fraudulent claims.

251. But for Defendants' false statements, the false claims at issue would not have been submitted for payment and would not have been paid by the State's Medicaid program.

252. To the extent that such prescribing is considered consistent with generally accepted standards of medical practice, clinically appropriate and/or consistent with established treatment, it is only because standards of practice have been tainted by Defendants' deceptive marketing.

253. The State, unaware of the falsity of the records, statements and claims made, used, or presented or caused to be made, used or presented by Defendants, paid claims that would not be paid but for Defendants' illegal business practices.

254. By reason of Defendants' unlawful acts, the State has been damaged, and continues to be damaged, in a substantial amount to be determined at trial. The State's damages from false claims submitted, or caused to be submitted, by each Defendant exceed $5,000 in value. From 2011-2015, the State's Medicaid program spent $3.5 million to pay for some 7,886 prescriptions and suffered additional damages for the costs of providing and using opioids long-term to treat chronic pain.

255. Because Defendants' unbranded marketing caused doctors to prescribe and the State to pay for long-term opioid treatment using opioids manufactured or distributed by other drug makers, Defendants caused and are responsible for those costs and claims as well.

256. Pursuant to RSA 167:61-b(I), the State requests an order compelling Defendants to pay three times the amount of damages sustained by the State for each violation of RSA 167:61-b.

257. Pursuant to RSA 167:61-b(I), the State requests an order assessing a civil penalty of not less than $5,000 and not more than $10,000 against Defendants for each violation of RSA 167:61-b.

258. Pursuant to RSA 167:61-b(II)(b), the State requests an order compelling Defendants to pay the State's costs and attorneys' fees arising from this action

COUNT FOUR

PUBLIC NUISANCE

259. 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.

260. 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.

261. 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 Hampshire families and communities; (d) lost employee productivity; (e) the creation and maintenance of a secondary, criminal market for opioids; (g) greater demand for emergency services, law enforcement, addiction treatment, and social services; and (h) increased health care costs for individuals, families, and the State.

262. At all times relevant to the Complaint, Purdue's deceptive 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. Purdue also interfered with enjoyment of the public right by failing to report suspicions of illicit prescribing to law enforcement and the Board of Medicine.

263. 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) recruiting physician speakers; (c) disseminating advertisements and publications; (d) sponsoring and creating flawed and biased scientific research and prescribing guidelines; (e) sponsoring and collaborating with third parties to disseminate false and misleading messages about opioids; and (f) failing to report suspicious prescribing to law enforcement and the Board of Medicine. 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.

264. Purdue's actions were, at the very least, a substantial factor 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 Defendants' actions, opioid use would not have become so widespread, and the opioid epidemic that now exists in New Hampshire would have been averted or would be much less severe.

265. The public nuisance was foreseeable to Purdue, which knew or should have known of the harm it would cause. 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. A reasonable person in Purdue's position would foresee not only a vastly expanded market for

chronic opioid therapy as the likely result of Purdue's conduct—that was Purdue's goal—but also that widespread problems of opioid addiction and abuse would result. In fact, 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.

266. This public nuisance can be abated 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.

267. The State therefore requests an order providing for abatement of the nuisance that Purdue created or was a substantial factor in creating, and enjoining Purdue from further conduct contributing to the nuisance.

COUNT FIVE

UNJUST ENRICHMENT

268. The State realleges and incorporates by reference each of the allegations contained in the preceding paragraphs of this Complaint as though fully alleged herein.

269. Purdue has unjustly retained a benefit to the State detriment, and the Defendants' retention of that benefit violates the fundamental principles of justice, equity, and good conscience.

270. As alleged herein, the State has reimbursed opioid prescriptions covered by its employee health and workers' compensation plans. By deceptively and illegally promoting opioids to treat chronic pain, Purdue has caused health care providers to write, and the State to reimburse, prescriptions for opioids that otherwise would not have been written and reimbursed.

271. Purdue has reaped revenues and profits from the State's payments, enriching itself at the State's expense, even as the State continues to cope with a crisis of opioid addiction,

overdose, injury, and death that Purdue helped create. This enrichment was without justification, and the State lacks an adequate remedy provided by law.

272. Accordingly, under principles of equity, Defendants should be disgorged of money retained by reason of their deceptive and illegal acts that in equity and good conscience belong to the State and its citizens.

COUNT SIX

FRAUDULENT OR NEGLIGENT MISREPRESENTATION

273. The State realleges and incorporates by reference each of the allegations contained in the preceding paragraphs of this Complaint as though fully alleged herein.

274. As alleged in the Complaint, Purdue engaged in false representation and concealment of material facts about the use of opioids to treat chronic pain.

275. Purdue knew, deliberately ignored, or recklessly disregarded , that:

a. its statements about the use of opioids to treat chronic pain were false or misleading;

b. statements about opioids that it caused to be made or disseminated were false or misleading;

c. its statements made to promote the use of opioids to treat chronic pain omitted or concealed material facts; and

d. it failed to correct prior misrepresentations and omissions about the risks and benefits of opioids.

e. for many patients the pain relief of "12-hour" OxyContin dosing lasts well short of 12 hours; and

f. there is no evidence to support statements that AD formulations of Purdue's opioids make the drugs less likely to be abused or diverted or less addictive; and

g. it lacked the commitment it professed to reducing or deterring abuse and to cooperating with law enforcement, as evidenced by its failure to report suspicious prescribers as required by law.

276. The statements Purdue made, or caused to be made about the use of opioids to treat chronic pain, the duration of pain relief provided by 12-hour dosing of OxyContin, and AD formulations of its opioids, were not supported by or were contrary to the scientific evidence, as confirmed by the CDC and FDA based on that evidence.

277. Further, Purdue's omissions, which were false and misleading in their own right, rendered even seemingly truthful statements about opioids false and misleading.

278. Purdue intended that healthcare providers and patients would rely on its misrepresentations and deceptive marketing regarding the use of opioids to treat chronic pain, the characteristics of Purdue's branded opioids, and Purdue's efforts to cooperate with law enforcement and assist in avoiding addiction, abuse, and overdose.

279. Purdue had a duty to the State and its citizens to exercise due care in the advertising, marketing, promotion, and sale of opioid drugs.

280. Purdue had a duty to the State and its citizens not to make false, misleading, or deceptive statements about opioids and treatment for chronic pain.

281. Purdue had a duty, as one who volunteered information to others not having equal knowledge, with the intention that they would act upon it, to exercise reasonable care to verify the truth of their statements before making them.

282. Purdue had a duty to the State and its citizens to report suspicious prescribers and to refrain from providing opioids to providers and pharmacies it believed, or had reason to believe, were dispensing its opioids illegally.

283. Purdue so negligently, carelessly, and recklessly advertised, marketed, promoted, and sold its opioid drugs and the use of opioids to treat chronic pain, and so negligently, carelessly, and recklessly misrepresented the risks and benefits of using opioids to treat chronic

pain that they breached their duties and directly and proximately caused New Hampshire consumers to suffer opioid addiction, abuse, overdose, death and associated economic damage, resulting in the damages alleged in this Complaint.

284. Purdue knew, or should have known, that prescribers and patients would rely on its misrepresentations and deceptive statements, and would be misled by its material omissions.

285. Purdue identified many prescribers or pharmacists engaged in suspicious prescribing of its opioids, but failed to report its suspicions, as required by law, and failed to stop supplying the prescribers it suspected of illegal activity with more drugs.

286. Purdue knew, or should have known, that as an inevitable consequence of the conduct described herein, New Hampshire citizens would suffer opioid addiction, overdose, death, and associated economic loss, and the State would suffer economic loss. Further, Purdue knew, or should have known, that its failure to report suspicious prescribing has resulted in continued illicit prescribing of opioids by physicians who could have been investigated and stopped.

287. In light of the facts alleged herein, Defendants breached their duty to use due care in the advertising, marketing, promotion, and sale of opioids.

288. In addition, Defendants' false representations and concealments were reasonably calculated to deceive the State and health care providers who treated patients whose care was paid for or reimbursed by the State.

289. Prescribers and the State relied to their determinant on Purdue's misrepresentations and concealment of material fact.

290. But for Defendants' misrepresentation and concealment of material facts, the State would not have incurred damages in paying for medically unnecessary prescriptions and in addressing the public health crisis that Defendants' actions have created.

291. As a direct and proximate result of Defendants' acts and omissions as alleged herein, the State has sustained and will sustain substantial expenses and damages, described in this Complaint.

292. Defendants' conduct, as alleged herein, was wanton, malicious, and/or oppressive.

VI. PRAYER FOR RELIEF

293. WHEREFORE, the State prays for an order:

a. awarding judgment in its favor and against defendants on each cause of action asserted in the Complaint;

b. permanently enjoining Purdue from engaging in the deceptive acts and practices and unfair methods of competition described in the Complaint;

c. directing disgorgement of money Purdue wrongfully and unjustly acquired by virtue of the conduct described in the Complaint;

d. awarding restitution and damages, including enhanced compensatory damages, as appropriate, for the costs incurred by the State, cities, counties, and consumers in paying for the prescribing of opioids and their direct costs in abuse, addiction, abuse, overdose, injury, and death;

e. assessing civil penalties of $10,000 for each violation of the Consumer Protection Act;

f. requiring Purdue to abate the public nuisance its conduct has created;

g. requiring Purdue to pay the costs of the suit, including attorneys' fees; and

h. awarding such other, further, and different relief as this Court may deem just.

DATED: _____, 2017.

Dated: 8/8/2017

THE STATE OF NEW HAMPSHIRE

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