STATE OF SOUTH CAROLINA	)	IN THE COURT OF COMMON PLEAS
	)	
COUNTY OF RICHLAND	)	FIFTH JUDICIAL CIRCUIT
THE STATE OF SOUTH CAROLINA, ex rel. Alan Wilson, in his official capacity as Attorney General of the State of South Carolina, Plaintiff, vs. Purdue Pharma L.P., Purdue Pharma, Inc., and The Purdue Frederick Company, Defendants.	)	Civil Action No.: **Complaint** **Jury Trial Requested**

COMPLAINT FOR INJUNCTIVE AND OTHER RELIEF UNDER SOUTH CAROLINA'S CONSUMER PROTECTION AND COMMON LAWS, AND FOR VIOLATION OF PRIOR CONSENT JUDGMENT

CONTENTS

I. PRELIMINARY STATEMENT

1. The Attorney General brings this action pursuant to his *parens patriae*, constitutional, statutory, and common law authority, including the authority granted to him by the South Carolina Unfair Trade Practices Act, S.C. Code §§ 39-5-10, *et seq.* ("SCUTPA") to redress Purdue Pharma, L.P.'s; Purdue Pharma, Inc.'s; and the Purdue Frederick Company's (together, "Defendants" or "Purdue") campaign of unfairly and deceptively marketing opioids, for creating a public nuisance, for unjust enrichment, and for violating its previously entered Consent Judgment[1] with the State of South Carolina.

2. Defendants Purdue Pharma, L.P., Purdue Pharma Inc., and the Purdue Frederick Company 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

[1] The Consent Judgment is attached to this Complaint as Exhibit A.

South Carolina.

3. Prescription opioids are narcotics. They are derived from and possess properties similar to opium and heroin, and they are regulated as controlled substances.[2] While opioids can work to dampen the perception of pain, they also can create an addictive, euphoric high. At higher doses, they can slow the user's breathing, causing potentially fatal respiratory depression. Most patients receiving more than a few weeks of opioid therapy will experience often prolonged withdrawal symptoms—including severe anxiety, nausea, headaches, tremors, delirium, and pain—if opioid use is delayed or discontinued. When using opioids continuously, patients grow tolerant to their analgesic effects—requiring progressively higher doses and increasing the risks of withdrawal, addiction, and overdose.

4. Because the medical community recognized these dangers, they originally used opioids cautiously and sparingly, typically only for short-term acute pain—where brief use limited the need for escalating doses and the risk of addiction—or for palliative (end-of-life)

[2] Since 1970, opioids have been regulated both nationally and in South Carolina under the Controlled Substances Act, 21 U.S.C. § 801 *et seq.*, ("CSA") and the South Carolina Controlled Substances Act, S.C. Code § 44-53-10 *et seq.* Controlled substances are categorized in five schedules, ranked in order of their potential for abuse, with Schedule I the highest. Both federal and state acts impose 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. *See* 21 U.S.C. § 812; S.C. Code § 44-53-200. 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 psychological dependence. *See* 21 U.S.C. § 812; S.C. Code § 44-53-220. OxyContin, Hysingla ER, MS Contin, Dilaudid, Dilaudid HP, and Targiniq ER are Schedule II drugs; Butrans is a Schedule III drug.

care.[3] Consequently, the market for prescription opioids was sharply restricted.

5. As Purdue developed OxyContin in the mid-1990s, it knew that to expand its market and profits, it needed to change the perception of opioids to permit and encourage the use of opioids long-term for widespread chronic conditions, like back pain, migraines, and arthritis. Purdue helped cultivate a narrative that pain was undertreated and pain treatment should be a higher priority for health care providers. This paved the way for increased prescribing of opioids for chronic pain. Purdue's promotional efforts dovetailed with this narrative, as Purdue began to promote opioids generally, and its own opioids in particular, as safe, effective, and appropriate for even long-term use for routine pain conditions. As part of this strategy, Purdue misrepresented the risk of addiction as modest, manageable, and outweighed by the benefits of opioid use.

6. Purdue's deceptive marketing efforts continued over the next several years, eventually coming under investigation by a number of state and federal entities. In 2007, Purdue and three of its executives pleaded guilty to federal criminal charges for deceptively marketing opioids and reached civil settlements with South Carolina, 25 other states, and the District of Columbia. However, rather than reforming its opioid marketing to comply with the law, Purdue continued to mislead and obfuscate. To this day, Purdue not only purposely benefits from—and fails to correct—its earlier misrepresentations, but persists in disseminating the same types of misleading messages, violating South Carolina law and Purdue's Consent Judgment with the State.

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

7. After 2007, Purdue spent hundreds of millions of dollars on promotional activities and materials that continued to falsely deny or trivialize the risk of addiction and overstated the benefits of opioids. Purdue continued to deceptively market opioids to prescribers through advertising, websites, and in-person sales calls. Purdue also relied upon continuing medical education ("CME") seminars, non-credit education programs, treatment guidelines, and other publications and programs by patient advocacy groups, professional associations, and physicians that were flawed and misleading, but seemed independent and therefore credible.

8. Purdue was able to persuade doctors that opioids were not addictive, despite the previous medical consensus and scientific evidence to the contrary, through a variety of means. Purdue convinced prescribers that, even if opioids had some limited potential to be addictive, any risk of addiction could be managed by doctors carefully supervising their use by appropriate patients. Part of Purdue's message was that doctors should treat the right patients: legitimate patients who took the drugs as directed (orally) to treat their pain, rather than abusers seeking to snort or inject the drugs for recreation. By defining the class of individuals who should not receive opioids as only these abusers, Purdue gave doctors a false sense of security that they could safely prescribe opioids to any other pain patients, particularly if screened and tested.

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

10. In 2007, Purdue and three of its executives pled guilty to federal charges for

misleading doctors, patients, and regulators about the risk of addiction and OxyContin's potential to be abused. As laid out in its plea agreement, Purdue systematically misrepresented the risk of addiction, including promising that opioid addiction occurred in less than 1% of patients and that opioids were not addictive when legitimately prescribed. This was how Purdue explained away what doctors had previously believed about opioids: it was not that opioids were not addictive, but rather opioids would not addict patients under a doctor's care.

11. The State of South Carolina recently learned that Purdue's guilty plea and Consent Judgment had no effect on Purdue's operations and marketing. In the decade that followed, Purdue created and sustained a multi-billion dollar pain franchise through the same pattern of deceptive marketing. Specifically:

a. Purdue continued to tell doctors that patients receiving opioid prescriptions for pain generally would not become addicted, and that doctors could use screening tools to exclude patients who might.

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

c. Purdue continued to tell doctors that opioids relieved pain when used long-term, without any studies to support this claim and without disclosing the other risks from long-term use of opioids.

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

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

12. Purdue also developed new deceptive marketing practices after 2007 in response to increasing awareness of the problems with opioids. Rather than admit responsibility, Purdue simply blamed abuse and addiction on people snorting or injecting opioids. In 2010, Purdue developed an "abuse-deterrent" formulation ("ADF") of OxyContin but deceptively marketed it to doctors, claiming:

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

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

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

13. After 2007, Purdue also claimed to work closely with law enforcement and government agencies, while failing to report doctors that it knew engaged in suspicious prescribing to the South Carolina Board of Medical Examiners.

14. In 2010, when Purdue introduced a reformulated OxyContin, purportedly designed to reduce certain forms of abuse, Purdue also launched a new campaign—capitalizing upon growing concern about the rising tide of opioid addiction, overdose, and death—falsely promoting the effectiveness of its abuse-deterrent opioids in preventing abuse. Like pseudoaddiction, this marketing was intended to, and did, reassure prescribers who became concerned about addiction that they not only could continue to prescribe opioids, but in fact needed to switch to Purdue's opioids because they were safer.

15. In the same vein, Purdue also misrepresented its efforts to rein in the diversion and abuse of opioids, while privately failing to report suspicious prescribing. By failing to take reasonably appropriate steps to address suspicious prescribing of opioids, including failing to notify state and federal authorities regarding South Carolina prescribers, Purdue has violated South Carolina law and its Consent Judgment with the State.

16. Purdue's scheme was resoundingly successful. Chronic opioid therapy—the prescribing of opioids long-term to treat chronic pain—has been a commonplace, and often first-line, treatment since at least the mid-2000s. While previously a small minority of opioid sales, today between 80% and 90% of opioids (measured by weight) used are for chronic pain. In

2015, Purdue reaped an estimated $2.4 billion in revenue, virtually all of it from opioids. Since its launch in 1996, OxyContin alone has generated $35 billion in sales. South Carolina has spent $15.8 million on Purdue opioids through its Medicaid program from the third quarter of 2007 through the first quarter of 2017, and over $28 million on Purdue opioids through its State Health Plan for public employees from January 1, 2010 to July 14, 2017.

17. Purdue's deceptive marketing caused prescribing not only of Purdue opioids, but of opioids as a class, to balloon. Opioids are now among the most prescribed classes of drugs. In 2015, health care providers wrote enough opioid prescriptions to medicate every American around the clock for three weeks, and on an average day, more than 650,000 opioid prescriptions are dispensed in the U.S. In South Carolina, for each year from 2012 through 2016, there has been more than one opioid prescription for every resident of the state. In 2016, South Carolina ranked ninth in the nation in opioid prescribing rates.

18. Purdue knew that its representations regarding the risks and benefits of opioids were not supported by or were directly contrary to the scientific evidence. Indeed, the falsity of its representations has been confirmed by the U.S. Food and Drug Administration ("FDA") in recent public statements (*see* ¶ 50, *infra.*) and the Centers for Disease Control and Prevention ("CDC") in its 2016 *Guideline for Prescribing Opioids for Chronic Pain* ("CDC Guideline"), which exhaustively reviewed the evidence on opioids.

19. Rather than compassionately helping patients, this explosion in opioid use—and 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."[4] As one doctor noted: "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."

20. As a direct result of Purdue's dangerously false marketing, 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."[5] The increased volume of opioid prescribing correlates directly to skyrocketing addiction, overdose, and death; black markets for diverted prescription opioids; and a concomitant rise in heroin and fentanyl abuse by individuals who could no longer legally acquire—or simply could not afford—prescription opioids.

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

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

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

22. The outcomes in South Carolina are equally catastrophic—and getting worse. Over the past five years, more than 3,000 South Carolinians have died from overdoses of prescription opioids. Heroin overdoses in the state have increased by 57% from 2014 to 2015 as a result of patients who cannot get access to prescription opioids turning to heroin. Combined heroin and prescription opioid overdose deaths in South Carolina exceeded the number of homicides in the state in 2015.

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

24. Purdue's conduct has violated, and continues to violate, SCUTPA's prohibitions on unfair or deceptive acts and practices and unfair competition, S.C. Code §§ 39-5-10, *et seq.* Additionally, Purdue's conduct constitutes a common law public nuisance and unjust enrichment. Purdue has also violated the Consent Judgment.

25. Accordingly, the Attorney General brings this action to hold Purdue accountable for its conduct from 2007 through the present; and seeks disgorgement, restitution, civil penalties, abatement, damages, and any other injunctive and equitable relief within this Court's powers to redress and halt these deceptive practices.

II. PARTIES

A. Plaintiff

26. The Plaintiff State of South Carolina brings this action, by and through its Attorney General, Alan Wilson, in its sovereign capacity in order to protect the interests of the State and its citizens. The Attorney General brings this action pursuant to his *parens patriae*,

constitutional, statutory, and common law authority, including the authority granted to him by the South Carolina Unfair Trade Practices Act, S.C. Code §§ 39-5-10, *et seq.*

27. The Plaintiff State of South Carolina also represents the State Medicaid Program and the South Carolina Public Employee Benefit Authority and asserts proprietary claims on behalf of those state entities.

B. Defendants

28. 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. The Purdue Frederick Company is a Delaware corporation with its principal place of business in Stamford, Connecticut.

29. Purdue manufactures, promotes, sells, and distributes opioids such as OxyContin (oxycodone hydrochloride, approved in 1995), MS Contin (morphine sulfate, approved in 1987), Dilaudid and Dilaudid-HP (hydromorphone hydrochloride, approved in 1984 as an injection, 1992 as an oral solution and tablet), Butrans (buprenorphine, approved in 2010), Hysingla ER (hydrocodone bitartrate, approved in 2014) in the United States and in South Carolina.[6] OxyContin is Purdue's best-selling opioid: since 2009, Purdue's annual sales of OxyContin have fluctuated between $2 and $3 billion. Nationwide, OxyContin constitutes roughly 25% of the entire market, by spending, for prescription opioids.

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

III. JURISDICTION AND VENUE

30. This Court has jurisdiction over the subject matter of this case pursuant to S.C. Const. Art. V. § 11, which gives the Circuit Court general jurisdiction over civil actions. This Court has personal jurisdiction over the Defendants because the Defendants do business in South Carolina and/or have the requisite minimum contacts with South Carolina necessary to constitutionally permit the Court to exercise jurisdiction, with such jurisdiction also being within the contemplation of South Carolina's "long arm" statute, S.C. Code § 36-2-803.

31. Venue is appropriate in Richland County pursuant to S.C. Code § 15-7-10, *et seq.*, § 39-5-50, and § 35-1-603.

32. On May 17, 2017, the Attorney General issued notice to Purdue as required by S.C. Code § 39-5-50. The Attorney General has determined that Purdue's conduct, as a result of the specific practices outlined herein, constitutes a threat to the health and safety of the public and requires immediate action.

33. The claims underlying this action are brought within the requisite filing period. Based on the statutes of limitations for the claims asserted, to include claims based on SCUTPA, the 2007 Consent Judgment, and common law, and based on when the Attorney General knew or should have known that Purdue's conduct gave rise to these claims, the statute of limitations has not run for any claim alleged herein.

IV. ADDITIONAL ALLEGATIONS COMMON TO ALL COUNTS

34. For the last two decades, Purdue has engaged in a campaign to create and sustain a market for opioids for long-term use to treat chronic pain, primarily by covering up the risk of addiction and overstating the benefits of using opioids long-term.

35. Beginning in the late 1990s, Purdue presented OxyContin—and later, Butrans and Hysingla ER—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.

36. 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.

37. Thus, Purdue's deceptive marketing created a cadre of doctors who looked for pain and treated it with opioids, which created an even broader cohort of patients who expected and required opioids. This laid the groundwork for today's epidemic of opioid addiction, injury, and death. Purdue skewed the medical and public understanding of opioids to minimize their risks and exaggerate their benefits—a distortion that Purdue failed to correct and continued to practice to its benefit. Purdue's deceptive marketing persisted even after entering into the Consent Judgment with South Carolina and other jurisdictions in 2007 and provided the foundation on which Purdue's equally deceptive post-2007 marketing schemes were built.

A. Purdue Falsely Trivialized, Mischaracterized, and Failed to Disclose the Known, Serious Risk of Addiction

38. Purdue relied heavily on its sales representatives to convey its marketing messages and materials to prescribers in targeted, in-person settings. In South Carolina, Purdue made tens of thousands of sales visits to thousands of prescribers and pharmacies. Some South Carolina prescribers recall seeing Purdue's sales representatives as often as every week or other week.

39. To ensure that sales representatives delivered the desired messages to prescribers, Purdue directed and monitored its sales representatives through detailed action plans, trainings, tests, scripts, role-plays, supervisor tag-alongs, and review of representatives' "call notes" from each visit. Purdue likewise required its sales representatives to use sales aids reviewed, approved, and supplied by the company and forbade them to use promotional materials not approved by the company's marketing and compliance departments. Purdue further ensured marketing consistency nationwide through national and regional sales representative training. Thus, Purdue's sales force in South Carolina used the same deceptive messages about the risks and benefits of its opioids that Purdue employed nationwide.

1. Minimizing or mischaracterizing the risk of addiction

40. To convince South Carolina prescribers and patients that opioids are safe, Purdue continued in 2007 and after to deceptively represent that the risk of abuse and addiction is modest and manageable and limited to illegitimate patients, not those with genuine pain. This created the dangerously misleading impressions that: (1) patients receiving opioid prescriptions for chronic pain would not become addicted, (2) patients at greatest risk of addiction could be identified, (3) all other patients could safely be prescribed opioids, and (4) even high risk patients could be prescribed opioids if closely managed.

41. Purdue's sales representatives regularly omitted from their sales conversations with South Carolina prescribers any discussion of the risk of addiction from long-term use of opioids. These omissions rendered other arguably truthful statements about opioids false and misleading, and they both reinforced and failed to correct Purdue's prior misrepresentations regarding the risk of addiction.

42. Purdue also deceptively undermined evidence that opioids are addictive by suggesting or stating that the risk of addiction is limited to specific, high-risk patients.

According to Purdue, doctors can screen patients to identify those who are likely to become addicted, and therefore they could safely prescribe to everyone else. Purdue discounted general concerns or warnings regarding addiction by reassuring doctors that their patients would not become addicted. One former Purdue sales representative confirmed Purdue's message that opioids were appropriate and safely prescribed to legitimate patients with actual pain. These assurances were false and unsafe, as prescribers cannot accurately predict which patients are at higher risk of addiction. *See* Section IV.2, *infra.* In addition, Purdue sales representatives also failed to disclose to South Carolina prescribers the difficulty of withdrawing from opioids. Discontinuing or delaying opioids can cause intense physical and psychological effects, including anxiety, nausea, headaches, and delirium, among others. This difficulty in terminating use is a material risk, which can leave many patients unwilling or unable to give up opioids and heightens the risk of addiction.

43. Promotional materials and other publications disseminated or made available by Purdue in South Carolina have included similar messages minimizing the risk of addiction.

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

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

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

47. *A Policymaker's Guide to Understanding Pain & Its Management*, a 2011 APF publication that Purdue sponsored, claimed that pain generally had been "undertreated" due to "[m]isconceptions about opioid addiction." This guide also asserted, without basis, that "less than 1% of children treated with opioids become addicted" and perpetuated the concept of pseudoaddiction. Purdue provided substantial funding in the form of a $26,000 grant to APF and closely collaborated with APF in creating *A Policymaker's Guide.* On information and belief, based on Purdue's close relationship with APF and the periodic reports APF provided to Purdue about the project, Purdue had editorial input into *A Policymaker's Guide.* It is still available to South Carolina prescribers online.[7]

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

48. Purdue also maintained a website from 2008 to 2015, *In the Face of Pain,* that downplayed the risks of chronic opioid therapy. Purdue deactivated this website in October 2015 following an investigation by the New York Attorney General. Although it included the Purdue copyright at the bottom of each page, the site did not refer to any specific Purdue products and cultivated the "impression that it [was] neutral and unbiased."[8]

49. *In the Face of Pain* asserted that policies limiting access to opioids are "at odds with best medical practices" and encouraged patients to be "persistent" in finding doctors who will treat their pain. While a document linked from the website briefly mentioned opioid abuse, the site itself never mentioned the risk of addiction. At the same time, the website contained testimonials from several dozen physician "advocates" speaking positively about opioids. Eleven of these advocates received a total of $231,000 in payments from Purdue from 2008 to 2013—a fact notably omitted from the site.[9]

50. Purdue's efforts to trivialize the risk of addiction were, and remain, at odds with the scientific evidence. Studies have shown that at least 8-12%, and as many as 30-40% of long-term users of opioids experience problems with addiction. In March 2016, the FDA emphasized

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guide.pdf.

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

[9] *Id.*

the "known serious risk[] of . . . addiction"—"even at recommended doses" —of all opioids."[10] That same month, after a "systematic review of the best available evidence" by a panel excluding experts with conflicts of interest, the CDC published the CDC Guideline for prescribing opioids for chronic pain. The CDC Guideline noted that "[o]pioid pain medication use presents serious risks, including overdose and opioid use disorder" (a diagnostic term for addiction).[11] The CDC also emphasized that "continuing opioid therapy for 3 months substantially increases risk for opioid use disorder."[12]

2. Overstating the efficacy of screening tools

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

52. Such misrepresentations regarding safe opioid prescribing made health care providers more comfortable prescribing opioids to their patients, and patients more comfortable starting chronic opioid therapy. These misrepresentations were especially insidious because Purdue aimed them at general practitioners and family doctors who lack the time and expertise to

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

[11] CDC Guideline at 2.

[12] *Id.* at 21.

closely manage higher-risk patients on opioids. Moreover, these misrepresentations were critical to assure doctors that they could safely prescribe opioids and that addiction was the result of other prescribers failing to rigorously manage and weed out problem patients.

53. Purdue conveyed these safe prescribing messages through in-person sales calls to doctors. Former Purdue sales representatives acknowledged conveying that doctors could screen out patients at high risk of addiction through urine tests and patient contracts, and that doctors could mitigate risk by prescribing only to trusted patients. Numerous South Carolina prescribers used these recommended screening tools and patient opioid agreements to manage addiction risk.

54. On information and belief, based on their use elsewhere, sales representatives in South Carolina also shared the *Partners Against Pain* "Pain Management Kit," which contained several "drug abuse screening tools." These included the "Opioid Risk Tool," which is a five question, one-minute screening tool that relies on patient self-reporting to identify whether there is a personal history of substance abuse, sexual abuse, or "psychological disease," ignoring the sensitivity of the topic and the nature of addiction.

55. Purdue also promoted screening tools as a reliable means to manage addiction risk in CME programs and scientific conferences attended by or available to South Carolina prescribers.

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

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

deceptively instructed doctors that, through the use of screening tools, more frequent refills, and other techniques, high-risk patients showing signs of addictive behavior could be treated with opioids.

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

59. The 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 CDC Guideline recognizes that available risk screening tools "show *insufficient accuracy* for classification of patients as at low or high risk for [opioid] abuse or misuse" and counsels that doctors "should not overestimate the ability of these tools to rule out

risks from long-term opioid therapy."[13]

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

60. Purdue deceptively advised doctors to ignore signs of addiction as the product of an unfounded condition it called pseudoaddiction. Pseudoaddiction was a concept invented to convey the idea that signs of addiction, including shopping for doctors willing to newly write or refill prescriptions for opioids or seeking early refills, actually reflected undertreated pain that should be addressed with more opioids—the medical equivalent of fighting fire by adding fuel.

61. In the same vein, a former Purdue sales representative described the difference between addiction and tolerance, and noted that while doctors might believe a patient had become addicted, the patient may just have become tolerant, indicating it was appropriate to increase the dose.

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

63. The Federation of State Medical Boards ("FSMB"), a trade organization representing South Carolina's state medical board as well as others, finances opioid- and pain-specific programs through grants from Purdue and other pharmaceutical manufacturers. A 2004

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

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

version of the FSMB *Model Guidelines for the Use of Controlled Substances for the Treatment of Pain* ("FSMB Guidelines"), and the 2007 book adapted from them, *Responsible Opioid Prescribing*, advanced the concept of "pseudoaddiction."

64. *Responsible Opioid Prescribing* was sponsored by Purdue and other opioid manufacturers. The FSMB website described the book as the "leading continuing medical education (CME) activity for prescribers of opioid medications." In all, more than 163,000 copies of *Responsible Opioid Prescribing* were provided to and distributed by state medical boards, including 8,070 copies in South Carolina. Prescribers in South Carolina received and relied on the book.

65. The 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,"[15] and that physicians should "reassess[] pain and function within 1 month" in order to decide whether to "minimize risks of long-term opioid use by discontinuing opioids" because the patient is "not receiving a clear benefit."[16]

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

1. Mischaracterizing the benefits of long-term use

66. To convince South Carolina prescribers and patients that opioids should be used

[15] CDC Guideline at 13.

[16] *Id.* at 25.

to treat chronic pain, Purdue had to persuade them of a significant upside to long-term opioid use. But as the CDC Guideline makes clear, there is "*insufficient evidence* to determine the long-term benefits of opioid therapy for chronic pain."[17] In fact, the CDC found that "[n]o evidence shows a long-term benefit of opioids in pain and function versus no opioids for chronic pain with outcomes examined at least 1 year later (with most placebo-controlled randomized trials $\leq$ 6 weeks in duration)"[18] and that other treatments were more or equally beneficial and less harmful than long-term opioid use. The FDA, too, has recognized the lack of evidence to support long-term opioid use. In 2013, the FDA stated that it was "not aware of adequate and well-controlled studies of opioids use longer than 12 weeks."[19] As a result, the CDC recommends that opioids be used not in the first instance and only after prescribers have exhausted alternative treatments.

67. Similarly, the South Carolina Joint Revised Pain Management Guidelines suggest that the limited evidence of benefit from long-term opioid therapy be discussed with patients to obtain informed consent, that doctors follow a bio-social, rather than an "opio-centric" model, and that doctors consider discontinuing opioids if they see no objective improvement in the patient. The South Carolina Joint Revised Guidelines further caution that "[c]linicians should avoid over-reliance on opioids as the primary or only treatment modality, including using opioid dose escalation as the only response to a complaint of inadequate pain relief."[20]

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[17] *Id.* at 10.

[18] *Id.* at 9.

[19] Letter from Janet Woodcock, M.D, Dir., Center for Drug Eval. and Research, to Andrew Kolodny, M.D. (Sept. 10, 2013).

[20] *Joint Revised Pain Management Guidelines*, Approved by the South Carolina Boards

68. Nevertheless, Purdue touted the purported benefits of long-term opioid use, while falsely and misleadingly suggesting that these benefits were supported by scientific evidence. Moreover, based on interviews with South Carolina prescribers, Purdue sales representatives regularly did not disclose in their sales conversations the lack of evidence supporting long-term use.

69. Two prominent professional medical membership organizations, the American Pain Society ("APS") and the American Academy of Pain Medicine ("AAPM"), each received substantial funding from Purdue. Upon information and belief, Purdue exercised considerable influence over their work on opioids. Both organizations issued a consensus statement in 1997, *The Use of Opioids for the Treatment of Chronic Pain*, that endorsed opioids to treat chronic pain and claimed that the risk that patients would become addicted to opioids was low. The co-author of the statement, Dr. David Haddox, was at the time a paid speaker for Purdue and later became a senior executive for the company. Dr. Russell Portenoy, a pain management specialist who received Purdue research grants and was a Purdue consultant, was the sole consultant. The consensus statement remained on AAPM's website until 2011. The statement was taken down from AAPM's website only after a doctor complained.

70. AAPM and APS issued treatment guidelines in 2009 ("AAPM/APS Guidelines")

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of Medical Examiners, Dentistry, and Nursing (November 2014), http://www.llr.state.sc.us/POL/Nursing/PDF/Joint_Revised_Pain_Management_Guidelines.pdf.

which continued to recommend the use of opioids to treat chronic pain. Treatment guidelines, like the AAPM/APS 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. Six of the twenty-one panel members who drafted the AAPM/APS Guidelines, including Dr. Portenoy, received support from Purdue, and another eight received support from other opioid manufacturers.

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

72. Dr. Gilbert Fanciullo, a retired professor at Dartmouth College's Geisel School of Medicine who served on the AAPM/APS Guidelines panel, has since described them as "skewed" by 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.

73. 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.

74. Purdue also published misleading studies to enhance the perception that opioids

are effective long-term for chronic pain conditions. One study asserts that OxyContin is safe and effective for the chronic pain condition osteoarthritis. The study, sponsored by Purdue, involved providing oxycodone for 30 days, and then randomizing participants and providing a placebo, IR oxycodone with acetaminophen (like Percocet), or OxyContin. Only 107 of the 167 patients went on to the second phase of the study, and most who withdrew left because of adverse events (nausea, vomiting, drowsiness, dizziness, or headache) or ineffective treatment. Despite relating to a chronic condition, opioids were provided only short-term. The authors even acknowledge that the "results... should be confirmed in trials of longer duration to confirm the role of opioids in a chronic condition such as OA [osteoarthritis]."[21] Yet, the authors conclude that "[t]his clinical experience shows that opioids were well tolerated with only rare incidence of addiction and that tolerance to the analgesic effects was not a clinically significant problem when managing patients with opioids longterm."[22] 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.

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

75. Purdue also claimed—without evidence—that long-term opioid use would help patients resume their lives and jobs. Based on interviews with prescribers in South Carolina, Purdue's sales representatives promoted the ability of opioids to improve patients' function and

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

[22] *Id.*

quality of life.

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

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

78. As one pain specialist observed, "opioids may work acceptably well for a while, but over the long term, function generally declines, as does general health, mental health, and social functioning. Over time, even high doses of potent opioids often fail to control pain, and

these patients are unable to function normally."[23] Studies of patients with lower back pain and migraine headaches, for example, have consistently shown that patients experienced deteriorating function over time, as measured by ability to return to work, physical activity, pain relief, rates of depression, and subjective quality-of-life measures. Analyses of workers' compensation claims have found that workers who take opioids are almost four times more likely to reach costs over $100,000, stemming from greater side effects and slower returns to work. According to these studies, receiving an opioid for more than seven days also increased patients' risk of being on work disability one year later.

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

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

[24] CDC Guideline at 15.

[25] *Id.* at 20.

[26] The FDA has warned other drug makers that claims of improved function and quality of life were misleading. *See,* Warning Letter from Thomas Abrams, Dir., FDA Div. of Mktg., Adver., & Commc'ns, to Doug Boothe, CEO, Actavis Elizabeth LLC (Feb. 18, 2010), *available at* (rejecting claims that Actavisthe opioid, Kadian, had an "overall positive impact on a patient's work, physical and mental functioning, daily activities, or enjoyment of life."); Warning Letter from Thomas Abrams, Dir., FDA Div. of Mktg., Adver., & Commc'ns, to Brian A. Markison, Chairman, President and Chief Executive Officer, King Pharmaceuticals, Inc. (March 24, 2008), (finding the claim that "patients who are treated with [Avinza (morphine sulfate ER)] experience

and death "can cause distress and inability to fulfill major role obligations."[27] The CDC Guideline concluded that "[w]hile benefits for pain relief, function and quality of life with long-term opioid use for chronic pain are uncertain, risks associated with long-term opioid use are clearer and significant."[28] 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]."[29]

3. Omitting or mischaracterizing adverse effects of opioids

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

81. In addition to failing to disclose in promotional materials the risks of addiction, abuse, overdose, and respiratory depression, Purdue routinely ignored the risks of hyperalgesia, a

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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.

[27] CDC Guideline at 2.

[28] *Id* at 18.

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

"known serious risk associated with chronic opioid analgesic therapy,"[30] in which the patient becomes more sensitive to certain painful stimuli over time, hormonal dysfunction; decline in immune function; mental clouding, confusion, and dizziness; increased falls and fractures in the elderly; neonatal abstinence syndrome (when an infant exposed to opioids prenatally withdraws from the drugs after birth); and potentially fatal interactions with alcohol or benzodiazepines, which are used to treat post-traumatic stress disorder and anxiety (often among veterans, though post-traumatic stress disorder and anxiety also can accompany chronic pain symptoms).

82. Purdue sponsored APF's *Treatment Options: A Guide for People Living with Pain* (2007), which counseled patients that opioids differ from NSAIDs in that they have "no ceiling dose" and are therefore the most appropriate treatment for severe pain. The publication inaccurately attributes 10,000 to 20,000 deaths annually to NSAIDs (the actual figure is approximately 3,200, far fewer than from opioids).[31] This publication also warned that risks of NSAIDs increase if "taken for more than a period of months," with no corresponding warning about opioids.

83. Purdue also sponsored APF's *Exit Wounds* (2009), a book aimed at veterans. This book omits warnings of the potentially fatal risk of interactions between opioids and benzodiazepines, a class of drug commonly prescribed to veterans with post-traumatic stress disorder. This book is available from Amazon.com and other retailers.

84. Purdue sponsored a CME program, *Overview of Management Options*, published

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

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

by the American Medical Association in 2003, 2007, 2010, and 2013, and discussed further below. The CME was edited by Dr. Russell Portenoy, among others, and taught that NSAIDs and other drugs, but not opioids, are unsafe at high doses.

85. These omissions are significant and material to patients and prescribers. A Cochrane Collaboration review of evidence relating to the use of opioids for chronic pain found that 22% of patients in opioid trials dropped out before the study began because of the "intolerable effects" of opioids.[32]

86. Again, Purdue's misrepresentations were effective. A study of 7.8 million doctor visits nationwide between 2000 and 2010 found that opioid prescriptions increased from 11.3% to 19.6% of visits while NSAID and acetaminophen prescriptions fell from 38% to 29%.

D. Purdue Continued to Tell Doctors that Opioids Could Be Taken in Ever-Higher Doses without Disclosing Their Greater Risks

87. Purdue falsely claimed to South Carolina prescribers and consumers that opioids could be taken in ever-increasing strengths to obtain pain relief, without disclosing that higher doses increased the risk of addiction and overdose. This was particularly important because patients on opioids for more than a brief period develop tolerance, requiring increasingly high doses to achieve pain relief. Purdue needed to generate this comfort level among doctors to ensure the doctors maintained patients on the drugs. Further, as described in more detail in Section E, Purdue encouraged doctors to prescribe higher doses, rather than prescribe OxyContin

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

more frequently than twice-a-day—despite knowing that OxyContin frequently did not provide 12 hours of relief.

88. Purdue told one South Carolina prescriber that she could increase her patients' doses until they achieved relief, but did not disclose the risks associated with increasing the dose. Purdue and Purdue-sponsored publications and CMEs available in South Carolina also misleadingly suggested that higher opioid doses carried no added risk.

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

90. *A Policymaker's Guide,* the 2011 publication on which, upon information and belief, Purdue collaborated with APF, taught that dose escalations are "sometimes necessary," but did not disclose the risks from high dose opioids. This publication is still available online.[33]

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

92. These claims conflict with the scientific evidence. Patients receiving high doses of opioids (*e.g.*, doses greater than 100 mg morphine equivalent dose ("MED") per day) as part of long-term opioid therapy are three to nine times more likely to suffer overdose from opioid-related causes than those on low doses.[34] As compared to available alternative pain remedies,

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[33] *See* n. 7, *supra.*

[34] Kate M. Dunn, *et al.*, *Opioid Prescriptions for Chronic Pain and Overdose: A Cohort*

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.

93. The CDC Guideline concludes that the "[b]enefits of high-dose opioids for chronic pain are not established" while "there is an increased risk for serious harms related to long-term opioid therapy that appears to be dose-dependent."[35] That is why the CDC advises doctors to "avoid increasing doses" above 90 mg MED.[36]

94. In 2014, the South Carolina Board of Medical Examiners updated guidelines it previously published in 2009, cautioning that "[r]isks associated with opioids increase with escalating doses."[37] They further caution prescribers to avoid dose escalation without adequate attention to risks or alternative treatments.

Study, 152(2) Annals of Internal Med. 85-92 (Jan. 19, 2010). Most overdoses were medically serious and 12% were fatal.

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

[36] CDC Guideline at 16.

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

E. Purdue Misleadingly Promoted OxyContin as Supplying 12 Hours of Pain Relief When Purdue Knew That, For Many Patients, It Did Not.

95. To convince South Carolina prescribers and patients to use OxyContin, Purdue misleadingly promoted the drug as providing 12 continuous hours of pain relief with each dose. In reality, OxyContin does not last for 12 hours in many patients, a fact Purdue has known since the product's launch. While OxyContin's FDA-approved label directs 12 hour dosing, Purdue sought that dosing frequency in order to maintain a competitive advantage over more frequently dosed opioids. Yet Purdue has gone well beyond the label's instructions to take OxyContin every 12 hours by affirmatively claiming that OxyContin lasts for 12 hours and by failing to disclose that OxyContin fails to provide 12 hours of pain relief to many patients.

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

97. OxyContin has been FDA-approved for twice-daily—"Q12"—dosing frequency since its debut in 1996. Yet it was Purdue's decision to submit OxyContin for approval with 12-hour rather than 8-hour dosing.

98. Under FDA guidelines for establishing dosing, Purdue merely had to show that OxyContin lasted for 12 hours for at least half of patients, and Purdue submitted a single study that cleared that bar. While the OxyContin label indicates that "[t]here are no well-controlled clinical studies evaluating the safety and efficacy with dosing more frequently than every 12 hours," Purdue has conducted no such studies.

99. From the outset, Purdue leveraged 12-hour dosing to promote OxyContin as providing continuous, round-the-clock pain relief with the convenience of not having to wake to

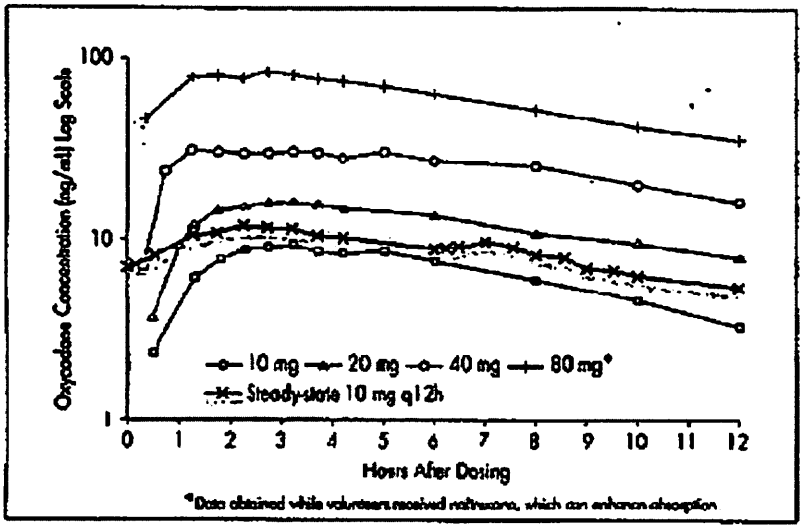
take a third or fourth pill. The 1996 press release for OxyContin touted 12-hour dosing as providing "smooth and sustained pain control all day and all night." But the FDA has never approved such a marketing claim. To the contrary, the FDA found in 2008, in response to a Citizen Petition by the Connecticut Attorney General, that a "substantial number" of chronic pain patients taking OxyContin experienced "end of dose failure"—*i.e.*, little or no pain relief at the end of the dosing period.

100. 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, as shown below:

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

101. Moreover, Purdue itself long has known, dating to its development of OxyContin, that the drug wears off well short of 12 hours in many patients. In one early Purdue clinical trial,

a third of patients dropped out because the treatment was ineffective. Researchers changed the rules to allow patients to take supplemental painkillers—"rescue medication"—in between OxyContin doses. In another study, most patients used rescue medication, and 95% resorted to it at least once. In other research conducted by Purdue, the drug wore off in under 6 hours in 25% of patients and in under 10 hours in more than 50%.

102. End-of-dose failure renders OxyContin even more dangerous because patients begin to experience distressing psychological and physical withdrawal symptoms, followed by a euphoric rush with their next dose—a cycle that fuels a craving for OxyContin. For this reason, Dr. Theodore Cicero, a neuropharmacologist at the Washington University School of Medicine in St. Louis, has called OxyContin's 12-hour dosing "the perfect recipe for addiction."[38] Many patients will exacerbate this cycle by taking their next dose ahead of schedule or resorting to a rescue dose of another opioid, increasing the overall amount of opioids they are taking.

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

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[38] 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/.

confirmed by South Carolina prescribers.

104. Without appropriate caveats, promotion of 12-hour dosing by itself is misleading because it implies that the pain relief supplied by each dose lasts 12 hours, which Purdue knew to be untrue for many, if not most, patients. FDA approval of OxyContin for 12-hour dosing does not give Purdue license to misrepresent the duration of pain relief it provides to patients; moreover, Purdue had a responsibility to correct its label to reflect appropriate dosing, to disclose to prescribers what it knew about OxyContin's actual duration, and not to promote more dangerous higher dosing, rather than increased frequency of use, regardless of any marketing advantage.[39]

105. Purdue emphasized 12-hour dosing in detailing visits to numerous South Carolina prescribers, who understood it to mean that OxyContin lasts a full 12 hours, though that was not these doctors' clinical experience. One prescriber noted that doctors typically follow a pharmaceutical company's recommendations regarding use of the drug, which he believes are based on scientific evidence—identifying precisely the danger of this type of misrepresentation.

106. Purdue was also aware of some physicians' practice of prescribing OxyContin more frequently than 12 hours—a common occurrence. Purdue's promoted solution to this problem was to increase the dose, rather than the frequency, of prescriptions, even though higher dosing carries its own risks—including increased danger of addiction, overdose, and death. It means that patients will experience higher highs and lower lows, increasing their craving for

[39] 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.

their next pill. Nationwide, based on an analysis by the *Los Angeles Times*, more than 52% of patients taking OxyContin longer than three months are on doses greater than 60 milligrams per day—which converts to the 90 milligrams of morphine equivalent that the CDC Guideline urges prescribers to "avoid" or "carefully justify."[40]

F. Purdue Overstated the Efficacy of Abuse-Deterrent Opioid Formulations

107. By the mid-2000s, widespread addiction to and abuse of OxyContin had emerged in the public eye. Rather than acknowledge that these problems were the inevitable result of widespread prescribing of OxyContin for chronic pain, Purdue claimed that abuse and addiction resulted from diversion by abusers snorting or injecting the drugs. Purdue also brought to market an "abuse-deterrent" formulation of OxyContin but deceptively marketed it to doctors as a solution to the opioid epidemic.

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

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

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[40] CDC Guideline at 16.

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

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

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

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

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

111. Purdue knew or should have known that "reformulated OxyContin is not better at tamper resistance than the original OxyContin"[41] 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.

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

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

113. A 2013 article presented by Purdue employees based on review of data from poison control centers, while concluding that ADF OxyContin can reduce abuse, ignored important negative findings. The study reveals that abuse merely shifted to other drugs and that, when the actual incidence of harmful exposures was calculated, there were *more* harmful exposures to opioids (including heroin) after the reformulation of OxyContin. In short, the article emphasized the advantages and ignoring disadvantages of ADF OxyContin—reflecting the same pattern of tilting scientific research and literature to support the promotion of opioids discussed in Section IV.A.2.

114. The CDC Guideline confirms that "*[n]o* studies" support the notion that "abuse-deterrent technologies [are] a risk mitigation strategy for deterring or preventing abuse," noting that the technologies "do not prevent opioid abuse through oral intake, the most common route of opioid abuse, and can still be abused by nonoral routes."[42] Tom Frieden, the Director of the CDC, reported that his staff could not find "any evidence showing the updated opioids [ADF opioids] actually reduce rates of addiction, overdoses, or death."[43]

115. In 2015, claiming a need to further assess its data, Purdue abruptly withdrew a

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

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

supplemental new drug application related to reformulated OxyContin one day before FDA staff were to release its assessment of the application. The staff review preceded an FDA advisory committee meeting related to new studies by Purdue "evaluating the misuse and/or abuse of reformulated OxyContin" and whether those studies "have demonstrated that the reformulated product has a meaningful impact on abuse."[44] Upon information and belief, Purdue never presented the data to the FDA because the data would not have supported claims that OxyContin's ADF properties reduced abuse or misuse.

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

117. In South Carolina, Purdue's sales representatives made claims about abuse deterrence that go well beyond the drugs' labeling. Purdue representatives in South Carolina emphasized OxyContin's purported abuse-deterrent properties to prescribers, contending that opioids with abuse-deterrent properties were safer, would not be abused, and were less likely to be sought after. Purdue did not disclose that ADF opioids 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, including those that would have covered South Carolina patients.

118. The recollections of South Carolina prescribers about such marketing claims are

[44] 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.

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 2010-2012 period—even before OxyContin's ADF labeling was approved—show Purdue detailers in the South emphasizing the reduced abuse potential of OxyContin. Given the consistency of sales messages, which are centrally controlled and directed, upon information and belief, deceptive messages were delivered to South Carolina providers.

119. Generic versions of OxyContin, which became available in February 2011, threatened to erode Purdue's market share and the price it could charge. Through a Citizen Petition, Purdue was able to secure a determination by the FDA in April 2013 that original OxyContin should be removed from the market as unsafe (lacking abuse-deterrent properties), and thus non-ADF generic copies could not be sold. As a result, Purdue extended its branded exclusivity for OxyContin until the patent protection on the abuse-deterrent coating expires.

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

G. Purdue Also Engaged In Other Unlawful, Deceptive, and Unfair Conduct by Failing to Report Suspicious Prescribing

121. Purdue deceptively and unfairly failed to report to South Carolina authorities illicit or suspicious prescribing of its opioids, even as it has publicly and repeatedly touted its "constructive role in the fight against opioid abuse," including its commitment to ADF opioids and its "strong record of coordination with law enforcement."[45]

122. As described in Section IV.A.1, Purdue's public stance long has been that "bad apple" patients and drug diversion to illicit secondary channels—and not widespread prescribing of OxyContin and other opioids for chronic pain—are to blame for widespread addiction and abuse. To address the problems of illicit use and diversion, Purdue promotes its funding of various drug abuse and diversion prevention programs and introduction of ADF opioids. This 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.

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

124. Touting the benefits of ADF opioids, Purdue's website asserts: "[W]e are acutely

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[45] 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/.

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 . . . ."[46] Purdue's statement on "Opioids Corporate Responsibility" likewise states that "[f]or many years, Purdue has committed substantial resources to combat opioid abuse by partnering with . . . communities, law enforcement, and government."[47] 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."[48]

125. These public pronouncements create the misimpression that Purdue is proactively working with law enforcement and government authorities, nationwide and in South Carolina, 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 Consent Judgment, and make its current marketing seem more trustworthy and truthful. In fact, Purdue has consistently failed to report suspicious prescribing it

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

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

[48] 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.

observed to authorities.

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

127. Purdue identified those doctors – *internally*. Since at least 2002, Purdue maintained a database of health care providers suspected of inappropriately prescribing OxyContin or other opioids. Physicians could be added to this database based on observed indicators of illicit prescribing such as excessive numbers of patients, cash transactions, patient overdoses, and unusual prescribing of the highest-strength pills (80 mg OxyContin pills or "80s," as they were known on the street, were a prime target for diversion). Health care providers added to the database no longer were detailed, and sales representatives received no compensation tied to these providers' prescriptions.

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

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

tablets.

130. Purdue's failure to report suspicious prescribing not only conflicts with its public statements, but violates the company's 2007 Consent Judgment. Paragraph 13 obligates Purdue to "establish, implement and follow an OxyContin abuse and diversion detection program consisting of internal procedures designed to identify potential abuse or diversion of OxyContin in certain settings (the 'OxyContin Abuse and Diversion Detection Program')." After laying out a non-exclusive list of signs of abuse or diversion (such as excessive number of patients or crowded waiting rooms or brief patient-prescriber interactions), the Consent Judgment directs Purdue to "conduct an internal inquiry" and "take such further steps as may be appropriate based on the facts and circumstances," including ceasing to detail the prescriber, providing further education to the prescriber, "or providing notice of such potential abuse or diversion to appropriate medical, regulatory or law enforcement authorities."

131. Purdue's duties to report, investigate, and address abuse and diversion ran for ten years from May 2007. However, before and after the Consent Judgment, Purdue was obligated by federal regulation applicable to manufacturers of controlled substances to monitor and report suspicious conduct. *See* 21 U.S.C. 823(e); 21 C.F.R. 1301.74(b); Consent Judgment at ¶ 13. 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."

132. However, Purdue did not report a *single* prescriber to state regulatory authorities, the Department of Labor, Licensing, and Regulation, or to the Board of Medical Examiners.

H. By Increasing Opioid Prescriptions and Use, Purdue's Deceptive Marketing Scheme Fueled the Opioid Epidemic and Significantly Harmed South Carolina and Its Citizens

133. Purdue's misrepresentations prompted South Carolina health care providers to prescribe, patients to take, and payors to cover opioids for the treatment of chronic pain. Through its early marketing, Purdue overcame barriers to widespread prescribing of opioids for chronic pain with deceptive messages about the risks and benefits of long-term opioid use. Through its continued deceptive marketing from 2007 to the present, it has both benefited from and extended its prior misrepresentations, sustaining and expanding a market for its opioids.

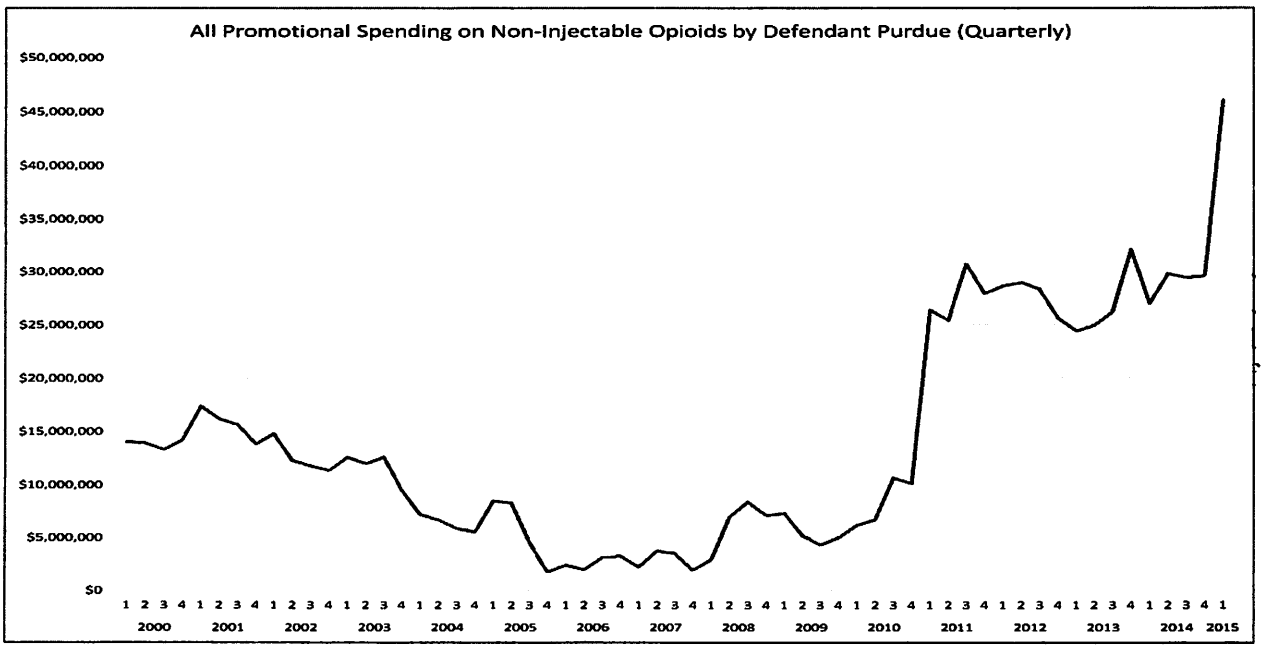
134. Purdue's deceptive marketing substantially contributed to an explosion in the use of opioids. Approximately 20% of the population between the ages of 30 and 44, and nearly 30% of the population over 45, have used opioids. Opioids are the most common treatment for chronic pain, and 20% of office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

135. Both historically and currently, Purdue accounts for the lion's share of sales of brand name opioids. In 2013, there were 6 million prescriptions of OxyContin, resulting in $2.6 billion in sales—giving Purdue 44% of market value for ER/LA opioids, and 24% of the overall market (which includes widely prescribed generics). No other branded drug accounts for more than 3% of the ER/LA prescriptions annually. Within the Medicaid population in South Carolina, Purdue opioids account for nearly 20% of opioid analgesic revenue from the Third

Quarter of 2007 through the First Quarter of 2017.[49]

136. Overall sales of opioids in South Carolina have skyrocketed. In 2016, nearly 5 million opioid prescriptions were dispensed in the state—more than its total population. South Carolina ranked ninth in the nation in opioid prescribing rates in 2016. The South Carolina State Health Plan's compensation to Purdue increased from under $3 million per year in 2010 to over $4.3 million in 2014. Prescriptions for Purdue's opioids likewise increased from 7,000 per year in 2010 to over 11,000 in 2014.

137. The increase in opioid prescribing corresponds with Purdue's marketing push. As shown in the chart below, according to data obtained from a marketing research company, Purdue spent roughly $15 million per quarter in 2000. Its spending decreased from 2000 to 2007, as the company came under investigation by the U.S. Department of Justice and various state attorneys general. But by 2010, with the introduction of Butrans and reformulated OxyContin, Purdue ramped up its marketing once again. In 2011, Purdue's marketing spiked to more than $25 million per quarter, and by the end of 2015, with the introduction of Hysingla ER,



it soared to more than $40 million per quarter.

138. The largest component of this spending was attributable to sales representative visits to individual prescribers, with total detailing expenditures rising from roughly $45 million annually in 2000 to more than $108 million in 2014.

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

140. 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."

141. The vast 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 to make their patients feel better—if they provide opioids, the patient is appeased; if they do not, they face a patient who feels underserved

and may, with Purdue's encouragement, seek another doctor who will.

142. 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 South Carolina. 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."[50]

143. In August 2016, then U.S. Surgeon General Vivek Murthy published an open letter to physicians nationwide, enlisting their help in combating this "urgent health crisis" and linking that crisis to deceptive marketing. He wrote that the push to aggressively treat pain, and the "devastating" results that followed, had "coincided with heavy marketing to doctors . . . . [m]any of [whom] were even taught—incorrectly—that opioids are not addictive when prescribed for legitimate pain."[51]

144. 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,"[52] with

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

[51] *See* n.5, *supra*.

[52] 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).

particularly compelling data for extended release oxycodone—*i.e.*, OxyContin.

145. 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."[53]

146. Opioids were involved in 42% of all fatal drug overdoses in 2015, and another 25% involved heroin. According to the CDC, between 1999 and 2015, more than 194,000 people died in the United States from prescription-related overdoses In South Carolina, there were 565 known fatalities from opioid overdoses (including both prescription opioids and heroin) in 2015, up from 494 only a year earlier. In 2015, the number of deaths from heroin and opioid overdoses in South Carolina surpassed the number of homicides. Greenville County saw *95 overdoses in 2015, compared to 11 homicides in the same year.*

147. Purdue's conduct has significantly harmed veterans. Sixty percent (60%) of veterans returning from deployment suffer from chronic pain, double the national average of thirty percent (30%) of U.S. citizens. Veterans are twice as likely to suffer addiction and to die from opioid abuse than non-veterans according to a 2011 Veterans Administration study. More than 400,000 South Carolina citizens, representing more than ten (10%) percent of the State's population, are veterans of military service.

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[53] 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.

148. Overdose deaths are only one consequence. Opioid addiction and misuse also result in an increase in emergency room visits, emergency responses, and emergency medical technicians' administration of naloxone—the antidote to opioid overdose. In South Carolina, administrations of naloxone (or Narcan) rose from 4,187 in 2015 to 6,427 in 2016. In Horry County alone, local officials used *Narcan over 1,000 times* in 2016.

149. Rising opioid use and abuse have 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. Many of those taking painkillers still said they experienced pain daily.

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

151. The abuse of opioids, including OxyContin, have caused additional medical conditions that have injured South Carolina residents and required care often paid for by the

State. The number of chronic Hepatitis C in South Carolina cases *grew from 3,258 in 2011 to 4,668 in 2015*. The increase is largely a result of intravenous drug use stemming from the opioid epidemic.

152. The deceptive marketing and overprescribing of opioids also had a significant detrimental impact on children in South Carolina. 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.

153. Even infants have not been immune to the impact of opioid abuse. There has been a dramatic rise in the number of infants who are born addicted to opioids due to prenatal exposure and suffer from neonatal abstinence syndrome ("NAS," also known as neonatal opioid withdrawal syndrome, or "NOWS"). These infants painfully withdraw from the drug once they are born, cry nonstop from the pain and stress of withdrawal, experience convulsions or tremors, have difficulty sleeping and feeding, and suffer from diarrhea, vomiting, and low weight gain, among other serious symptoms. The long-term developmental effects are still unknown, though research in other states has indicated that these children are likely to suffer from continued, serious neurologic and cognitive impacts, including hyperactivity, attention deficit disorder, lack of impulse control, and a higher risk of future addiction. When untreated, NAS can be life-threatening. In 2009, more than 13,000 infants in the United States were born with NAS, or about one every hour. In South Carolina, the incidence of NAS quadrupled between 2000 and 2013 from roughly 1 infant per 1,000 hospital births to 4 per 1,000, which would amount to 221 infants in 2013.

154. Children are also injured by the dislocation caused by opioid abuse and addiction. The number of South Carolina children removed from homes with substance abuse nearly

doubled from 397 in the year ending July 2011 to 641 in the year ending July 2016.

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

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

157. Contrary to Purdue's misrepresentations, most of the illicit use originates from *prescribed* opioids. It has been estimated that 60% of the opioids that are abused come, directly or indirectly, through physicians' prescriptions. In 2011, 71% of people who abused prescription opioids got them through friends or relatives, not from drug dealers or the internet. Addiction treatment centers in South Carolina report that at least 50% of their patients migrated from prescription opioids to heroin. Often, patients on prescription opioids fail pill checks or other strategies recommended to monitor addiction, are discharged by their doctors, and then turn to heroin as an alternative.

158. Because heroin is cheaper than prescription painkillers, many prescription opioid addicts migrate to heroin. Roughly 80% of heroin users previously used prescription opioids. Greenville County Sheriff Will Lewis calls heroin addiction a "pandemic," and reports that opioids now account for 43% of all fatal drug overdoses in the county. Statewide, overdoses involving heroin increased by 57% from 2014 to 2015. A recent, even more deadly problem stemming from the prescription opioid epidemic involves fentanyl—a powerful opioid carefully prescribed for cancer pain or in hospital settings that, in synthetic form, is now making its way into South Carolina communities through trafficking.

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

159. 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 likewise, Purdue paid 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.

160. 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.

161. 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. PURDUE'S DECEPTIVE CONDUCT EXTENDED, AND FAILED TO CORRECT, ITS PRIOR UNLAWFUL CONDUCT AND WARRANTS HEIGHTENED CIVIL PENALTIES

162. Over the last decade, Purdue used the same strategies and messages it had in the prior decade. The criminal plea and Consent Judgment entered in 2007 failed to cause a shift in Purdue's conduct or culture. In fact, Purdue did not allow anything to interrupt its marketing efforts—its denial that pain patients would become or were addicted as a result of using opioids long-term, its claim that Purdue's opioids were safer or worked longer than other opioids, its use of sloppy or manipulated science, and its use of sales representatives to reach doctors least able to question its misleading marketing. The devastating harms caused by Purdue's conduct and the level of wantonness reflected in its continued lawbreaking justify the steepest penalties permitted by law. Purdue's marketing was all the more culpable because it built upon and took advantage of the very same messages that Purdue acknowledged in 2007 were false.

VI. CAUSES OF ACTION

COUNT I

FOR A FIRST CAUSE OF ACTION

SOUTH CAROLINA UNFAIR TRADE PRACTICES ACT – DECEPTIVE AND UNFAIR ACTS AND PRACTICES

163. Paragraphs 1 through 162 of the Complaint are hereby repeated and re-alleged as if fully set forth herein.

164. At all times relevant to this Complaint, Purdue was engaged in the trade or

commerce of manufacturing, marketing, selling, and distributing prescription opioid pain medications. For 20 years Purdue has been the leading force in the prescription opioid market, both nationwide and in South Carolina.

165. By engaging in the acts and practices alleged herein, Purdue made or caused to be made to South Carolina consumers, directly or indirectly, explicitly or by implication, misrepresentations that, reasonably interpreted, are material, false, and likely to mislead.

166. In overstating the benefits of opioids and understating their very serious risks, including the risk of addiction; in falsely promoting abuse-deterrent formulations as reducing abuse; in falsely claiming that OxyContin provides 12 hours of relief; and in falsely portraying its efforts or commitment to rein in the diversion and abuse of opioids, including in South Carolina, Purdue has engaged in misrepresentations and knowing omissions of material fact.

167. Specifically, from 2007 to the present, Purdue made misrepresentations or omissions including, but not limited to:

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

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

c. screening tools effectively prevent addiction;

d. opioid doses can be increased until pain relief is achieved;

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

f. evidence supports the long-term use of opioids for chronic pain;

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

h. its abuse-deterrent opioids reduce tampering and abuse;

i. OxyContin provides a full 12 hours of pain relief; and

j. Purdue cooperates with and supports efforts to prevent opioid abuse

and diversion.

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

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

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

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

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

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

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

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

h. Purdue failed to report suspicious prescribers.

169. 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.

170. Further, Purdue's omissions, which were false and misleading in their own right, rendered even seemingly truthful statements about opioids false and misleading and likely to deceive South Carolina consumers when taken in the context of the surrounding circumstances.

171. Purdue's acts and practices as alleged in this Complaint had a capacity or tendency to deceive. When considered from the perspective of a reasonable consumer, these acts

or practices were likely to mislead South Carolina consumers.

172. Purdue's acts and practices regarding South Carolina consumers as alleged in this Complaint are offensive to established public policy, immoral, and unethical.

173. At all times relevant to this Complaint, Purdue also violated S.C. Code § 39-5-20 by engaging in the following unfair acts or practices:

a. promoting long-term, high dose prescribing and use of opioids, in contravention of longstanding public policy to avoid and minimize the risk of addiction and abuse of controlled substances, as reflected in the South Carolina Controlled Substances Act, S.C. Code § 44-53-10 and the South Carolina Joint Revised Pain Management Guidelines approved by the S.C. Boards of Medical Examiners, Dentistry, and Nursing;

b. frustrating prescribers' ability to ensure informed consent by accurately outlining the risks and benefits of opioid use, as required by the Pain Management Guidelines set forth by the Board of Medical Examiners;

c. frustrating the public policy in favor of, and the State's efforts to reduce the overprescribing, overuse, misuse, and abuse of addictive prescription opioids, including through the Prescription Drug Monitoring Program, South Carolina Joint Revised Pain Management Guidelines approved by the S.C. Boards of Medical Examiners, Dentistry, and Nursing; and

d. failing to report its knowledge of suspicious prescribing in South Carolina to law enforcement or regulatory authorities, in violation of its commitments under the Consent Judgment and the public policy of preventing the diversion of controlled substances, expressed through, *inter alia*, the South Carolina Controlled Substances Act, S.C. Code § 44-53-10, the State's Prescription Drug Monitoring Program, the South Carolina Joint Revised Pain Management Guidelines approved by the S.C. Boards of Medical Examiners, Dentistry, and Nursing, and as reflected as well in federal regulations requiring manufacturers and distributors of controlled substances to report suspicious orders.

174. These acts or practice were unfair in that they offended established public policy, reflected in the State's Constitution, that "[t]he health, welfare, and safety of the lives and property of the people of this State and the conservation of its natural resources are matters of

public concern." S.C. Const. art. XII, § 1.

175. These acts or practices were unfair in that they offended the State's public policy, expressed in the Act itself, to protect consumers from deceptive marketing that causes consumers to act differently than they would otherwise have acted, as well as the public policy of preventing addiction to and abuse of controlled substances and the State's effort to stem the harm from Defendants' deceptive and unfair acts and practices.

176. 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 South Carolina.

177. These acts or practices have resulted in a substantial injury to South Carolina consumers that is not outweighed by any countervailing benefits to consumers or competition. Purdue's marketing has caused South Carolina 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.

178. Purdue's acts and practices as alleged herein substantially impacted the community of patients, health care providers, law enforcement, and other State government functions, and caused significant actual harm.

179. Purdue's acts and practices as alleged herein were motivated by a desire to retain

and increase its market share and profits. Its conduct in misrepresenting and concealing the truth reflects a corrupt corporate culture that persisted over many years.

180. Purdue's deceit was substantial, and the acts and practices regarding South Carolina consumers as alleged in this Complaint were undertaken in bad faith. These acts or practices were reprehensible and callously disregarded the public health and welfare. The statutory violations were especially egregious in that they represented a decision to affirmatively mislead the medical community, law enforcement, and regulatory authorities.

181. 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.

182. Purdue is publicly described as reaping some $35 billion in sales since 1995 and up to $3 billion per year in revenues, primarily from the sale of prescription opioids, and has the ability to pay the civil penalties sought in this Complaint.

183. At all times Purdue knew or should have known that its conduct violated the South Carolina Unfair Trade Practices Act and therefore is willful for purposes of S.C. Code § 39-5-110, justifying civil penalties.

184. Purdue's acts and practices regarding South Carolina consumers as alleged herein are capable of repetition and affect the public interest.

185. This action seeks to protect the citizens of South Carolina from unfair and deceptive acts in the conduct of trade and commerce.

186. Purdue's acts and practices as alleged herein have directly and proximately caused substantial injury to consumers within South Carolina and to the State.

187. The State has suffered, and continues to suffer, ascertainable loss of money or property as a result of the unfair and deceptive practices alleged herein and is entitled to restitution and/or damages for such loss.

188. The State's Medicaid Program and State Health Plan are "persons" within the meaning of S.C. Code § 39-5-10(a) and S.C. Code § 39-5-140.

189. Purdue's conduct was willful or knowing under S.C. Code § 39-5-140.

190. Purdue's acts or practices alleged herein constitute unfair or deceptive acts or practices in violation of S.C. Code § 39-5-20.

191. Every deceptive, unfair, and/or misrepresentative act by Purdue constitutes a separate and distinct violation of S.C. Code § 39-5-20

COUNT II

FOR A SECOND CAUSE OF ACTION

SOUTH CAROLINA UNFAIR TRADE PRACTICES ACT – UNFAIR COMPETITION

192. Paragraphs 1 through 162 of the Complaint are hereby repeated and re-alleged as if fully set forth herein.

193. 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 South Carolina. In particular, Purdue has stated or implied that:

a. twice-daily dosing of OxyContin provides 12 hours of pain relief with each dose;

b. abuse-deterrent formulations of its opioids make the drugs less likely to be abused; and

c. opioids, unlike NSAIDs, have no ceiling dose and are therefore the most appropriate treatment for severe pain.

194. 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.

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

196. By reason of Purdue's conduct, South Carolina consumers have suffered substantial injury, including but not limited to pain and suffering from inappropriate use of opioids, opioid addiction, injury, overdose, death, and economic loss.

197. 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.

198. Purdue's acts and practices as alleged herein substantially impacted the community of patients, health care providers, law enforcement, and other State government functions, and caused significant actual harm.

199. Purdue's acts and practices as alleged herein were motivated by a desire to retain and increase its market share and profits. Its conduct in misrepresenting and concealing the truth reflects a corrupt corporate culture that persisted over many years.

200. Purdue's deceit was substantial, and the acts and practices regarding South Carolina consumers as alleged in this Complaint were undertaken in bad faith. These acts or

practices were reprehensible and callously disregarded the public health and welfare. The statutory violations were especially egregious in that they represented a decision to affirmatively mislead the medical community, law enforcement, and regulatory authorities.

201. Purdue is publically described as earning some $35 billion in sales since 1995 and as currently obtaining approximately $3 billion per year in revenues, primarily from the sale of prescription opioids, and has the ability to pay the civil penalties sought in this Complaint.

202. At all times Purdue knew or should have known that its conduct violated the South Carolina Unfair Trade Practices Act and therefore is willful for purposes of S.C. Code § 39-5-110, justifying civil penalties.

203. Purdue's acts and practices regarding South Carolina consumers as alleged herein are capable of repetition and affect the public interest.

204. Purdue's acts and practices as alleged herein have directly and proximately caused substantial injury to consumers within South Carolina and to the State.

205. The State has suffered, and continues to suffer, ascertainable loss of money or property as a result of the unfair and deceptive practices alleged herein and is entitled to restitution and/or damages for such loss.

206. The State's Medicaid Program and State Health Plan are "persons" within the meaning of S.C. Code § 39-5-10(a) and S.C. Code § 39-5-140.

207. Purdue's unfair and deceptive acts were willful or knowing under S.C. Code § 39-5-140.

208. Purdue's acts or practices alleged herein constitute unfair competition in violation of S.C. Code § 39-5-20.

209. Every act of unfair competition by Purdue constitutes a separate and distinct

violation of S.C. Code § 39-5-20.

COUNT III

FOR A THIRD CAUSE OF ACTION

VIOLATIONS OF CONSENT JUDGMENT

210. Paragraphs 1 through 162 of the Complaint are hereby repeated and re-alleged as if fully set forth herein.

211. Purdue, by making written and/or oral claims that are false, misleading, or deceptive, as laid out in Count I and Count II, has violated, and continues to violate, Section II, ¶ 2 of the 2007 Consent Judgment, which provides that "Purdue shall not make any written or oral claim that is false, misleading or deceptive."

212. Purdue, by failing, despite the known, serious risks of addiction and other adverse effects, to present a fair balance of benefit and risk information in its promotion of opioids, has violated, and continues to violate, Section II, ¶ 4 of the 2007 Consent Judgment, which provides that:

> In the promotion and marketing of OxyContin Purdue shall provide "fair balance" statements, as defined in 21 C.F.R. § 202.1 as may be amended or supplemented, or as appearing in FDA Guidances for Industry from time to time, regarding contraindications and adverse events, including but not limited to statements regarding OxyContin's potential for abuse, addiction, or physical dependence as set forth in the Package Insert.

213. Purdue, by making misrepresentations with respect to OxyContin's potential for abuse and addiction, and by claiming that abuse-deterrent formulations of OxyContin are not subject to abuse, despite knowing that the abuse-deterrent features of reformulated OxyContin have not been effective to prevent abuse, has violated, and continues to violate, Section II, ¶ 5 of the 2007 Consent Judgment, which provides that:

> In the promotion and marketing of OxyContin Purdue shall not make misrepresentations with respect to OxyContin's potential for abuse, addiction, or

> physical dependence as set forth in the Package Insert. Further to this general prohibition on misrepresentations, Purdue, in the promotion and marketing of OxyContin, shall not represent, except as may be set forth in the Package Insert, that: a) OxyContin is "nonaddictive" or "virtually nonaddictive"; b) addiction to OxyContin occurs in "less than 1% of patients being treated with OxyContin; or c) OxyContin's potential for abuse, addiction or physical dependence differs from any other Schedule II opioid analgesic.

214. Purdue, by failing, after identifying suspicious prescribers or prescribing patterns, to provide notice of such potential abuse or diversion to appropriate medical, regulatory, or law enforcement authorities, has violated, and continues to violate, Section II, ¶ 13 of the Consent Judgment, which requires Purdue to "establish, implement and follow" an OxyContin Abuse and Diversion Detection Program. In particular, in failing *ever* to report a suspicious prescriber to South Carolina law enforcement or regulatory authorities, Purdue failed to carry out its obligation to "take such further steps as may be appropriate based on the facts and circumstances" of the prescriber, including "providing notice of such potential abuse or diversion to appropriate medical, regulatory or law enforcement authorities."

215. By reason of Purdue's conduct, South Carolina consumers have suffered substantial injury, including but not limited to, pain and suffering from inappropriate opioid use, opioid addiction, injury, overdose, death, and economic loss.

216. 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.

217. Purdue's acts and practices as alleged herein substantially impacted the community of patients, health care providers, law enforcement, and other State government functions, and caused significant actual harm.

218. Purdue's acts and practices as alleged herein were motivated by a desire to retain and increase its market share and profits. Its conduct in misrepresenting and concealing the truth

reflects a corrupt corporate culture that persisted over many years.

219. Purdue's deceit was substantial, and the acts and practices regarding South Carolina consumers as alleged in this Complaint were undertaken in bad faith. These acts or practices were reprehensible and callously disregarded the public health and welfare. The statutory violations were especially egregious in that they represented a decision to affirmatively mislead the medical community, law enforcement, and regulatory authorities.

220. Purdue is publically described as earning some $35 billion in sales since 1995 and as currently obtaining approximately $3 billion per year in revenues, primarily from the sale of prescription opioids, and has the ability to pay the civil penalties sought in this Complaint.

221. Civil penalties are desired to eliminate the benefits Purdue derived from its violations of the 2007 Consent Judgment and are necessary to vindicate the authority of State regulators.

222. Purdue's acts and practices as alleged herein affect the public interest, and the violations of Section II, ¶¶ 2, 4, and 5 are capable of repetition.

223. Purdue's acts and practices as alleged herein have directly and proximately caused substantial injury to consumers within South Carolina and to the State.

224. Purdue's acts or practices alleged herein constitute violations of the terms of an injunction issued under S.C. Code § 39-5-50.

225. Every violation of the 2007 Consent Judgment by Purdue constitutes a separate and distinct violation of an injunction under S.C. Code § 39-5-50 and gives rise to civil penalties under S.C. Code § 39-5-110(b).

COUNT IV

FOR A FOURTH CAUSE OF ACTION

PUBLIC NUISANCE

226. Paragraphs 1 through 162 of the Complaint are hereby repeated and re-alleged as if fully set forth herein.

227. 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 works hurt, inconvenience, or damage and interferes with the enjoyment of life or property.

228. 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.

229. This injury to the public includes, but is not limited to (a) 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; (b) high rates of opioid abuse and addiction, with which too many South Carolina residents will now struggle their entire lives; (c) overdoses, other serious diseases (like Hepatitis C), and fatalities, with grievous consequences to South Carolina communities and families; (d) children removed from their homes and newborns born addicted to opioids; (d) lost employee productivity due to opioid-related addiction and disability; (f) the creation and maintenance of a secondary, criminal market for opioids; (f) greater demand for emergency services, law enforcement, addiction treatment, and social services; and (h) increased health care costs for individuals, families, and the State.

230. 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 and by failing to disclose the lack of evidence supporting long-term use of opioids; (b) obscured or omitted the serious risk of addiction and other adverse effects arising from such use; and (c) overstated the impact of its abuse-deterrent formulations in reducing abuse, thus prompting doctors to continue to prescribe opioids in the false belief that these opioids were safer or prevented abuse. 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 the enjoyment of the public right by failing to report suspicions of illicit prescribing to law enforcement and the Board of Medical Examiners.

231. At all times relevant to the Complaint, Purdue exercised control over the instrumentalities constituting the nuisance—*i.e.*, its marketing as conveyed through sales representatives, other speakers, and publications, and its program to identify suspicious prescribing. As alleged herein, Purdue created, or was a substantial factor in creating, the nuisance through multiple vehicles, including: (a) making in-person sales calls; (b) disseminating advertisements and publications; (c) creating, sponsoring, and disseminating flawed and biased scientific research and prescribing guidelines; (d) sponsoring and collaborating with third parties to disseminate false and misleading messages about opioids; and (e) failing to report suspicious prescribing to law enforcement and the Board of Medical Examiners. 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.

232. 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 South Carolina would have been averted or would be much less severe.

233. 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.

234. 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.

COUNT V

FOR A FIFTH CAUSE OF ACTION

UNJUST ENRICHMENT

235. Paragraphs 1 through 162 of the Complaint are hereby repeated and re-alleged as if fully set forth herein.

236. The doctrine of unjust enrichment exists to prevent the wrongful retention of a

benefit in violation of good conscience and fundamental principles of justice and equity or to prevent a double recovery. Unjust enrichment permits recovery of that amount the defendant has been unjustly enriched at the expense of the plaintiff.

237. Purdue's acts and practices as alleged herein substantially impacted the community of patients, health care providers, law enforcement, and other State government functions, and caused significant actual harm.

238. Purdue's acts and practices as alleged herein were motivated by a desire to retain and increase its market share and profits and were undertaken in bad faith.

239. The State has suffered injuries in paying for opioids, and the direct costs related to opioid use, as a result of Purdue's unlawful conduct, and are entitled to restitution or disgorgement.

240. Purdue has been unjustly enriched in the form of increased revenues and profits as a result of their deceptive marketing in violation of the laws of the state of South Carolina. Under equitable principles and due to its unjust enrichment, Purdue should be required to disgorge any profits, plus interest, that were obtained as a result of its misrepresentations.

VII. PRAYER FOR RELIEF

WHEREFORE, the State requests the following relief:

241. A finding that by the acts alleged herein, Purdue engaged in unfair and deceptive acts and practices in the course of engaging in trade or commerce within South Carolina in violation of S.C. Code § 39-5-20;

242. A finding that by the acts alleged herein, Purdue engaged in unfair competition in the course of engaging in trade or commerce within South Carolina in violation of S.C. Code § 39-5-20;

243. An injunction pursuant to S.C. Code § 39-5-50 permanently enjoining Purdue from engaging in any acts that violate SCUTPA, including, but not limited to, the unfair and deceptive acts and practices, and unfair methods of competition alleged herein;

244. Civil penalties in the amount of $5,000, pursuant to S.C. Code § 39-5-110(a), for each and every willful violation of SCUTPA;

245. A finding that by the acts alleged herein, Purdue violated its 2007 Consent Judgment;

246. Civil penalties in the amount of $15,000, pursuant to S.C. Code § 39-5-110(b), for each and every willful violation of the 2007 Consent Judgment;

247. Pursuant to § 39-5-50(b), restoration of ascertainable losses, including any moneys or property lost by reason of the use or employment of Purdue's unlawful acts and practices;

248. Attorneys' fees and costs pursuant to S.C. Code § 1-7-85 for violations of SCUTPA;

249. Restitution of Purdue's unjust enrichment, benefits, and ill-gotten gains, plus interest, acquired as a result of the unlawful or wrongful conduct alleged herein pursuant to common law;

250. Disgorgement of Purdue's unjust enrichment, benefits, and ill-gotten gains, plus interest, acquired as a result of the unlawful or wrongful conduct alleged herein pursuant to common law;

251. A finding that Purdue has created a public nuisance;

252. An injunction permanently enjoining Purdue from engaging the acts and practices that caused the public nuisance;

253. An order directing Purdue to abate the public nuisance;

254. An order directing Purdue to pay damages for the public nuisance it created;

255. Pre-and post-judgment interest; and

256. Such other and further relief as this Court deems just and equitable.

DATED: August 15, 2017

THE STATE OF SOUTH CAROLINA

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EXHIBIT

A

STATE OF SOUTH CAROLINA COUNTY OF RICHLAND	)	IN THE COURT OF COMMON PLEAS
STATE OF SOUTH CAROLINA, Petitioner, -vs- Purdue Pharma L.P., et al., Respondents.	)	C/A No. 2007-CP-40-2844 **CONSENT JUDGMENT**

This Consent Judgment (hereinafter referred to as "Judgment") is entered into between the Attorneys General or other entities[1] of the States and Commonwealths of Arizona, Arkansas, California, Connecticut, District of Columbia, Idaho, Illinois, Kentucky, Louisiana, Maine, Maryland, Massachusetts, Montana, Nebraska, Nevada, New Mexico, North Carolina, Ohio, Oregon, Pennsylvania, South Carolina, Tennessee, Texas, Vermont, Virginia, Washington, and Wisconsin (hereinafter referred to as "Signatory Attorneys General"), acting on behalf of their respective states, and pursuant to their respective consumer protection statutes; and Purdue Pharma L.P., et al (hereinafter referred to as "Purdue").

[1] For the purposes of this agreement, when the entire group is referred to as "Signatory Attorneys General," such designation, as it pertains to CONNECTICUT, shall refer to the Commissioner of the Department of Consumer Protection, who enters this Consent pursuant to the Connecticut Unfair Trade Practices Act, Conn. Gen. Stat. Sec. 42-110j, acting by and through his counsel, Richard Blumenthal, Attorney General for the State of Connecticut. For MONTANA, such designation shall refer to the Consumer Protection Office of the Department of Justice who enters into this settlement pursuant to the Montana Unfair Trade and Consumer Protection Act of 1973 MCA 30-14-101 *et al.*, acting by and through his counsel, Mike McGrath, Attorney General for the State of Montana.

I. DEFINITIONS

1. The following definitions shall be used in construing this Consent Judgment (hereinafter "Judgment"):

A. "Covered Persons" shall mean all officers, employees and all contract or third-party sales representatives, including Medical Liaisons, of Purdue or retained by Purdue having direct responsibility for marketing and promoting OxyContin to Health Care Professionals.

B. "Effective Date" shall mean the date on which Purdue receives a copy of this Judgment, duly executed by Purdue and by the Signatory Attorney General and filed with the Court.

C. "FDA Guidances for Industry" shall mean documents published by the United States Department of Health and Human Services, Food and Drug Administration ("FDA") that represent the FDA's current recommendations on a topic.

D. "Health Care Professional" or "Health Care Professionals" shall mean any person or persons duly licensed by relevant federal and/or state law to prescribe Schedule II pharmaceutical products, as well as duly licensed pharmacists, nurses and other licensed health professionals.

E. "Off-Label Promotion" shall mean the marketing and promotion of an Off-Label Use. Off-Label Promotion shall not mean discussion of the abuse and diversion of OxyContin that is not inconsistent with the Package Insert.

F. "Off-Label Use" shall mean any use inconsistent with the "Indications and Usage" section of the Package Insert.

G. "OxyContin" shall mean any controlled-release drug distributed by Purdue which contains oxycodone as an active pharmaceutical ingredient.

H. "Package Insert" shall mean the FDA approved label (as described in 21 C.F.R. §§ 201.56 and 57) for OxyContin, including all modifications to the label theretofore approved by the FDA.

I. "Parties" shall mean Purdue and the Signatory Attorneys General.

J. "Purdue" shall mean Purdue Pharma Inc., Purdue Pharma L.P., The Purdue Frederick Company, Inc (d/b/a The Purdue Frederick Company), and all of their United States affiliates, subsidiaries, predecessors, successors, parents and assigns, who manufacture, sell, distribute and/or promote OxyContin.

K. "Remuneration" shall mean any gift, fee, or payment, exceeding twenty-five dollars ($25.00) in value, provided by Purdue directly or indirectly in connection with marketing or promotion of OxyContin.

L. "Signatory Attorney General" shall mean the Attorney General, or his or her designee, who has agreed to this Judgment.

M. "Subject Matter of this Judgment" shall mean the investigation under the State Consumer Protection Laws[2] of Purdue's promotional and marketing practices regarding OxyContin.

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[2] ARIZONA Consumer Fraud Act, Ariz. Rev. Stat. §44-1521, *et. seq.*; ARKANSAS - Deceptive Trade Practices Act, Ark. Code Ann. § 4-88-101 *et seq.*; CALIFORNIA Business and Professions Code § 17200 *et seq* 17500 *et seq* ; CONNECTICUT – Connecticut Unfair Trade Practices Act, Conn. Gen. Stat. §42-110 *et seq.*; DISTRICT OF COLUMBIA – District of Columbia Consumer Protection Procedures Act, D.C. Code § 28-3901 *et seq.*; IDAHO - Consumer Protection Act, Idaho Code § 48-601 *et seq.*; ILLINOIS - Consumer Fraud and Deceptive Business Practices Act, 815 ILCS § 505/1 *et seq.* (2002); KENTUCKY - Consumer Protection Statute, KRS 367.170; LOUISIANA – Unfair Trade Practices and Consumer Protection Law, LSA-R.S. 51:1401 *et seq.*; MAINE – Unfair Trade Practices Act, 5 M.R.S.A. section 205-A *et.* seq; MARYLAND - Consumer Protection Act, Maryland Commercial Law Code Annotated § 13-101 *et seq.*; MASSACHUSETTS - Consumer Protection Act, M.G.L. c. 93A *et seq.*; MONTANA - Mont. Code Ann. § 30-14-101 *et seq.*; NEBRASKA – Consumer Protection Act: Neb.Rev.Stat. 59-1601, *et seq.* (Reissue 2004 & RS Supp. 2006), Uniform

II. COMPLIANCE PROVISIONS

2. In the promotion and marketing of OxyContin, Purdue shall not make any written or oral claim that is false, misleading or deceptive.

3. In the promotion and marketing of OxyContin, Purdue shall not market or promote OxyContin in a manner that is, directly or indirectly, inconsistent with the "Indication and Usage" section of the Package Insert for OxyContin. Further, Purdue shall, consistent with the Package Insert, or as otherwise permitted by the FDA, not promote or market OxyContin in a manner that: (a) avoids or minimizes the fact that OxyContin is indicated for moderate to severe pain when a continuous around-the-clock analgesic is needed for an extended period of time; or (b) avoids, minimizes, or is inconsistent with individualizing treatment using a plan of pain management, such as outlined by the World Health Organization, the Agency for Healthcare Research and Quality (formerly known as the Agency for HealthCare Policy and Research), the Federation of State Medical Boards Model Guidelines or the American Pain Society , as referenced in the Package Insert.

4. In the promotion and marketing of OxyContin, Purdue shall provide "fair balance" statements, as defined in 21 C.F.R. §202.1 as may be amended or supplemented, or as

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Deceptive Trade Practices Act: Neb.Rev.Stat. 87-301 *et seq.* (Reissue 1999 & RS Supp. 2006); NEVADA - Deceptive Trade Practices Act, Nevada Revised Statutes 598.0903 *et seq.*; NEW MEXICO – Unfair Practices Act" NMSA 1978, S 57-12-1 *et seq.* (1967); NORTH CAROLINA - Unfair and Deceptive Trade Practices Act, N.C.G.S. § 75-1.1 *et seq.*; OHIO - Consumer Sales Practices Act, R.C. § 1345.01 *et seq.*; OREGON - Unlawful Trade Practices Act, ORS 646.605 to 646.656; PENNSYLVANIA - Unfair Trade Practices and Consumer Protection Law, 73 P.S. § 201-1 *et seq.*; SOUTH CAROLINA - Unfair Trade Practices Act, Sections 39-5-10 *et seq.*; TENNESSEE - Consumer Protection Act, Tenn. Code Ann. § 47-18-101 *et seq.*, (1977); TEXAS - Deceptive Trade Practices and Consumer Protection Act, Tex. Bus. And Com. Code § 17.41 *et seq.*, (Vernon 2002); VERMONT - Consumer Fraud Act, 9 V.S.A. § 2451 *et seq.*; VIRGINIA - Virginia Consumer Protection Act, Va. Code Ann. § 59.1-196 *et seq.*; WASHINGTON - Washington Consumer Protection Act – R.C.W. 1986 *et seq*; WISCONSIN - Wis. Stat. § 100.18 (Fraudulent Representations).

appearing in FDA Guidances for Industry from time to time, regarding contraindications and adverse events, including but not limited to statements regarding OxyContin's potential for abuse, addiction, or physical dependence as set forth in the Package Insert.

5. In the promotion and marketing of OxyContin, Purdue shall not make misrepresentations with respect to OxyContin's potential for abuse, addiction, or physical dependence as set forth in the Package Insert. Further to this general prohibition on misrepresentations, Purdue, in the promotion and marketing of OxyContin, shall not represent, except as may be set forth in the Package Insert, that: a) OxyContin is "nonaddictive" or "virtually nonaddictive"; b) addiction to OxyContin occurs in "less than 1%" of patients being treated with OxyContin; or c) OxyContin's potential for abuse, addiction or physical dependence differs from any other Schedule II opioid analgesic.

6. In the promotion and marketing of OxyContin, Purdue shall not make any written or oral promotional claim of safety or effectiveness for Off-Label Uses of OxyContin in a manner that violates the Food, Drug and Cosmetic Act, 21 U.S.C. § 301 *et seq.* ("FDCA"), and accompanying regulations as may be amended or supplemented, or as appearing in FDA Guidances for Industry from time to time.

7. Except upon a request for such information without solicitation by Purdue to make the request, Purdue shall not provide to Health Care Professionals written materials describing the Off-Label Use of OxyContin that have not appeared in a scientific or medical journal or reference publication or any portion thereof. Purdue shall maintain records for three (3) years of the identity of all Health Care Professionals to whom such materials relating to the Off-Label Use of OxyContin have been provided. "Scientific or medical journal" is a publication whose articles are published in accordance with regular peer-reviewed procedures;

that uses experts to review or provide comment on proposed articles; and that is not in the form of a special supplement that has been funded in whole or in part by one or more manufacturers. "Reference publication" is a publication that has no common ownership or other corporate affiliation with a pharmaceutical or medical device manufacturer; that has not been written, edited, excerpted, or published specifically for, or at the request of, such a manufacturer; and that has not been edited or significantly influenced by such a manufacturer.

8. A. When Purdue provides an individual or entity with any educational grant, research grant, or other similar Remuneration relating to OxyContin, Purdue shall obtain the recipient's agreement: (i) to clearly and conspicuously disclose the existence of said funding or Remuneration to the readers of any resulting letter, study, research or other materials which was supported by said funding or Remuneration, and (ii) to refund said funding or Remuneration if such disclosure is not made.

B. Purdue shall require that a recipient of any Remuneration from Purdue for the promotion of OxyContin agree: (i) to clearly and conspicuously disclose the existence, nature and purpose of the Remuneration to the participants in any educational event at which the recipient discusses an Off-Label Use of OxyContin, and (ii) to refund said Remuneration if such disclosure is not made.

C. Purdue shall itself clearly and conspicuously disclose the existence of any grant or other form of Remuneration that it has provided for the publication of a letter, study, research or other material relating to OxyContin when Purdue disseminates or refers to said letter, study, research or other material in communications with Health Care Professionals.

9. Purdue shall comply with all applicable Accreditation Council for Continuing Medical Education ("ACCME") Guidelines.

10. Purdue shall comply with paragraphs 2, 3, 4, 5, 7 and 8 of the Pharmaceutical Research and Manufacturers of America Code (effective on July 1, 2002) with respect to payments, gifts and other compensation to Health Care Professionals regarding OxyContin.

11. In the promotion and marketing of OxyContin, Purdue shall not misrepresent the existence, non-existence, or findings of any medical or scientific evidence, including anecdotal evidence, relating to Off-Label Uses of OxyContin. Purdue shall not provide any information that is misleading or lacking in fair balance, as defined in 21.C.F.R. 202.1, as may be amended or supplemented, or as appearing in FDA Guidances for Industry from time to time, in any discussion of the Off-Label Uses of OxyContin.

12. Purdue shall not sponsor or fund any educational events where Purdue has knowledge at the time the decision for sponsorship or funding is made that a speaker will recommend the Off-Label Use of OxyContin. Further, Purdue shall not promote or fund Health Care Professionals' attendance at educational events where Purdue has knowledge, at the time of said promotion, that Off-Label Use of OxyContin will be recommended or encouraged.

13. Purdue shall, no later than thirty (30) business days after the Effective Date of this Judgment, establish, implement and follow an OxyContin abuse and diversion detection program consisting of internal procedures designed to identify potential abuse or diversion of OxyContin in certain settings (the "OxyContin Abuse and Diversion Detection Program"). The OxyContin Abuse and Diversion Detection Program will apply to Purdue employees and contract or third-party sales representatives, including Medical Liaisons, who contact practicing Health Care Professionals in person or by telephone for the purpose of promoting OxyContin. That Program directs those persons to report to the Office of the General Counsel situations, including, but not limited to the following examples, to the extent that such information or activities are observed

or learned of by them: a) an apparent pattern of an excessive number of patients for the practice type, such as long lines of patients waiting to be seen, waiting rooms filled to standing-room-only capacity, or patient-prescriber interactions that are exceedingly brief or non-existent; b) an atypical pattern of prescribing techniques or locations, such as repeated prescribing from an automobile, or repeated prescribing at atypical times, such as after usual office hours when the Health Care Professional is not on call; c) information from a highly credible source or several sources (e.g., pharmacists, law enforcement, other health care workers) that a Health Care Professional or their patients are abusing or diverting medications; d) sudden, unexplained changes in prescribing or dispensing patterns that are not accounted for by changes in patient numbers or practice type; e) a Health Care Professional who has a disproportionate number of patients who pay for office visits and dispensed medications with cash; f) multiple allegations that individuals from a particular practice have overdosed; or g) unauthorized individuals signing prescriptions or dispensing controlled substances. Upon identification of potential abuse or diversion involving a Health Care Professional with whom Purdue employees or its contract or third-party sales representatives, including Medical Liaisons, interact, Purdue will conduct an internal inquiry which will include but not be limited to a review of the Health Care Professional's prescribing history, to the extent such history is available and relevant, and shall take such further steps as may be appropriate based on the facts and circumstances, which may include ceasing to promote Purdue products to the particular Health Care Professional, providing further education to the Health Care Professional about appropriate use of opioids, or providing notice of such potential abuse or diversion to appropriate medical, regulatory or law enforcement authorities. Purdue's obligations under this Section shall expire ten (10) years following the Effective Date of this Judgment or three months from the date on which the last of

Purdue's patents covering OxyContin expires, whichever is earlier, but in no event shall be earlier than seven (7) years following the Effective Date of this Judgment.

14. Purdue shall implement and maintain a training and education program with respect to the OxyContin Abuse and Diversion Detection Program, and shall require all Purdue employees and contract or third-party sales representatives, including Medical Liaisons, who contact practicing Health Care Professionals in person or by telephone for the purpose of promoting OxyContin to complete the training and education program no later than thirty (30) business days after the Effective Date of this Judgment. Further, Purdue shall require those Purdue employees and contract or third-party sales representatives, including Medical Liaisons, who contact practicing Health Care Professionals in person or by telephone for the purpose of promoting OxyContin to complete the training and education program before being allowed to market or promote OxyContin. Purdue's obligations under this Section shall expire ten (10) years following the Effective Date of this Judgment or three months from the date on which the last of Purdue's patents covering OxyContin expires, whichever is earlier, but in no event shall be earlier than seven (7) years following the Effective Date of this Judgment.

15. Within 90 days of the Effective Date of this Judgment, Purdue shall provide to each Health Care Professional whom Covered Persons contact, written, non-branded educational information related to detecting and preventing abuse and diversion of opioid analgesics. To the extent that Purdue concludes that a specific Health Care Professional needs repeated exposure to such non-branded educational materials, Purdue will provide those materials. Purdue's obligations under this Section will remain in effect for ten (10) years following the Effective Date of this Judgment.

16. Purdue shall continue to review news media stories addressing the abuse or diversion of OxyContin and undertake appropriate measures as reasonable under the circumstances to address abuse and diversion so identified, including but not limited to, (i) correcting misinformation, (ii) offering non-branded educational materials to local substance abuse prevention and treatment initiatives, or (iii) directing Health Care Professionals to Purdue's Medical Services group for fair and balanced information on appropriate use of opioid analgesics, prevention and detection of abuse and diversion. Purdue's obligations under this Section shall expire ten (10) years following the Effective Date of this Judgment or three months from the date on which the last of Purdue's patents covering OxyContin expires, whichever is earlier, but in no event shall be earlier than seven (7) years following the Effective Date of this Judgment.

17. No sales incentive (bonus) program for sales of OxyContin shall allow incentive credit to be earned for a Health Care Professional who has been identified through the OxyContin Abuse and Diversion Detection Program as one upon whom sales representatives shall not call. In addition, Purdue shall not employ a compensation structure for persons involved in marketing or promoting OxyContin that is based exclusively on the volume of OxyContin sales.

18. For a period of ten (10) years following the Effective Date of this Judgment, Purdue's performance evaluation of persons involved in marketing or promoting OxyContin shall meaningfully take into account that sales persons inform Health Care Professionals to whom the sales persons promote OxyContin about its potential for abuse and diversion, and how to minimize those risks; failure to do so shall be considered as a basis for disciplinary action, including, but not limited to censure, probation and termination.

19. In its promotion and marketing of OxyContin, Purdue shall not misrepresent, in any written or oral claim relating to OxyContin, that its sales, medical or research personnel have experience or credentials or are engaging in research activities if they do not in fact possess such credentials or experience, or are not engaging in such activities.

20. All material used in promoting OxyContin, regardless of format (audio, internet, video, print) and whether directed primarily to patients or to Health Care Professionals, shall, not inconsistent with the Package Insert, contain only information that is truthful, balanced, accurately communicated, and not minimize the risk of abuse, addiction or physical dependence associated with the use of OxyContin.

21. Purdue shall not provide samples of OxyContin to Health Care Professionals.

22. The obligations of Purdue under this Judgment shall be prospective only. No Signatory Attorney General shall institute any proceeding or take any action against Purdue under its State Consumer Protection Laws or any similar state authority, or under this Judgment, based on Purdue's prior promotional or marketing practices for OxyContin.

23. Nothing in this Judgment shall require Purdue to:

(a) take an action that is prohibited by the FDCA, the Controlled Substances Act or any regulation promulgated thereunder, or by FDA or the Drug Enforcement Administration;

(b) fail to take an action that is required by the FDCA, the Controlled Substances Act or any regulation promulgated thereunder, or by FDA or the Drug Enforcement Administration;

(c) refrain from dissemination of safety information concerning OxyContin; or

(d) refrain from making any written or oral promotional claim which is the same or substantially the same as the language permitted by FDA under the OxyContin Package Insert

and which accurately portrays the data or other information referenced in the OxyContin Package Insert.

24. Purdue shall:

(a) to the extent necessary for compliance with this Judgment, no later than ninety (90) days after the Effective Date of this Judgment, institute compliance procedures which are designed to begin training currently employed Covered Persons on the contents of this Judgment, and about how to comply with this Judgment;

(b) submit to the Attorney General (per the Notice below), no later than one hundred and twenty (120) days after the Effective Date of this Judgment, a written description of such training;

(c) submit to the Attorney General (per the Notice below), one (1) year after the Effective Date of this Judgment, a written affirmation setting forth Purdue's compliance with this paragraph;

(d) for a period of three (3) years from the Effective Date of this Judgment, Purdue shall advise in writing all Covered Persons of the requirements of Paragraphs 2 through 23 of this Judgment;

(e) beginning one (1) year after the Effective Date of this Judgment, for a period of three (3) years, produce and provide on an annual basis to the Attorney General on the anniversary of the Effective Date of this Consent Judgment a report containing basic statistics on Purdue's Abuse and Diversion Detection Program including, but not limited to, statistics on the number of reports , the number of investigations, and a summary of the results, including the number of "Do Not Call" determinations, but shall not include the names of any specific Health Care Professionals; and

(f) upon written request, the Attorney General may obtain state-specific information as described in subsection (e). In addition, Purdue agrees to accept service of a civil investigative demand or similar process by the Attorney General requesting the names of any specific Health Care Professionals described in subsection (e). The Attorney General in receipt of such information shall not disclose it except as provided by law.

III. PAYMENT TO THE STATES

25. No later than thirty (30) days after the Effective Date of this Judgment, Purdue shall pay nineteen million and five hundred thousand U.S. dollars ($19,500,000.00, to be paid by Purdue to the States by electronic fund transfer made payable to the Oregon Department of Justice (as instructed by that Office) which shall divide and distribute these funds as designated by and in the sole discretion of the Signatory Attorneys General as part of the consideration for the termination of their respective investigations under the State Consumer Protection Laws regarding the Subject Matter of this Judgment. Said payment shall be used by the States as and for attorneys' fees and other costs of investigation and litigation, or to be placed in, or applied to, the consumer protection enforcement fund, including future consumer protection enforcement, consumer education, litigation or local consumer aid fund or revolving fund, used to defray the costs of the inquiry leading hereto, and may be used to fund or assist in funding programs directed at combating prescription drug abuse, addiction and/or diversion, including, but not limited to, education, outreach, prevention or monitoring programs, or for other uses permitted by state law, at the sole discretion of each Signatory Attorney General.

IV. GENERAL PROVISIONS

26. This Judgment shall be governed by the laws of the State of South Carolina.

27. This Judgment is entered into by the Parties as their own free and voluntary act and with full knowledge and understanding of the nature of the proceedings and the obligations and duties imposed by this Judgment.

28. Nothing in this Judgment constitutes any agreement by the Parties concerning the characterization of the amounts paid pursuant to this Judgment for purposes of the Internal Revenue Code or any state tax laws, or the resolution of any other matters.

29. This Judgment does not constitute an approval by the Attorney General of any of Purdue's business practices, including its promotional or marketing practices, and Purdue shall make no representation or claim to the contrary.

V. REPRESENTATIONS AND WARRANTIES

30. Purdue warrants and represents that it and its predecessors, successors and assigns manufactured, sold and promoted OxyContin. Purdue further acknowledges that it is a proper party to this Judgment. Purdue further warrants and represents that the individual(s) signing this Judgment on behalf of Purdue is doing so in his (or her) official capacity and is fully authorized by Purdue to enter into this Judgment and to legally bind Purdue to all of the terms and conditions of the Judgment.

31. Each of the Parties represents and warrants that it negotiated the terms of this Judgment in good faith.

32. Each of the Signatory Attorneys General warrants and represents that he or she is signing this Judgment in his or her official capacity, and that he or she is fully authorized by his or her state to enter into this Judgment, including but not limited to the authority to grant the release contained in Paragraphs 34 and 35 of this Judgment, and to legally bind the state to all of the terms and conditions of this Judgment.

33. Purdue acknowledges and agrees that the Attorney General has relied on all of the representations and warranties set forth in this Judgment and that, if any representation is proved false, unfair, deceptive, misleading, or inaccurate in any material respect, the Attorney General has the right to seek any relief or remedy afforded by law or equity in the state.

VI. RELEASE

34. Based on his or her inquiry into Purdue's promotion of OxyContin, the Attorney General has concluded that this Judgment is the appropriate resolution of any alleged violations of the State Consumer Protection Laws. The Attorney General acknowledges by his or her execution hereof that this Judgment terminates their inquiry under the State Consumer Protection Laws into Purdue's promotion of OxyContin prior to the Effective Date of this Judgment.

35. In consideration of the Compliance Provisions, payments, undertakings, and acknowledgments provided for in this Judgment, and conditioned on Purdue's making full payment of the amount specified in Paragraph 25, and subject to the limitations and exceptions set forth in Paragraph 36, the State releases and forever discharges, to the fullest extent permitted by law, Purdue and its past and present officers, directors, shareholders, employees, co-promoters, affiliates, parents, subsidiaries, predecessors, assigns, and successors (collectively, the "Releasees"), of and from any and all civil causes of action, claims, damages, costs, attorney's fees, or penalties that the Attorney General could have asserted against the Releasees under the State Consumer Protection Law by reason of any conduct that has occurred at any time up to and including the Effective Date of this Judgment relating to or based upon the Subject Matter of this Judgment ("Released Claims").

36. The Released Claims set forth in Paragraph 35 specifically do not include the following claims:

(a) private rights of action by consumers, provided, however, that this Judgment

does not create or give rise to any such private right of action of any kind;

(b) claims relating to Best Price, Average Wholesale Price or Wholesale Acquisition Cost reporting practices or Medicaid fraud or Abuse;

(c) claims of antitrust, environmental or tax liability;

(d) claims for property damage;

(e) claims to enforce the terms and conditions of this Judgment; and

(f) any state or federal criminal liability that any person or entity, including Releasees, has or may have to the State.

VII. NO ADMISSION OF LIABILITY

37. This Judgment does not constitute an admission by Purdue for any purpose, of any fact or of a violation of any state law, rule, or regulation, nor does this Judgment constitute evidence of any liability, fault, or wrongdoing, by Purdue nor does Purdue's agreement in this Judgment not to engage in certain conduct constitute an admission that Purdue has ever engaged in such conduct. Purdue enters into this Judgment for the purpose of resolving the concerns of the Attorney General regarding Purdue's promotional and marketing practices regarding OxyContin. Purdue does not admit any violation of the State Consumer Protection Laws, and does not admit any wrongdoing that could have been alleged by the Attorney General.

38. This Judgment shall not be construed or used as a waiver or any limitation of any defense otherwise available to Purdue. This Judgment is made without trial or adjudication of any issue of fact or law or finding of liability of any kind. Nothing in this Judgment, including this paragraph, shall be construed to limit or to restrict Purdue's right to use this Judgment to assert and maintain the defenses of res judicata, collateral estoppel, payment, compromise and settlement, accord and satisfaction, or any other legal or equitable defenses in any pending or future legal or administrative action or proceeding.

VIII. DISPUTES REGARDING COMPLIANCE

39. For the purposes of resolving disputes with respect to compliance with this Judgment, should the Attorney General have legally sufficient cause (which shall include, at a minimum, a reasonable basis to believe that Purdue has violated a provision of this Judgment) to object to any promotional or marketing practices relating to OxyContin subsequent to the Effective Date of this Judgment, then the Attorney General shall notify Purdue in writing of the specific objection, identify with particularity the provisions of this Judgment and/or the State Consumer Protection Laws that the practice appears to violate, and give Purdue thirty (30) business days to respond to the notification; provided, however, that the Attorney General may take any action upon notice to Purdue where the Attorney General concludes that, because of the specific practice, a threat to the health or safety of the public requires immediate action.

40. Upon receipt of written notice and within the thirty (30) business-day period, Purdue shall provide a good faith written response to the Attorney General's objection. The response shall include an affidavit containing either:

a. A statement explaining why Purdue believes it is in compliance with the Judgment; or

b. A detailed explanation of how the alleged violation[s] occurred; and

i. A statement that the alleged breach has been cured and how it has been cured; or

ii. A statement that the alleged breach cannot be reasonably cured within thirty (30) business days from receipt of the notice, but (1) Purdue has begun to take corrective action to cure the alleged breach; (2) Purdue is pursuing such corrective action with reasonable and due diligence; and (3) Purdue has provided the Attorney General with a detailed and reasonable time table for curing the alleged breach.

41. Nothing herein shall prevent the Attorney General from agreeing in writing to provide Purdue with additional time beyond the thirty (30) business-day period to respond to the notice.

42. Nothing herein shall be construed to exonerate any failure to comply with any provision of this Judgment after the date of entry or to compromise the authority of the Signatory Attorney General to initiate a proceeding for failure to comply. Further, nothing in this subsection shall be construed to limit the authority of the Signatory Attorney General to protect the interests of the State.

43. The Signatory Attorney General represents that he or she will seek enforcement of the provisions of this Judgment with due regard for fairness and, in so doing, shall take into account efforts that Purdue has taken to cure any claimed violation of this Judgment.

44. Upon giving Purdue thirty (30) business days to respond to the notification described in Paragraph 39 above, the Attorney General shall be permitted to request and Purdue shall produce relevant, non-privileged, non-work-product records and documents in the possession, custody or control of Purdue that relate to Purdue's compliance with each provision of this Judgment as to which legally sufficient cause has been shown.

IX. MODIFICATION OF CERTAIN OPERATIONAL PROVISIONS

45. Any party to this Judgment may petition the Court for modification on thirty (30) days' notice to all other parties to this Judgment. Purdue may petition for modification if it believes that the facts and circumstances that led to the Attorney General's action against Purdue have changed in any material respect. The parties by stipulation may agree to a modification of this Judgment, which agreement shall be presented to this Court for consideration; provided that the parties may jointly agree to a modification only by a written instrument signed by or on

behalf of both Purdue and the Attorney General. If Purdue wishes to seek a stipulation for a modification from the State, it shall send a written request for agreement to such modification to the Attorney General at least 30 days prior to filing a motion with the Court for such modification. Within 30 days of receipt from Purdue of a written request for agreement to modify, the Attorney General shall notify Purdue in writing if the Attorney General agrees to the requested modification. The Attorney General shall not unreasonably withhold his/her consent to the modification.

X. PENALTIES FOR FAILURE TO COMPLY

46. The State may assert any claim that Purdue has violated this Judgment in a separate civil action to enforce this Judgment, or to seek any other relief afforded by law. In any such action or proceeding, relevant evidence of conduct that occurred before the Effective Date shall be admissible on any material issue, including alleged willfulness, intent, knowledge, or breach, to the extent permitted by law. By this Paragraph, Purdue does not waive any evidentiary objection or any other objection it may have as permitted by law to the admissibility of any such evidence.

XI. COMPLIANCE WITH ALL LAWS

47. Except as expressly provided in this Judgment, nothing in this Judgment shall be construed as:

(a) relieving Purdue of its obligation to comply with all state laws, regulations or rules, or granting permission to engage in any acts or practices prohibited by such law, regulation or rule; or

(b) limiting or expanding in any way any right the State may otherwise have to obtain information, documents or testimony from Purdue pursuant to any state law, regulation or rule, or any right Purdue may otherwise have to oppose any subpoena, civil investigative demand,

motion, or other procedure issued, served, filed, or otherwise employed by the State pursuant to any such state law, regulation, or rule.

XII. NOTICES

48. Any notices required to be sent to the State or to Purdue by this Judgment shall be sent by overnight United States mail. The documents shall be sent to the following addresses:

For the State:

C. Havird Jones, Jr.
Senior Assistant Attorney General
1000 Assembly Street (29201)
P. O. Box 11549
Columbia, SC 29211

For Purdue:

Vice President, Associate General Counsel
Purdue Pharma L.P.
One Stamford Forum
201 Tresser Boulevard
Stamford, CT 06901-3431

APPROVED:

Judge, Fifth Judicial Circuit

May 15, 2007

FOR PURDUE

Robin E. Abrams
Vice President, Associate General Counsel
Purdue Pharma L.P.
The Purdue Frederick Company
Purdue Pharma Inc.
Tel: 203-588-8477
Fax: 203-588-6204

Date: May 1, 2007

Steve Morrison
Nelson Mullins Riley & Scarborough
1320 Main Street
17th Floor
Columbia, SC 29201
Tel.: 803-255-9410
Fax: 803-255-9472
SC Bar No. 4103

Date: May 4, 2007

FOR THE STATE

C. HAVIRD JONES, JR. 5/7/02
Senior Assistant Attorney General
P. O. Box 11549
Columbia, SC 29211