IN THE UNITED STATES DISTRICT COURT
FOR THE MIDDLE DISTRICT OF ALABAMA
NORTHERN DIVISION

THE STATE OF ALABAMA,	)	
	)	
Plaintiff,	)	
	)	
v.	)	
	)	
PURDUE PHARMA L.P.; PURDUE PHARMA, INC.; THE PURDUE FREDERICK COMPANY, INC.; RHODES PHARMACEUTICALS, L.P.,	)	**CIVIL ACTION NO.:** 2:18-cv-89
	)	
	)	***TRIAL BY JURY REQUESTED***
Defendants.	)	

COMPLAINT

The State of Alabama files this Complaint against Defendants Purdue Pharma L.P., Purdue Pharma, Inc.; The Purdue Frederick Company, Inc.; and Rhodes Pharmaceuticals, L.P. (collectively "Purdue") and alleges as follows:

PRELIMINARY STATEMENT

1. The State of Alabama, by and through its Attorney General, brings this action to protect its citizens from deceptive and unfair marketing practices in the sale of opioids that are ravaging the State's communities, burdening the State with increasing monetary and societal costs, and fueling an ever-growing crisis in Alabama.

2. Opioids are highly addictive synthetic drugs derived from opium which is pharmacologically similar to heroin. The U.S. Drug Enforcement Administration ("DEA") has categorized opioids as having a "high potential for abuse[.]"[1] The Centers for Disease Control and Prevention ("CDC") declared that "[o]pioid pain medication use presents serious risks,

[1] DEA / Drug Scheduling, https://www.dea.gov/druginfo/ds.shtml (last visited Jan 22, 2018).

including overdose and opioid use disorder" (a diagnostic term for addiction).[2] As the Director of the CDC has noted: "We know of no other medication routinely used for a nonfatal condition that kills patients so frequently."[3] Opioids are categorized as Schedule II controlled substances.

3. Alabama's opioid crisis has been, and is still being, fueled by pharmaceutical manufacturer Purdue, which has deceptively and illegally marketed opioids in order to generate billions of dollars in sales. Purdue is the largest opioid marketer in Alabama.

4. As discussed below, Purdue's misrepresentations regarding the risks and benefits of opioids enabled, and is continuing to enable, the widespread prescribing of opioids for common chronic pain conditions like lower back pain, arthritis, and headaches.[4] As a direct consequence, the rampant use, overuse, and abuse of opioids is devastating both the citizens and State of Alabama.

5. Purdue, the largest opioid marketer in Alabama, primarily manufactures and sells opioids and it has virtually no other product line.

6. During the 1990s, the opioid market was small. This was due to doctors' fears that opioids were too addictive to be used long-term and too dangerous to be used for relatively minor chronic pain conditions. Thus, doctors mostly reserved opioid prescriptions for acute cancer pain, post-surgery recovery pain, and end-of-life care.

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[2] Deborah Dowell *et al.*, *CDC Guideline for Prescribing Opioids for Chronic Pain — United States, 2016*, 65 Morbidity and Mortality Weekly Report 1 (March 18, 2016), https://www.cdc.gov/mmwr/volumes/65/rr/rr6501e1.htm.

[3] Thomas R. Frieden and Debra Houry, *Reducing the Risks of Relief—The CDC Opioid-Prescribing Guideline*, 372 New Eng. J. Med 1501, 1503 (2016).

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

7. Purdue knew, and has known for years, that, except as a last resort, opioids were addictive and subject to abuse – particularly when used long-term for chronic pain. Purdue further knew, and has known for years, that with prolonged use, the effectiveness of opioids wanes, requiring increases in doses and markedly enhancing the risk of significant side effects and addiction.[5]

8. In order to expand the market for opioids, and thereby increase profits, Purdue needed to transform the medical and public perception to one that would permit the use of opioids not only for acute and palliative care, but also for long periods of time to treat more common aches and pains, like lower back pain, arthritis, and headaches.

9. Purdue created a sophisticated and highly deceptive marketing campaign that began in the 1990s, which continues to the present, that set out to, and did, reverse the medical understanding of prescription opioids.

10. Purdue accomplished their marketing goal by utilizing respected doctors, seemingly neutral patient advocacy groups, and professional associations to aggressively market its opioids as being effective to treat chronic pain without a significant risk of addiction. Purdue spent millions of dollars: (a) developing and disseminating seemingly truthful scientific and educational materials that misrepresented the risks, benefits, and superiority of opioids as a long-term treatment option for chronic pain; (b) deploying sales representatives who visited doctors and other prescribers and delivered misleading messages about the use of opioids; (c) recruiting prescribing physicians as paid speakers, as means of both securing those physicians' future "brand loyalty" and extending their research to the physicians' peers; (d) funding, assisting, encouraging, and directing doctors, known as "key opinion leaders" (KOLs), not only to deliver

[5] *See, e.g.*, Russell K. Portenoy, *Opioid Therapy for Chronic Nonmalignant Pain: Current Status*, 1 Progress in Pain Res. & Mgmt., 247-287 (H.L. Fields and J.C. Liebeskind eds., 1994).

scripted talks, but to draft misleading studies, conduct "continuing medical education programs" (CMEs) that were deceptive and lacked balance, and serve on the boards and committees of professional societies and patient advocacy groups that delivered messages and developed guidelines supporting chronic opioid therapy; and (e) funding, assisting, directing, and encouraging seemingly neutral and credible professional societies and patient advocacy groups (Front Groups) that developed educational materials and treatment guidelines urging doctors to prescribe, and patients to use, opioids long-term to treat chronic pain.

11. Purdue misrepresented the risks and benefits of using opioids, and touted the superiority of using opioids to treat chronic pain, claiming that its abuse-deterrent opioids were not only safer than alternatives, but prevented abuse, diversion, and injury – claims not only unsupported by, but contrary to, the evidence available to Purdue. Purdue's promotional claims were dangerously, and too often fatally, false.

12. In truth, roughly one in four patients who receive prescription opioids for long-term for chronic pain in primary care settings will become addicted. According to the CDC, within a median of 2.6 years after the first opioid prescription, one out of every 550 patients started on opioid therapy dies of opioid-related causes.[6] Moreover, several studies show that long-term opioid use may actually worsen pain and function. This is in addition to the symptoms of withdrawal that long-term users often face.

13. Purdue's marketing campaign has been extremely effective for distribution and sale of opioids in Alabama.

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[6] Eric Kaplovitch *et al.*, *Sex Differences in Dose Escalation and Overdose Death during Chronic Opioid Therapy: A Population-Based Cohort Study.* PLoS One (August 8, 2015), http://journals.plos.org/plosone/article?id=10.1371%2Fjournal.pone.0134550 (last visited Jan 22, 2018).

14. While Purdue reaped significant profits, opioids have created a national and a statewide emergency. According to the CDC, 145 Americans now die every day from opioid overdoses. In Alabama, hundreds of deaths are attributable to opioid overdoses every year.[7]

15. Alabama has one of the highest prescription rates for opioids in the nation – 1.2 prescriptions per person compared to the national average of 0.72.[8] Moreover, 6.5% of BlueCross BlueShield of Alabama members were on a long-duration opioid regiment in 2015, compared to 3.8% nationwide.

16. The State of Alabama and its citizens have borne the costs, both in money and heartache, of Purdue's deceptive marketing. Accordingly, the State of Alabama seeks: (a) injunctive relief to stop Purdue's deceptive marketing; (b) damages for the loss of tax revenue for the State; (c) damages for, and abatement of, the public health epidemic that Purdue has created; (d) civil penalties for each violation of Alabama's Deceptive Trade Practices Act; (e) damages, including punitive damages, for money spent by the State of Alabama as a result of Purdue's conduct; (f) disgorgement of Purdue's unjust profit; and (g) the maximum civil penalties allowed for each violation of the law, along with any other injunctive and equitable relief within this Court's powers to redress and halt Purdue's unlawful practices.

PARTIES

17. Plaintiff, the State of Alabama, brings this action, by and through its Attorney General, Steve Marshall, in its sovereign capacity in order to protect the interests of the State of Alabama and its citizens as *parens patriae*. The Attorney General brings this action pursuant to

[7] For example, no fewer than 282 deaths were attributable to opioid overdose in 2015 alone in Alabama. The Henry J. Kaiser Family Foundation, *Opioid Overdose Deaths and Opioid Overdose Deaths as a Percent of All Drug Overdose Deaths* (2015).

[8] CDC, *U.S. State Prescribing Rates, 2016,* https://www.cdc.gov/drugoverdose/maps/rxstate2016.html.

his constitutional, statutory, and common law authority, including the authority granted to him by ALA. CODE § 36-15-12.

18. Purdue Pharma, L.P. is a limited partnership organized under the laws of Delaware with its principal place of business in Stamford, Connecticut. Purdue Pharma, Inc. is a New York corporation with its principal place of business in Stamford, Connecticut. The Purdue Frederick Company Inc. is a New York corporation with its principal place of business in Stamford, Connecticut. Rhodes Pharmaceuticals, L.P. is a limited partnership organized under the laws of Delaware with its principal place of business in Coventry, Rhode Island. These parties are collectively referred to as "Purdue."

19. Through each of these entities, Purdue manufactures, markets, and sells prescription opioid pain medications, including the brand name drugs OxyContin, MS Contin, Dilaudid/Dilaudid HP, Butrans, Hysingla ER, and Targiniq ER, as well as generic opioids. Purdue has been a leading force in the prescription opioid market, both nationwide and in Alabama. OxyContin constitutes roughly 30% of the entire market for analgesic drugs (painkillers).

JURISDICTION AND VENUE

20. Count V (Unjust Enrichment) presents a federal common law claim. Therefore, this Court has jurisdiction under Article III, Section 2 of the United States Constitution.

21. The remaining counts present state-law claims over which this Court has supplemental jurisdiction. *See* 28 U.S.C. § 1367.

22. Venue is proper in this District pursuant to 28 U.S.C. § 1391(b).

23. The State understands that this Complaint may be transferred by the United States Judicial Panel on Multi-District Litigation ("JPML") to the United States District Court for the

Northern District of Ohio for coordinated or consolidated pretrial proceedings in MDL No. 2804. *See* 28 U.S.C. § 1407. Should transfer occur, the State reserves the right to seek a remand of any and all issues and claims not resolved in the Transferee Court back to this Court for a jury trial.

FACTUAL ALLEGATIONS

I. The Known Risks Far Outweigh the Unproven Benefits of Opioids for Treating Chronic Pain in Non-Cancer Patients.

24. Opioids are a class of drugs that interact with central nervous system to relieve pain. They encompass several different opioid molecules – morphine, hydrocodone, oxycodone, oxymorphone, hydromorphone, tapentadol, buprenorphine, and methadone being the most common.

25. Opioids are manufactured in two basic formulations – immediate release and extended release. Immediate release opioids deliver the full dose quickly as the pill dissolves. Extended release opioids are concentrated versions of the same active ingredients as immediate release, but these ingredients are contained in a time-release matrix that is supposed to release the drug over time. OxyContin, for example, is an extended release opioid that claims to deliver the drug oxycodone over 12 hours.

26. Purdue's drugs compose a majority of the extended release market. As such, they are marketed for use with chronic non-cancer pain patients which, as explained below, are the most dangerous method of use.

27. Prescription opioids constitute the largest component of the opioid epidemic, both in quantity and damage caused. In 2015, almost half of all opioid deaths involved prescription opioids, and from 1999 to 2015, 183,000 deaths involved prescription opioids.[9] Overdose deaths directly correlate with the prescription rates of opioids.[10]

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[9] Rose A. Rudd *et al., Increases in Drug and Opioid-Involved Overdose Deaths – United States, 2010 – 2015*, 65

28. Both opioid use disorder and overdose risk are present even when opioids are taken as prescribed.[11] Therefore, the opioid epidemic is not a crisis of abuse – it is a crisis of use.

a. Opioids are ineffective for pain relief and improvement of chronic, non-cancer pain.

29. Central to Purdue's marketing efforts is the claim that reliable evidence supports its representation that opioids either relieve pain or improve function when taken long-term for chronic pain. This claim, however, is unsupported by any evidence.

30. In 2016, the Centers for Disease Control (CDC) published a guideline for prescribing opioids for chronic pain. This guideline, published after a "systematic review of the best available evidence" by an expert panel free of conflicts of interest,[12] determined that no study exists showing that opioids are effective for outcomes related to pain, function, and quality of life.[13]

31. Additionally, Dr. Thomas Frieden, former Director of the CDC, and Dr. Debra Houry, Director of the National Center for Injury Prevention and Control explained that "the science of opioids for chronic pain is clear: for the vast majority of patients, the known, serious, and too-often-fatal risks far outweigh unproven and transient benefits."[14]

Morbidity and Mortality Weekly Report 1145 (December 30, 2016), https://www.cdc.gov/mmwr/volumes/65/wr/mm655051e1.htm.

[10] *Id.*

[11] Letter from Janet Woodcock, M.D., Dir., Ctr. for Drug Eval. & Res., to Andrew Kolodny, M.D., Pres. Physicians for Responsible Opioid Prescribing, Re Docket No. FDA-2012-P-0818 (Sept. 10, 2013).

[12] Dowell, *supra* note 2.

[13] *Id.*

[14] Frieden, *supra* note 3.

32. There are no controlled studies of the use of opioids beyond 16 weeks, and no evidence that opioids improve patients' pain and function long-term.[15] The first random, placebo-controlled studies appeared in the 1990s and revealed evidence only for short-term efficacy and only in a minority of patients.[16] A 2004 study reviewed 213 randomized, controlled trials of treatments for cancer pain and found that, while opioids had short-term efficacy, the data was insufficient to establish long-term effectiveness. Subsequent reviews of the use of opioids for cancer and non-cancer pain consistently note the lack of data to assess long-term outcomes. For example, a 2007 systematic review of opioids for back pain concluded that opioids have limited, if any, efficacy for back pain and that evidence did not allow judgments regarding long-term use. Similarly, a 2011 systematic review of studies for non-cancer pain found that evidence of long-term efficacy is poor. One year later, a similar review reported poor evidence of long-term efficacy for morphine, tramadol, and oxycodone, and fair evidence for transdermal fentanyl (approved only for use for cancer pain).

33. On the contrary, evidence exists to show that opioid drugs are not effective to treat chronic pain, and may worsen a patients' health. A 2006 meta-analysis of studies found that opioids as a class did not demonstrate improvement in functional outcomes over other non-addicting treatments.[17] Most notably, it stated: "For functional outcomes, the other analgesics were significantly more effective than were opioids."[18] Another review of evidence relating to

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[15] *Id.;* The Effectiveness and Risks of Long-term Opioid Treatment of Chronic Pain, Agency for Healthcare Res. & Quality. (Sept. 19, 2014).

[16] Nathaniel Katz, *Opioids: After Thousands of Years, Still Getting to Know You*, 23 (4) Clin. J. Pain 303, 306 (2007); Roger Chou, *et al., Research Gaps on Use of Opioids for Chronic Noncancer Pain*, 10(2) J. Pain 147-159 (2009).

[17] Andrea D. Furlan, *Opioids for chronic noncancer pain: a meta-analysis of effectiveness and side effects*, 174 (11) Can. Med. Ass'n J. 1589-1594 (2006).

[18] *Id.* This same study revealed that efficacy studies do not typically include data on opioid addiction. In many cases, patients who may be more prone to addiction are pre-screened out of the study pool. This does not reflect

the use of opioids for chronic pain found that a review of evidence relating to the use of opioids for chronic pain found that up to 22.9% of patients in opioid trials dropped out before the study began because of the intolerable effects of opioids and that the evidence of pain relief over time was weak.[19]

34. The lack of evidence for the efficacy of long-term opioid use has been well-documented in the context of workers' compensation claims, where some of the most detailed data exists. Claims involving workers who take opioids are almost four times more likely to reach costs of over $100,000 than claims involving workers who do not take opioids because opioid patients suffer greater side effects and are slower to return to work.[20] Even adjusting for injury severity and self-reported pain score, receiving an opioid for more than seven days and receiving more than one opioid prescription increased the risk that a patient will be on work disability one year later.[21] A prescription for opioids as the first treatment for a workplace injury doubled the average length of the claim.[22]

35. Despite the ever-increasing amount of evidence debunking Purdue's claims, it continued to market drugs for which there was no evidence of effectiveness.

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how doctors actually prescribe the drugs, because even patients who have past or active substance use disorders tend to receive higher doses of opioids. Karen H. Seal, *Association of Mental Health Disorders With Prescription Opioids and High-Risk Opioids in US Veterans of Iraq and Afghanistan*, 307(9) J. Am. Med. Ass'n 940-47 (2012).

[19] Meredith Noble, *et al., Long-term opioid management for chronic noncancer pain (Review)*, 1 Cochrane Database of Systematic Reviews (2010).

[20] Jeffrey A. White, *et al., The Effect of Opioid Use on Workers' Compensation Claim Cost in the State of Michigan*, 54(8) J. of Occupational & Environ. Med. 948-953 (2012).

[21] Gary M. Franklin, *et al., Early Opioid Prescription and Subsequent Disability Among Workers with Back Injuries: The Disability Risk Identification Study Cohort*, 33 (2) Spine 199-204 (2008).

[22] Dongchun Wang, *et al., Longer-Term Use of Opioids*, Workers Comp. Res. Inst. (Oct.2012).

b. Evidence confirms that opioids are highly addictive.

36. Opioids are extremely addictive. Studies have found diagnosed addiction rates in primary care settings as high as 26%.[23] Among opioid users who received four prescriptions in a year, 41.3% meet diagnostic criteria for a lifetime opioid-abuse disorder.[24]

37. Once a patient begins opioid treatment, it is extraordinarily difficult to stop. A 2017 CDC study determined that the probability of long-term use escalates most sharply after five days and surges again when one month of opioids are prescribed.[25] A patient initially prescribed one month of opioids has a 29.9% chance of still using at one year.[26] In one study, almost 60% of patients who used opioids for 90 days were still using them five years later.[27]

38. Patients first prescribed extended release opioids have significant difficulty in stopping their use. Patients who initiated treatment on an extended release opioid such as OxyContin have a 27.3% likelihood to be using them one year later and a 20.5% likelihood of using them three years later.[28]

39. Due to concerns about their addictive qualities, opioids have been regulated as controlled substances by the DEA since 1970. The labels for scheduled opioid drugs carry black

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[23] Dowell, *supra* note 2.

[24] Joseph A. Boscarino, Stuart N. Hoffman & John J. Han, *Opioid-Use Disorder Among Patients on Long-Term Opioid Therapy: Impact of Final DSM-5 Diagnostic Criteria on Prevalence and Correlates*, 6 Substance Abuse and Rehabilitation 83 (2015); *see also* Joseph A. Boscarino et al., *Prevalence of Prescription Opioid-Use Disorder Among Chronic Pain Patients: Comparison of the DSM-5 vs. DSM-4 Diagnostic Criteria*, 30 Journal of Addictive Diseases 185 (2011) (showing a 34.9% lifetime opioid use disorder).

[25] Anuj Shah, Corey J. Hayes & Bradley C. Martin, *Characteristics of Initial Prescription Episodes and Likelihood of Long-Term Opioid Use – United States, 2006-2015*, 66 Morbidity and Mortality Weekly Report 265–269 (2017).

[26] *Id.*

[27] Bradley C. Martin et al., *Long-Term Chronic Opioid Therapy Discontinuation Rates from the TROUP Study*, 26 J. Gen. Internal. Med. 1450 (2011).

[28] Shah, *supra.*

box warnings of potential addiction and "[s]erious, life-threatening, or fatal respiratory depression," as a result of an excessive dose.

40. Most patients receiving more than a few weeks of opioid therapy will experience withdrawal symptoms if opioids are discontinued (commonly referred to as "dependence").[29] Once dependent, a patient experiences deeply unpleasant symptoms when his or her current dose of opioids loses its effect and is not promptly replaced with a new dose. Among the symptoms reported in connection with opioid withdrawal are severe anxiety, nausea, vomiting, headaches, agitation, insomnia, tremors, hallucinations, delirium, pain, and other serious symptoms, which may persist for months, or even years, after a complete withdrawal from opioids, depending on how long opioids were used.[30]

41. Opioids elicit a euphoric response by stimulating pleasure centers in the brain. In fact, Dr. Andrew Kolodny, who previously served as Chief Medical Officer for Phoenix House, a national addiction treatment program, has explained the effect of opioids as akin to "hijacking the brain's reward system," which in turn convinces a user that "the drug is needed to stay alive."[31] A patient's fear of the unpleasant effects of discontinuing opioids combined with the negative reinforcement during a period of actual withdrawal can drive a patient to seek further opioid treatment – even where ineffective or detrimental to quality of life – simply to avoid the deeply unpleasant effects of withdrawal.[32]

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[29] Richard A. Deyo, *et al.*, *Opioids for Back Pain Patients: Primary Care Prescribing Patterns and Use of Services*, 24 J. Am. Bd. Of Fam. Prac. 725 (2011).

[30] *See* Jane Ballantyne, *New Addiction Criteria: Diagnostic Challenges Persist in Treating Pain With Opioids*, 21(5) Pain Clinical Updates (Dec. 2013).

[31] David Montero, *Actor's Death Sows Doubt Among O.C.'s Recovering Opioid Addicts*, The Orange Cnty. Regi. (Feb. 3, 2014), http://www.ocregister.com/articles/heroin-600148-shaffer-hoffman.html.

[32] *See* Mary Jeanne Kreek, *et al.*, *Pharmacotherapy of Addictions*, 1 (9) Nature Reviews: Drug Discovery 710-26 (Sept. 2002) (Describing counter-adaptive drug-induced changes that prompt "continued drug use through negative reinforcement mechanisms.").

42. When under the continuous influence of opioids over a period of time, patients grow tolerant to their analgesic effects. As tolerance increases, a patient typically requires progressively higher doses to obtain the same levels of pain reduction he or she has become accustomed to – up to and including dosage amounts that are considered by many physicians to be "frighteningly high."[33] At higher doses, the effects of withdrawal are more substantial, leaving a patient at a much higher risk of addiction. The U.S. Food & Drug Administration ("FDA") has acknowledged that available data suggests a relationship between increased doses and the risk of adverse-effects.[34]

43. Patients receiving high doses of opioids as part of long-term opioid therapy are three to nine times more likely to suffer overdose from opioid-related causes than those on low doses.[35] As compared to available alternative pain remedies, scholars have suggested that tolerance to the respiratory depressive effects of opioids develops at a slower rate than tolerance to opioids' analgesic effects. Accordingly, the practice of continuously escalating dosages to match pain tolerance can, in fact, lead to overdose even where opioids are taken as recommended.[36]

44. Further, "a potential side effect from chronic use [of opioids] can be abuse and addiction.... [I]n fact, correct use and abuse of these agents are not polar opposites – they are complex, inter-related phenomena."[37] It is very difficult to tell whether a patient is physically

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[33] Mitchell H. Katz, *Long-term Opioid Treatment of Nonmalignant Pain: A Believer Loses His Faith*, 170(16) Archives of Internal Med., 1422-1424 (Sept. 13, 2010).

[34] Letter from Janet Woodcock, *supra* note 11.

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

[36] *See* Laxmaiah Manchikanti, *et al.*, *Opioid Epidemic in the United States*, 15 Pain Physician ES9-ES38 (2012) (60% of opioid overdoses prescribed within guidelines).

[37] Wilson M. Compton & Nora D. Volkow, *Major Increases in Opioid Analgesic Abuse in the United States:*

dependent, psychologically dependent, or addicted. Drug-seeking behaviors, which are signs of addiction, will exist and emerge when opioids are suddenly not available, the dose is no longer effective, or tapering of a dose is undertaken too quickly.[38]

45. Studies have shown that between 30% and 40% of long-term users of opioids experience problems with opioid use disorders.[39]

46. Each of these risks and adverse effects – dependence, tolerance, and addiction – is fully disclosed in the labels for each of Defendants' opioids (though, as described below, not in Defendants' marketing).[40] Prior to Defendants' deceptive marketing scheme, each of these risks was well recognized by doctors and seen as a reason to use opioids to treat chronic pain sparingly and only after other treatments had failed. But through its deceptive marketing scheme, Defendants misled doctors about the addictive nature of prescription opioids and its lack of suitability for chronic pain. Thus, were it not for the Defendants' misrepresentations and their failure to disclose the actual risks of opioids, doctors would have continued to treat chronic pain sparingly and only after other treatments had failed.

47. While it was once thought that extended-release opioids would not be as susceptible to abuse and addiction as immediate-release opioids, this view has been discredited. OxyContin's label now states, as do all labels of Schedule II long-acting opioids, that the drug "exposes users to risks of addiction, abuse, and misuse, which can lead to overdose and death."

Concerns and Strategies, 81(2) Drug & Alcohol Dependence 103, 106 (Feb. 1, 2006).

[38] Jane Ballantyne, *Opioid Dependence vs. Addiction: A Distinction Without a Difference?*, Archives of Internal Med. (Aug. 13, 2012).

[39] Joseph A. Boscarino, *et al., Risk factors for drug dependence among out-patients on opioid therapy in a large US health-care system*, 105(10) Addiction 1776-82 (Oct. 2010); Joseph A. Boscarino, *et al., Prevalence of Prescription Opioid-Use Disorder Among Chronic Pain Patients: Comparison of the DSM5 vs. DSM-4 Diagnostic Criteria*, 30(3) Journal of Addictive Diseases 185-94 (July-Sept. 2011).

[40] For example, Purdue's OxyContin label (Oct. 5, 2011) states: "Physical dependence and tolerance are not unusual during chronic opioid therapy."

The FDA has required extended release and long-acting opioids to adopt "Risk Evaluation Mitigation Strateg[ies]" because they present "a serious public health crisis of addiction, overdose, and death."[41]

48. In 2013, in response to a petition to restrict the labels of extended-release opioid products, the FDA noted the "grave risks of opioids, the most well-known of which include addiction, overdose, and even death."[42] The FDA further warned that "[e]ven proper use of opioids under medical supervision can result in life-threatening respiratory depression, coma, and death."[43] The FDA required that, going forward, makers of extended-release opioid formulations clearly communicate these risks in their labels. Thus, the FDA confirmed what had previously been accepted practice in the treatment of pain – that the adverse outcomes from opioid use include "addiction, unintentional overdose, and death" and that long-acting or extended release opioids "should be used ***only when alternative treatments are inadequate***."[44]

49. Notably, in reaching its conclusion, the FDA did not rely on new or otherwise previously unavailable scientific studies regarding the properties or effects of opioids.

c. Opioids are most dangerous when taken long-term and in high doses.

50. The risk of addiction and negative consequences increases when opioids are administered long-term.[45] In 2013, the FDA noted that the data show that the risk of misuse and

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[41] FDA, Risk Evaluation and Mitigation Strategy (REMS) for Extended-Release and Long-Acting Opioids (Aug. 2014), *available at* http://www.fda.gov/Drugs/DrugSafety/InformationbyDrugClass/ucm163647.htm.

[42] Letter from Janet Woodcock, *supra* note 11.

[43] *Id.*

[44] *Id.* (emphasis in original).

[45] Compton, *supra* note 37.

abuse is greatest for extended release opioids and observed that these drugs are often used chronically.[46]

51. One study has shown that the duration of opioid therapy is a strong risk factor for opioid use disorder, even more important than daily dose – which itself is a strong predictor of continued opioid use.[47] In fact, a study published in 2015 found that 20% of patients on long-term opioid treatment will develop opioid use disorder.[48]

52. Higher doses of opioids are dangerous in a number of ways. A CDC clinical evidence review found that higher opioid dosages were associated with increased risks of motor vehicle injury, opioid use disorder, and overdoses, and that the increased risk rises in a dose-dependent manner.[49] Another study found that higher daily doses and possible opioid misuse were also strong predictors of continued use, and associated with increased risk of overdoses, fractures, dependence, and death.[50]

53. Accordingly, the CDC recommended that physicians carefully reassess increasing opioid doses beyond 50 morphine milligram equivalents (MMEs), and avoid exceeding 90 MMEs/day.[51] Roughly translated, a single 60-mg pill of oxycodone, the active ingredient in OxyContin, is 90 MME; a 40-mg pill is 60 MME; and a single 30-mg pill is 45 MME. Since

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[46] Letter from Janet Woodcock, *supra* note 11.

[47] Mark J. Edlund et al., *The Role of Opioid Prescription in Incident Opioid Abuse and Dependence Among Individuals with Chronic Non-cancer Pain*, 30 Clin. J. Pain 557–564 (2014).

[48] Louisa Degenhardt et al., *Agreement between definitions of pharmaceutical opioid use disorders and dependence in people taking opioids for chronic non-cancer pain (POINT): a cohort study*, 2 The Lancet Psychiatry 314–322 (2015).

[49] Dowell, *supra* note 2.

[50] Edlund, *supra.*

[51] Dowell, *supra* note 2.

patients take 12-hour OxyContin twice a day, a prescription for 30-mg pills of Oxycontin is already at the CDC's upper threshold.

54. Overall, 1 in every 550 patients on opioid treatment dies of opioid-related causes a median of 2.6 years after their first opioid prescription. That number increases to 1 in 32 for patients receiving 200 MMEs/day.[52]

55. In short, there are no safe opioid doses, but the higher the dose and the longer the treatment, the more likely a patient will suffer serious health consequences.

II. Despite the Evidence, Purdue Continues to Market Opioids for Non-Cancer Pain Management.

56. Purdue's opioid-related business model is centered on its misrepresentation of the risks of users becoming addicted as well as the benefits of its opioids. Before Purdue launched OxyContin in 1996, opioids were originally used to treat severe pain over the short-term except for terminally ill patients. This was because the medical community was aware of both the risks of opioids and relative ineffectiveness of long-term use. Dr. Russell Portenoy, whose theories were later adopted by Purdue, acknowledged the prevailing medical understanding regarding use of opioids long-term for non-cancer pain:

> The traditional approach to chronic non-malignant pain does not accept the long-term administration of opioid drugs. This perspective has been justified by the perceived likelihood of tolerance, which would attenuate any beneficial effect over time, and the potential for side effects, worsening disability, and addiction. According to conventional thinking, the initial response to an opioid drug may appear favorable, with partial analgesia and salutatory mood changes, but adverse effects will inevitably occur thereafter.[53]

[52] Frieden, *supra* note 3.

[53] Portenoy, *supra* note 5.

Thus, in 1994, conventional wisdom predicted that opioids would appear effective in the short-term but prove ineffective over time with increasing negative side effects.

57. But the market for acute and end-of-life pain was relatively small. Thus, when Purdue launched OxyContin, it sought to broaden its use to chronic pain – back pain, arthritis, and headaches, for example – which not only is more widespread, but entails months or even years of treatment – and, thus, sustained revenue. Purdue, however, found that doctors were too worried about the risk of turning their patients into addicts to prescribe its opioids for chronic pain.

58. Purdue set out to – and did – convince doctors that, while opioids were generally addictive, patients with legitimate pain who remained under a doctor's care would not become addicted. In doing so, Purdue failed to correct obvious misperceptions of OxyContin's strength and deliberately misrepresented its risks.

59. In addition to its branded promotion, Purdue also used general, unbranded materials, produced by Purdue or by seemingly independent third parties, to build the market for chronic opioids; unbranded promotion does not name a specific drug and is often more persuasive because it does not seem to be product advertising. The concept of "Pain as a Fifth Vital Sign," an initiative of the Joint Commission for the Accreditation of Hospital Organizations, ensured that virtually every health care facility and provider in the country, including those in Alabama, learned its recommendation that pain should be assessed along with a patient's pulse and blood pressure. Once doctors asked about pain, they were obligated to treat it, and Purdue made sure that doctors knew that opioids were an appropriate option.

60. The long-term use of opioids for chronic pain is particularly dangerous because patients develop tolerance to the drugs over time, requiring higher doses to achieve their effect.

At high doses, opioids depress the respiratory system, eventually causing the user to stop breathing, which is what makes opioid overdoses fatal. Patients also quickly become dependent on opioids and will often experience physically and psychologically agonizing withdrawal symptoms, which may last for weeks, making it very hard for patients to discontinue their use after even relatively short periods of time. The risk of addiction increases with the duration of use, and causes patients to use opioids at ever-higher doses, even when they are causing harm. It is this mix of tolerance, dependence, and addiction that has made the use of opioids for chronic pain so lethal.

61. Purdue attributed the problem of opioid abuse and overdose to patients who were seeking the opioids, not the drugs themselves. A public statement by Purdue executive Michael Friedman was typical of Purdue's tilt: "Virtually all of these reports [of opioid abuse] involve people who are abusing the medication, not patients with legitimate medical needs."[54] Yet, contrary to Purdue's misrepresentations, pain patients who use opioids precisely as prescribed by a legitimate doctor can – and do – become addicted. Addiction is the result of using opioids, not simply misusing, or abusing them.

62. Furthermore, Purdue has claimed in other contexts that its responsibility for the opioid epidemic is relieved by the independent actions of doctors who make their own decisions about whether to prescribe opioids and which drugs to use. However, Purdue's marketing deliberately set out to change prescribers' attitudes about opioids. Therefore, the company cannot credibly claim to be either surprised by or blameless for those results. Purdue knows from its own tracking that its promotion influences prescribers' decisions. That explains why Purdue

[54] Patrick Radden Keefe, *The Family That Built an Empire of Pain*, The New Yorker (Oct. 30, 2017), https://www.newyorker.com/magazine/2017/10/30/the-family-that-built-an-empire-of-pain.

invests heavily in ensuring that its sales representatives visit doctors frequently – because it works.

III. Purdue Continued to Aggressively and Deceptively Market its Opioids for Chronic Pain.

63. In 2007, Purdue entered into a plea agreement and settlements with federal and state governments to resolve potential civil and criminal enforcement actions. Purdue pleaded guilty to the federal felony of misbranding of a drug with intent to defraud or mislead, admitting that it had lied to doctors about OxyContin's abuse potential, and it paid $600 million in fines. Purdue also entered into Consent Judgments agreeing to cease its fraudulent marketing, to no longer misrepresent the risk of addiction to OxyContin, to provide "fair balance" in conveying the risks and benefits of OxyContin, and to implement an abuse and diversion detection system to identify and address suspicious prescribing.

64. The 2007 settlements, however, did not mark a change in Purdue's culture or conduct. Because what Purdue was told by doctors in the mid-1990s remains true – that doctors will not knowingly prescribe a highly addictive drug long-term for relatively modest pain – and so Purdue's multi-billion-dollar franchise depends upon its continuing to mislead doctors and consumers. Purdue developed and deployed a comprehensive and sophisticated strategy to do so.

65. Purdue inundated Alabama prescribers with promotional sales visits to deliver its message that opioids were appropriate for the treatment of chronic pain.

66. Purdue knew that certain doctors were responsible for a significant percentage of its sales in Alabama, and the prescribing patterns of those doctors should have sounded alarms. However, instead of reporting potentially suspicious prescribing by these doctors, Purdue did nothing and continued to profit from it.

67. For many years, Purdue drugs have constituted a substantial portion of the spending on branded schedule II and III opioid analgesics.

68. Sales visits are not Purdue's only marketing tactic. Purdue also used KOLs – experts in the field who were especially influential because of their reputations and seeming objectivity – to deliver paid talks and CMEs to prescribers that provided information about treating pain and the risks, benefits, and use of opioids. KOLs received substantial funding and research grants from Purdue, and the CMEs were often sponsored by Purdue – giving Purdue considerable influence over the messenger, the message, and the distribution of the program. Only doctors who were supportive of the use and safety of opioids for chronic pain received these funding and speaking opportunities. Dr. Russell Portenoy was a leading KOL who subsequently acknowledged that he gave lectures on opioids that reflected "misinformation" and were "clearly the wrong thing to do."[55]

69. In addition to talks and CMEs, these KOLs served on the boards of patient advocacy groups and professional associations, such as the American Pain Foundation and the American Pain Society, that were also able to exert greater influence because of their seeming independence. Purdue and other pharmaceutical companies exerted influence over these groups by providing major funding directly to them, as well. These front groups for the opioid industry put out patient education materials and treatment guidelines that supported the use of opioids for chronic pain, overstated their benefits, and understated their risks. In many instances, Purdue distributed these publications to prescribers or posted them on its website.

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[55] Thomas Catan and Evan Perez, *A Pain-Drug Champion Has Second Thoughts*, The Wall Street Journal (Dec. 17, 2012, https://www.wsj.com/articles/SB10001424127887324478304578173342657044604.

70. In addition, Purdue employees and KOLs identified, funded, published, and disseminated research that was designed to assist Purdue's marketing efforts and skewed or misreported the scientific evidence. For example, to substantiate its claims that opioids were rarely addictive, Purdue included in promotional and educational materials a cite to the prestigious *New England Journal of Medicine*, but failed to disclose its source was a letter to the editor. Drug companies used this letter to conclude that their new opioids were not addictive, "[b]ut that's not in any shape or form what we suggested in our letter," according to one of its authors, Dr. Hershel Jick.[56] A recent analysis in the *Journal* in June 2017 found that citation of the letter significantly increased after the introduction of OxyContin and "contributed to the North American opioid crisis by helping to shape a narrative that allayed prescribers' concerns about the risk of addiction associated with long-term opioid therapy."[57] It has continued to be widely cited in literature and materials available until the present.

71. Neither these third-party, unbranded materials, nor the marketing messages, nor the scripts relied on by Purdue's sales representatives, were reviewed or approved by the FDA. All of the messages described in this Complaint were disseminated to Alabama prescribers and patients through sales representative visits, medical education programs, websites, and other sources.

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[56] Taylor Haney and Andrea Hsu, *Doctor Who Wrote 1980 Letter on Painkillers Regrets That It Fed The Opioid Crisis*, National Public Radio (Jun. 16, 2017) http://www.npr.org/sections/health-shots/2017/06/16/533060031/doctor-who-wrote-1980-letter-on-painkillers-regrets-that-it-fed-the-opioid-crisis.

[57] *Id.*

IV. Purdue Misrepresents the Risk that Chronic Pain Patients Will Become Addicted to its Opioids.

72. Purdue misrepresented, and continues to misrepresent even today, the risk of opioid addiction to Alabama doctors and patients. Specifically, Purdue affirmatively misrepresents that: (a) pain patients do not become addicted to opioids; (b) its long-acting opioids are steady-state and less addictive; (c) doctors can identify and manage the risk of addiction; (d) patients who seem addicted are merely "pseudoaddicted," and should be treated with more opioids; (e) opioid addiction is the product of problem patients and doctors, not of opioids; and (f) opioid abuse and addiction manifests themselves through snorting and injecting the drugs, rather than through oral abuse. In addition, Purdue failed to disclose to the State of Alabama, Alabama prescribers, and patients the risks of addiction to, and withdrawal from, its opioids.

a. Misrepresenting or failing to disclose the risk of addiction.

73. Purdue's sales representatives often omitted from their sales conversations with Alabama prescribers any discussion of the risk of addiction from long-term use of opioids. This failure to disclose the risk of addiction – an adverse effect that Purdue knew was material – was deceptive in its own right, but it was especially so in light of Purdue's past misrepresentations regarding the risk of addiction, which Purdue failed to correct.

74. Moreover, Purdue continued to affirmatively misrepresent that pain patients would not become addicted to opioids. Alabama prescribers were told that, although OxyContin is a narcotic, patients being treated for chronic pain will not become addicted and that its drugs, used properly, were safe.

75. Purdue also disseminated misleading information about opioids and addiction through the front group American Pain Foundation ("APF"), over which Purdue exercised control. *A Policymaker's Guide to Understanding Pain & Its Management*, a 2011 APF publication that Purdue sponsored, claimed that pain had been "undertreated" due to "[m]isconceptions about opioid addiction." This guide also repurposed Purdue's pre-2007 assertion, now claiming that "less than 1% of children treated with opioids become addicted," which would help support OxyContin's market for children 11-years and older – an indication Purdue sought and received in 2015. A *Policymaker's Guide* also perpetuated the concept of pseudoaddiction. 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*. That guide is still available to Alabama prescribers online.

76. Purdue also maintained a website from 2008 to 2015, *In the Face of Pain,* which downplayed the risks of chronic opioid therapy. Purdue deactivated this website in October 2015 following an investigation by the New York Attorney General. While the website discussed opioids and side-effects from their use and the *fear* of addiction (as a barrier to use), it *never*, anywhere on the website, disclosed the risk of addiction to opioids. At the same time, the website contained testimonials from several dozen physicians 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 website.

77. As before the 2007 settlements and criminal pleas, Purdue continues to tell Alabama doctors in sales visits that its long-acting opioids are "steady-state," with no peaks and valleys. This promise of steady-release implies, and is understood by prescribers to mean, that

Purdue's opioids are less addictive because they do not trigger the euphoric rush and crash that fuel drug cravings.

78. Purdue sales representatives also failed to disclose to Alabama prescribers the difficulty of opioid withdrawal. Discontinuing or delaying opioids can cause agonizing physical and psychological effects that can last for weeks, including anxiety, nausea, headaches, painful muscle cramps, and delirium, among others. Withdrawal symptoms can leave many patients unwilling or unable to give up opioids and heightens the risk of addiction. In the words of one physician, "I see all these people who are convinced they are one of the 'legitimate' pain patients. They're on a massive dose of opioids and they're telling me they need this medication, which is clearly doing them *harm.* For many of them, the primary benefit of therapy, at this point, is not going into withdrawal."[58]

b. Overstating the ability of doctors to manage the risk of addiction and failing to disclose the lack of evidence that these strategies work.

79. Purdue sales representatives conveyed to doctors that they can screen out patients at high risk of addiction through screening tools, urine tests and patient contracts, and safely prescribe to their other "appropriate" patients. Purdue also promoted screening tools as a reliable means to manage addiction risk in CME programs and scientific conferences attended by or available to Alabama prescribers. Purdue failed to disclose the lack of evidence that these risk management strategies actually mitigate addiction risk.

80. Purdue shared its *Partners Against Pain* "Pain Management Kit," which contains several "drug abuse screening tools" and CDs with catalogues of Purdue materials, which included these tools, with Alabama prescribers.

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[58] Patrick R. Keefe, *The Family That Built an Empire of Pain*, The New Yorker (Oct. 30, 2017), https://www.newyorker.com/magazine/2017/10/30/the-family-that-built-an-empire-of-pain. (emphasis in original).

81. Purdue also sponsored an online CME program taught by Dr. Lynn Webster, another KOL whom the company also funded, 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." The CME currently is available online to Alabama prescribers and has been for approximately six years.[59] The CME has been and will continue to be viewed by additional Alabama prescribers.

82. Another Purdue-funded CME, *Chronic Pain Management and Opioid Use: Easing Fears, Managing Risks, and Improving Outcomes*, deceptively instructs doctors that, through the use of screening tools, more frequent refills, and other techniques, high-risk patients showing signs of addictive behavior can be treated safely with opioids. This CME was presented live on October 11, 2012, by webinar available in Alabama, and the CME currently is available online to Alabama prescribers. This CME has been available online for approximately five years and it has been viewed by additional Alabama prescribers since its live broadcast.

c. Promoting the unsubstantiated concept of pseudoaddiction to discount signs of addiction.

83. Purdue also deceptively advised doctors to ignore signs of addiction as the product of "pseudoaddiction." The theory of pseudoaddiction counseled that signs of addiction, such as asking for a drug by name or seeking early refills, reflect undertreated pain that should be addressed with more opioids. Purdue deceptively described pseudoaddiction as an accepted scientific concept, although the term was coined by a single doctor named David Haddox, who

[59] Emerging Solutions in Pain, *Managing Patient's Opioid Use: Balancing the Need and the Risk*, http://www.emergingsolutionsinpain.com/ce-education/opioid-management?option=com_continued&view=frontmatter&Itemid=303&course=209 (last visited Jan. 5, 2018).

was later hired by Purdue, and was based on the observation of a single patient. In *Providing Relief, Preventing Abuse,* a pamphlet published by Purdue for prescribers and law enforcement beginning in 2011, Purdue described pseudoaddiction as a term that "has emerged in the literature to describe the inaccurate interpretation of [drug-seeking] behaviors in patients who have pain that has not been effectively treated."

84. Purdue promoted pseudoaddiction through at least 2013 on its website, *Partners Against Pain.*[60]

85. Purdue also sponsored the publication *Responsible Opioid Prescribing* (2007), which taught that patient behaviors such as "requesting drugs by name, demanding or manipulative behavior," seeing more than one doctor to obtain opioids, and hoarding, are all signs of pseudoaddiction.

d. Falsely portraying addiction as a problem of opioid abuse diversion, not opioid use.

86. In addition to deceptively ascribing signs of addiction to pseudoaddiction, Purdue falsely portrayed "true" addiction in its narrowest form. *Providing Relief, Preventing Abuse* shows pictures of the signs of injecting or snorting opioids – track marks and perforated nasal septa – under the heading "Indications of Possible Drug Abuse." Purdue knew that these extremes are uncommon; users far more typically become dependent and addicted by swallowing intact pills. In fact, 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.

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[60] *Partners Against Pain* consists of both a website, styled as an "advocacy community" for pain care, and education resources distributed to prescribers by Purdue sales representatives. 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."

87. These skewed depictions misleadingly reassured doctors that, in the absence of these extreme signs, they need not worry that their patients are abusing, or addicted to, opioids.

88. Purdue used its involvement in the College on the Problems of Drug Dependence ("CPDD"), which provides training and support to addiction treatment professionals, to promote the idea that addiction risk can be managed. A Purdue employee served on the CPDD board of directors and Purdue has been a frequent presenter at CPDD conferences. One of Purdue's consistent themes was 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. Hundreds of addiction treatment specialists from across the country attended these conferences, including Alabama prescribers.

89. More generally, Purdue had no basis to assert that addiction is the result of patients who manipulate either the drugs or their doctors. Patients who "doctor-shop," that is, visit multiple prescribers to obtain opioid prescriptions, are responsible for roughly 2% of opioid prescriptions.[61] The epidemic of opioid overprescribing is not, as Purdue often asserts, the result of problem patients or doctors.

e. Purdue's statements and omissions regarding the risk of addiction are contrary to, and unsupported by, scientific evidence.

90. Purdue's efforts to trivialize the risk of addiction were, and remain, at odds with the scientific evidence. Prescription opioids are, for the most part, "no less addictive than

[61] National Institute on Drug Abuse, *Although Relatively Few, 'Doctor Shoppers' Skew Opioid Prescribing*, (May 27, 2014) https://www.drugabuse.gov/news-events/nida-notes/2014/05/although-relatively-few-doctor-shoppers-skew-opioid-prescribing (last visited Jan. 5, 2018).

heroin."[62] Studies have shown that at least 8-12%, and as many as 30-40%, of long-term users of opioids experience problems with addiction.

91. Purdue's own evidence bears that out.

92. More recently, in March 2016, after a "systematic review of the best available evidence," the CDC published the CDC Guideline for Prescribing Opioids for Chronic Pain ("CDC Guideline"). The CDC Guideline noted that "[o]pioid pain medication use presents serious risks, including overdose and opioid use disorder."[63] The CDC also emphasized that "continuing opioid therapy for 3 months substantially increases risk for opioid use disorder."[64]

93. There is no evidence that long-acting opioids, like Purdue's, are any less addictive than other opioids. In fact, long-acting opioids, including Hysingla and OxyContin, are, and have long been, Schedule II narcotics because of their "high potential for abuse" and because they "may lead to severe psychological or physical dependence." Purdue's representation that its long-acting opioids had fewer peaks and valleys or were less addictive was one of the deceptive statements acknowledged in its 2007 criminal plea and settlements, and that claim is just as false today as it was then.

94. The CDC Guideline also 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

[62] Frieden, *supra* note 3.

[63] Dowell, *supra* note 2, at 2.

[64] *Id.* at 21.

misuse" and counsels that doctors "should not overestimate the ability of these tools to rule out risks from long-term opioid therapy."[65]

95. No competent scientific source has validated the concept of pseudoaddiction. Not surprisingly, the CDC Guideline nowhere recommends attempting to provide more opioids to patients exhibiting symptoms of addiction. Dr. Lynn Webster, a Purdue KOL, admitted that pseudoaddiction "is already something we are debunking as a concept" and that it became "too much of an excuse to give patients more medication. It led us down a path that caused harm."[66]

V. Purdue Overstated the Benefits of Opioids for Chronic Pain While Hiding the Lack of Evidence Supporting Their Use.

96. To convince Alabama prescribers and patients that opioids should be used to treat chronic pain, Purdue also 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."[67] 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" and that other treatments were more or equally beneficial and less harmful than long-term opioid use. [68] The few longer-term studies of opioid use had "consistently poor results," and "several studies have showed that opioids for chronic pain may actually worsen pain and functioning . . . ."[69] As a result, the CDC recommends that

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[65] Dowell, *supra* note 2,at 28.

[66] John Fauber, *Painkiller Boom Fueled by Networking*, Milwaukee Wisc. J. Sentinel, Feb. 18, 2012.

[67] *Id.* at 10.

[68] *Id.* at 9.

[69] Frieden, *supra* note 3.

opioids be used not in the first instance, but only after prescribers have exhausted alternative treatments.

a. Failing to disclose the lack of evidence supporting the use of opioids long-term for chronic pain.

97. Nevertheless, Purdue touted the purported benefits of long-term opioid use, while falsely and misleadingly suggesting that scientific evidence supported these benefits. Moreover, Purdue sales representatives promoted its drugs for chronic pain, but did not disclose in their sales conversations the lack of evidence supporting long-term use.

98. Two 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, based on their funding and the involvement of Purdue KOLs in leadership roles, Purdue was able to exercise 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 (also responsible, as noted above, for coining the term "pseudoaddiction"), was at the time a Purdue KOL 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.

99. AAPM and APS issued treatment guidelines in 2009 ("AAPM/APS Guidelines") which continued to recommend the use of opioids to treat chronic pain. Treatment guidelines were particularly important to Purdue in securing acceptance for chronic opioid therapy. Such guidelines 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.

100. The AAPM/APS Guidelines promote opioids as "safe and effective" for treating chronic pain. The panel made "strong recommendations" despite the "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. Dr. Gilbert Fanciullo, a retired professor at Dartmouth College's Geisel School of Medicine who also served on the panel, 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.

101. The AAPM/APS Guidelines are still available online, were reprinted in the *Journal of Pain* and have influenced not only treating physicians and chemical dependency treatment providers, but also the body of scientific evidence on opioids.

102. Purdue also published misleading studies to enhance the perception that opioids are effective long-term for chronic pain conditions. For example, one study asserts that OxyContin is safe and effective for the chronic pain condition osteoarthritis. The study, sponsored by Purdue, related to a chronic condition, but only provided opioids for 30 days. The authors 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]."[70] Yet, the authors conclude that "[t]his clinical experience shows that opioids were well tolerated with only rare incidence of addiction and that tolerance to the analgesic effects was not a clinically significant problem when managing patients with opioids long-term."[71] 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. Another Purdue study of a chronic pain condition only evaluated patients over seven days, but found oxycodone effective in its treatment.[72]

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

103. Purdue also claimed, without evidence, through its sales representatives and other materials disseminated in Alabama, that long-term opioid use would help to improve patients' function and quality of life and get them back to work and to their lives.

104. Purdue and Purdue-sponsored materials distributed or made available in Alabama 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 chronic pain conditions – that implied functional improvement. For example, one advertisement

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[70] *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).

[71] *Id.*

[72] Martin E. Hale, Roy Fleischmann, Robert Salzman, James Wild, Tad Iwan, Ruth E. Smanton, Robert F. Kaiko, and Peter G. Lacouture, *Efficacy and Safety of Controlled-Release Versus Immediate-Release Oxycodone: Randomized, Double-Blind Evaluation in Patients with Chronic Back Pain*, The Clinical Journal of Pain, Sep. 1, 1999, https://www.ncbi.nlm.nih.gov/pubmed/10524470.

described a "writer with osteoarthritis of the hands" and implied that OxyContin would help him work more effectively.

105. Purdue sponsored the Federation of State Medical Boards' *Responsible Opioid Prescribing* (2007), which taught that relief of pain itself improved patients' function. *Responsible Opioid Prescribing* explicitly describes functional improvement as the goal of a "long-term therapeutic treatment course." This publication claimed that because pain had a negative impact on a patient's ability to function, relieving pain – alone – would "reverse that effect and improve function." However, the truth is far more complicated; functional improvements made from increased pain relief can be offset by several problems, including addiction.

106. Likewise, Purdue's claims that long-term use of opioids improves patient function and quality of life are unsupported by clinical evidence. As noted above, there are no controlled studies of the use of opioids beyond 16 weeks, and there is no evidence that opioids improve patients' pain and function long-term. On the contrary, the available evidence indicates opioids 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.

107. 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."[73] 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.

108. 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"[74] and advised that "there is no good evidence that opioids improve pain or function with long-term use."[75] Similarly, the FDA has warned other opioid product manufacturers that claims of improved function and quality of life were misleading.[76] The CDC also noted that the risks of addiction and death "can cause distress and inability to fulfill major role obligations."[77] Along those lines, a recent study by Princeton economist Alan Krueger found that opioids may be responsible for roughly 20% of the decline in workforce participation among prime-age men and 25% of the drop for women.[78]

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[73] 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.aspx?pageid=144&tabid=747

[74] Dowell, *supra* note 2,at 15.

[75] *Id.* at 20.

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

[77] Dowell, *supra* note 2,at 2.

[78] Alan B. Krueger, *Where Have All the Workers Gone? An Inquiry into the Decline of the U.S. Labor Force Participation Rate*, Brookings Papers on Economic Activity Conference Draft (Aug. 26, 2017).

109. 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."[79] According to Dr. Tom Frieden, then Director of 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]."[80]

c. Omitting or mischaracterizing adverse effects of opioids.

110. 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 favor opioids over other therapies such as over-the-counter acetaminophen or nonsteroidal anti-inflammatory drugs (or NSAIDs, like ibuprofen), which do not impose a risk of addiction. None of these claims were corroborated by scientific evidence.

111. In addition to failing to disclose in promotional materials the risks of addiction, abuse, overdose, and respiratory depression, Purdue also routinely omitted other significant risks from long-term opioid use, including: hyperalgesia, a "known serious risk associated with chronic opioid analgesic therapy," in which the patient becomes more sensitive to certain painful stimuli over time; hormonal or endocrine 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 painfully 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 that are often also used by pain patients.

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[79] Dowell, *supra* note 2,at 18.

[80] Frieden, *supra* note 3.

112. Purdue sponsored APF's *Treatment Options: A Guide for People Living with Pain* (2007) 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). This publication also warned that risks of NSAIDs increase if "taken for more than a period of months," with no corresponding warning about opioids.

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

114. These omissions regarding adverse side-effects 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.[81] Moreover, the CDC, in its evidence review, did not find evidence that opioids were more effective for pain reduction than NSAIDs for back pain or antidepressants for neuropathic pain (typically, nerve pain), and found that non-opioids were better tolerated and better at improving physical function, with little or no risk of addiction and lower risks of overdose and death.[82]

115. Purdue's misrepresentations were effective in increasing its own sales and driving down those of this alternative, less risky and less costly treatment. A study of 7.8 million doctor

[81] Noble, *supra* note 19.

[82] Frieden, *supra* note 3.

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%.[83]

VI. Purdue Promoted the Use of Opioids in Ever-Higher Doses Without Disclosing the Greater Risks.

116. Purdue falsely claimed to Alabama 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.

117. 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 find a doctor who would.

118. *A Policymaker's Guide* taught that dose escalations are "sometimes necessary," but did not disclose the risks from high dose opioids. Upon information and belief, Purdue collaborated with APF to create this publication. This publication is still available online.

119. The Purdue-sponsored online CME, *Overview of Management Options*, discussed above, instructed physicians that NSAIDs are unsafe at high doses (because of risks to patients' kidneys), but did not disclose risks from opioids at high doses. Not only does this statement raise issues with Purdue's claims regarding 12-hour dosing, but this advice was not accompanied by warnings regarding increased risk of addiction associated with increased doses.

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[83] M. Daubresse, *et al.*, *Ambulatory Diagnosis and Treatment of Nonmalignant Pain in the United States, 2000-2010,* 51*(10)* Med. Care, 870-878 (2013). For back pain alone, the percentage of patients prescribed opioids increased from 19% to 29% between 1999 and 2010, even as the use of NSAIDs or acetaminophen declined from 39.9% to 24.5% of these visits; and referrals to physical therapy remained steady.

120. Purdue's assertions and omissions are contrary to 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.[84]

121. The CDC Guideline concludes that the "[b]enefits of high-dose opioids for chronic pain are not established"[85] while "[o]verdose risk increases in a dose-response manner . . ."[86] That is why the CDC advises doctors to "avoid increasing doses" above 90 mg MED.[87]

VII. Purdue Misleadingly Promoted OxyContin as Supplying 12 hours of Pain Relief When Purdue Knew That, For Many Patients, it Did Not.

122. To convince prescribers and patients to use OxyContin, Purdue misleadingly promoted the drug as providing 12 continuous hours of pain relief with each dose. In reality, OxyContin does not last for 12 hours in many patients, a fact Purdue has known since the product's launch. While OxyContin's FDA-approved label directs 12-hour dosing, Purdue sought that dosing frequency in order to maintain a competitive advantage over other opioids that required more frequent dosing. 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.

123. Since it was launched in 1996, OxyContin has been FDA-approved for twice-daily – "Q12" – dosing frequency. It was Purdue's decision to submit OxyContin for approval

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[84] Dunn, *supra* note 35. Most overdoses were medically serious and 12% were fatal.

[85] Dowell, *supra* note 2,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."

[86] *Id.*.

[87] *Id.* at 16.

with 12-hour dosing. 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," that is because Purdue has conducted no such studies.

124. 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.

125. In fact, Purdue long has known, dating to its development of OxyContin, that the drug wears off well short of 12 hours in many patients. Upon information and belief, Purdue's own research shows that OxyContin wears off in under six hours in one quarter of patients and in under 10 hours in more than half. This is because OxyContin tablets release approximately 40% of their active medicine immediately, after which release tapers. This triggers a powerful initial response, but provides little or no pain relief at the end of the dosing period, when less medicine is released. This phenomenon is known as "end of dose" failure, and the FDA found in 2008 that a "substantial proportion" of chronic pain patients taking OxyContin experience it. This not only renders Purdue's promise of 12 hours of relief false and deceptive, it also makes OxyContin more dangerous because the declining pain relief patients experience toward the end of each dosing period drives them to take more OxyContin before the next dosing period begins, quickly increasing the amount of drug they are taking and spurring growing dependence. This is

consistent with the experience of Alabama doctors, who have reported that for many patients, the drug did not last 12-hours.

126. 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."[88] 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 number of opioids they are taking.

127. 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 disclose to prescribers what it knew about OxyContin's actual duration, regardless of any marketing advantage.

128. Twelve-hour dosing also is featured in most OxyContin promotional pieces. Upon information and belief, these pieces were distributed in Alabama, and neither piece discloses that the pain relief from each 12-hour dose will last well short of 12 hours for many patients.

129. Purdue was also aware of some physicians' practice of prescribing OxyContin more frequently than 12 hours – a common occurrence, including by Alabama prescribers. 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. Using higher doses also means

[88] 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/.

that patients will experience higher highs and lower lows, increasing their craving for their next pill.

VIII. To Protect its Market and Profits, Purdue Misrepresented the Impact of its Opioids in Reducing Abuse and Addiction.

130. With time, the toll of Purdue's highly successful marketing campaign became visible. Rather than remedy its prior deceptive marketing to rein in overprescribing, Purdue turned evidence of opioid abuse, overdose, and death into a new opportunity. In 2010, with the imminent expiration of its patent on OxyContin (and the prospect of generic competition for its marquee product), Purdue launched a reformulated OxyContin that was labeled "abuse-deterrent" because the pills are harder to crush and inject. Purdue promised doctors in Alabama that its abuse-deterrent opioids were safer for patients. But Purdue knew that many users are still able to tamper with OxyContin, that oral abuse persists, and that many users turn to heroin to satisfy their addiction – none of which it disclosed to doctors. By deceptively promoting its abuse-deterrent opioids as a strategy to cope with the epidemic of opioid addiction and death it helped unleash, Purdue has prolonged and deepened the crisis in Alabama, persuading doctors, and patients that they can continue to use opioids – so long as they are Purdue's opioids.

131. Reformulated, Abuse Deterrent Formula ("ADF") OxyContin was approved by the FDA in April 2010. 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 Purdue launched Hysingla ER, extended-release hydrocodone, in 2014, the product included similar abuse-deterrent properties.

132. The FDA noted in permitting ADF labeling that "the tamper-resistant properties will have no effect on abuse by the oral route (the most common mode of abuse)." Purdue's labels also acknowledge that abusers seek out the drugs because of their high likeability when

snorted, that the abuse deterrent properties can be defeated, and that they can be abused orally notwithstanding their abuse-deterrent properties, and do *not* indicate that ADF opioids prevent or reduce addiction, abuse, misuse, or diversion.

133. Nevertheless, Purdue's national marketing campaign touted OxyContin's tamper-resistant properties as a primary message.[89]

134. Purdue claimed that its abuse-deterrent opioids are a sign that it is a more responsible company than in the past and that it is aggressively trying to address the problem of opioid addiction and death. But Purdue's ADF marketing from sales representatives to Alabama prescribers was itself deceptive, as Purdue marketed its ADF products as safe, when they are not. Purdue failed to disclose that ADF opioids are subject to oral abuse. Purdue also failed to disclose that ADF opioids simply shift some abuse to other opioids, such as heroin, with even worse outcomes. Purdue also knew or should have known, but did not disclose, that "reformulated OxyContin is not better at tamper resistance than the original OxyContin,"[90] and, in fact, is still regularly tampered with and abused.

135. Websites and message boards used by drug abusers, such as bluelight.org and reddit.com, 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.

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[89] *In re OxyContin*, 1:04-md-01603-SHS, (Russell Gasdia Tr. Sept. 2013), 994 F. Supp.2d at 416.

[90] *In re OxyContin*, 1:04-md-01603-SHS, Docket No. 613, Oct. 7, 2013 hr'g, Testimony of Dr. Mohan Rao, 1615:7-10; 1616:7-10.

136. *One-third* of the patients in a non-Purdue 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, abuse simply shifted to other drugs such as heroin.

137. As in other areas, Purdue distorted its own research to support its promotional claims and to bury contradictory evidence.

138. 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." [91] The original FDA medical review of reformulated OxyContin explicitly stated in 2009 that "tamper-resistant properties will have no effect on abuse by the oral route (the most common mode of abuse)" – at the time estimated to be 72% of OxyContin abuse.[92] In the 2012 medical office review of Purdue's application to include an abuse-deterrence claim in its label for OxyContin, the FDA noted that the overwhelming majority of deaths linked to OxyContin were associated with oral consumption, and that only 2% of deaths were associated with recent injection and only 0.2% with snorting the drug.

139. The FDA's Director of the Division of Epidemiology stated in September 2015 – while Purdue was heavily promoting its abuse-deterrent formulations as safe and able to prevent abuse – that no data that she had seen suggested the reformulation of OxyContin "actually made a reduction in abuse," between continued oral abuse, shifts to injection of other drugs, and defeat of the ADF mechanism. Dr. Tom Frieden, then the Director of the CDC, reported that his staff

[91] Dowell, *supra* note 2,at 22 (emphasis added).

[92] U.S. Food and Drug Administration Center for Drug Evaluation and Research, *Medical Review of Application No. 22-272*, http://www.accessdata.fda.gov/drugsatfda_docs/nda/2010/022272s000MedR.pdf.

could not find "any evidence showing the updated opioids [ADF opioids] actually reduce rates of addiction, overdoses, or death."

140. Purdue itself knew that claiming ADF formulations reduces abuse was not supported by evidence.

141. In 2015, claiming a need to further assess its data, Purdue abruptly withdrew its 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."[93] Given the absence of any public hearings or advisory meetings on the topic, it seems that Purdue still has not presented the data to the FDA, presumably because the data would not have supported claims that OxyContin's ADF properties reduced abuse or misuse.

142. 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.

143. Purdue's misleading marketing preserved not only its price, but also its sales. 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

[93] 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.

to secure a determination by the FDA in April 2013 that original OxyContin should be removed from the market as unsafe (due to its lack of 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.

144. Purdue knew that its ADF marketing changed prescribers' perceptions of its opioids and their willingness to continue to prescribe them.

145. According to law enforcement, doctors, and treatment providers, OxyContin continues to be widely abused, even after its reformulation, in Alabama as elsewhere. It is still as sought after in illicit street sales; it is still snorted and injected; and it continues to result in overdoses and deaths.

IX. By Increasing Opioid Use, Purdue's Deceptive Marketing Fueled the Opioid Epidemic and Significantly Harmed Alabama

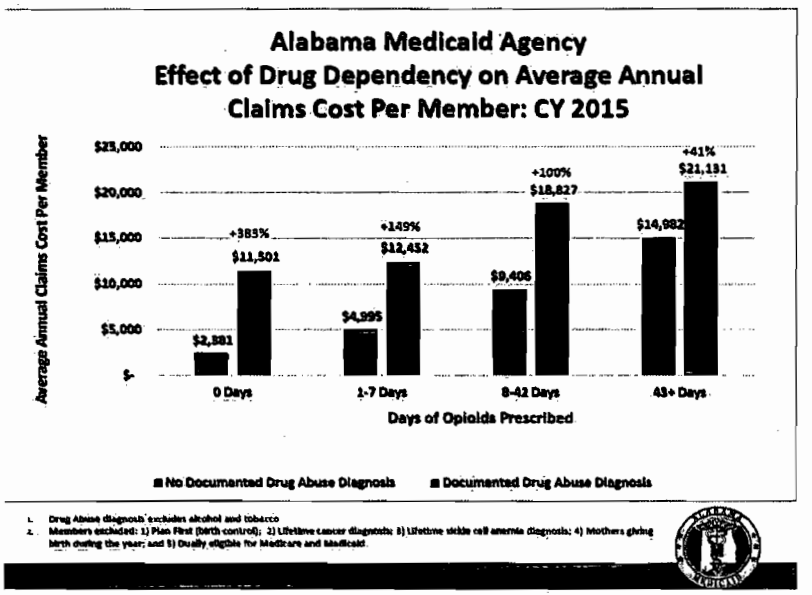
146. While Purdue has profited greatly from increased sales of OxyContin and their other opioids, Alabama and its taxpayers have borne its costs. These costs were imposed, in large measure, by Purdue, and should be borne by Purdue.

147. Opioids have had a particularly acute impact on rural states like Alabama. According to a recent report by the U.S. Department of Agriculture, "[r]ising rates of prescription medication abuse, especially of opioids, and the related rise in heroin-overdose deaths are contributing to this unprecedented rise in age-specific mortality rates after a century or more of steady declines. This trend, if it continues, will not only lower rural population but will increase what is known as the dependency ratio: the number of people likely to be not working (children and retirees) relative to the number of people likely to be wage earners (working-age adults)."[94]

[94] U.S. Dept. of Ag., Economic Information Bulletin 182, Rural America at a Glance (Nov. 2017).

148. Alabama has the highest rate of opioid prescriptions issued in the nation – 1.2 prescriptions per person compared with the national average of 0.71.[95] In 2015, no fewer than 282 deaths were attributable to opioid overdoses in Alabama.[96]

149. According to the Alabama Medicaid Agency, total federal and state expenditures on opioids increased more than 147% from 2011 ($9.9 million) to 2016 ($14.6 million). The Agency estimates the cost of claims per member increases drastically as the number of days that member is prescribed to opioids increases.[97]



150. Indeed, the likelihood of continued opioid use correlates with the number of days of first episode of opioid use.[98]

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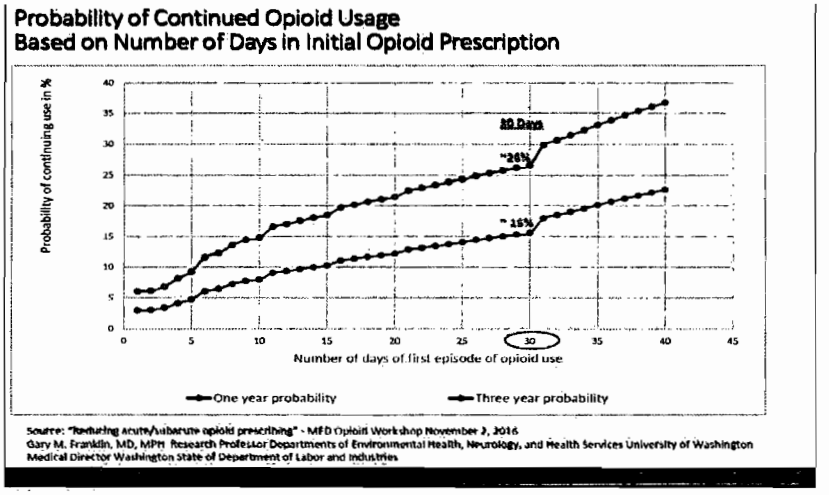
[95] CDC, *U.S. State Prescribing Rates, 2016,* https://www.cdc.gov/drugoverdose/maps/rxstate2016.html.

[96] The Henry J. Kaiser Family Foundation, *Opioid Overdose Deaths and Opioid Overdose Deaths as a Percent of All Drug Overdose Deaths* (2015).

[97] Robert Moon, MD. *Alabama Medicaid Opioid Prescribing Trends and Outcomes: The Opioid Crisis in Alabama: From Silos to Solutions*, (March 10, 2017).

[98] *Id.*



151. The tragic impact on the most vulnerable is similarly shocking. Neonatal Abstinence Syndrome (NAS) is neonatal withdrawal resulting from maternal use of opioids during pregnancy. The number of infants diagnosed with NAS increased 209% from 2010 (255) to 2015 (533). The average cost of a NAS delivery is eight times higher than a normal delivery.

152. Alabama has 24 certified opioid treatment programs. However, these treatment programs do not even begin to meet the need for services in Alabama.

153. In addition to intense counseling, many treatment programs prescribe additional drugs to treat opioid addiction. Nationally, in 2012, nearly 8 billion prescriptions of the two drugs commonly used to treat opioid addiction, buprenorphine/naloxone and naltrexone, were written and paid for. Studies estimate the total medical and prescription costs of opioid addiction and diversion to public and private healthcare payors at $72.5 billion. According to one estimate based on 2007 data showing $25 billion spent in health care costs from opioid abuse, Alabama has spent $234,480,306 in such costs, amounting to $48 per capita.[99]

[99] *See* Matrix Global Advisors, LLC, *Health Care Costs from Opioid Abuse: A State-by-State Analysis* (Apr. 2015).

154. Alabama is also incurring other costs related to overdose responses, naloxone spending for first responders, increased law enforcement spending, increased pretrial and post-trial incarceration costs, increased criminal defense costs, increased social services spending such as representing parents and children in neglect proceedings, loss of productivity, loss of tax revenues for the State of Alabama, and other costs and response measures needed to address the epidemic.

155. The State of Alabama will incur significant expenses in the future to abate the public nuisance caused by Purdue's deceptive promotion. This will include, but is by no means limited to, the costs of continuing to dispose of unused prescriptions; re-educating doctor and patients about the appropriate use of opioids and about the signs of addiction and the availability of treatment; and treatment for opioid addiction and overdose, including naloxone and medication-assisted addiction treatments, like buprenorphine.

156. The State of Alabama has taken action to address these additional expenses. On August 8, 2017, Governor Kay Ivey established the Alabama Opioid Overdose and Addiction Council to study the state's opioid crisis and identify a strategy to counteract its adverse consequences.[100]

157. Since 2005, the State of Alabama has participated in the Prescription Drug Monitoring Program which collects prescription records and, where necessary, provides information to law enforcement. One of the stated purposes of the program is to facilitate and encourage the identification, intervention with and treatment of individuals addicted to controlled substances.

[100] Executive Order No. 708, Establishing the Alabama Opioid Overdose and Addiction Council.

X. Although Purdue Knew that its Marketing of Opioids was False and Misleading, the Company Fraudulently Concealed its Misconduct.

158. Purdue has made, promoted, and profited from its misrepresentations about the risks and benefits of opioids for chronic pain even though it has known 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 accordingly, 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 to Purdue the harms caused by 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 findings based on existing medical evidence that conclusively expose the known falsity of Purdue's misrepresentations.

159. Notwithstanding this knowledge, at all times relevant to this Complaint, Purdue has taken steps to avoid detection of, and to fraudulently conceal, its unlawful, unfair, and deceptive conduct. Purdue has 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 has purposely hidden behind the assumed credibility of these sources and relied on them to establish the accuracy and integrity of its false and misleading messages about the risks and benefits of long-term opioid use for chronic pain. Purdue has masked – or never bothered to disclose – its role in shaping, editing, and approving the content of this information. Purdue also has distorted the meaning or import of studies it cited and offered them as evidence for propositions the studies did not support. Purdue thus

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

CLAIMS FOR RELIEF

COUNT I – VIOLATION OF ALAMABAMA'S DECEPTIVE TRADE PRACTICES ACT

160. The State of Alabama incorporates the preceding paragraphs as if fully set forth herein. As described in those paragraphs, Purdue engaged in trade or commerce in the State of Alabama.

161. The Alabama Deceptive Trade Practices Act ("ADTPA") vests the Attorney General with the authority to enforce the Act's provisions on behalf of the State. ALA. CODE §§ 8-19-4, 8-19-11.

162. Section 5 of the ADTPA declares certain acts and practices to be unlawful. ALA. CODE § 8-19-5. Purdue engaged in acts or practices that violated multiple provisions of Section 5, including but not limited to:

a. Causing confusion or misunderstanding as to the source, sponsorship, approval, or certification of goods and services. ALA. CODE § 8-19-5(2);

b. Representing that goods have characteristics, uses, benefits, or qualities that they do not have. ALA. CODE § 8-19-5(5);

c. Representing that goods or services are of a particular standard, quality, or grade, if they are of another. ALA. CODE § 8-19-5(7);

d. Advertising goods or services with the intent not to sell them as advertised. ALA. CODE § 8-19-5(9); and

e. Engaging in any other unconscionable, false, misleading, or deceptive act or practice in the conduct of trade or commerce. ALA. CODE § 8-19-5(27).

Each of these violations constitutes a distinct violation of the ADTPA that warrants a distinct remedy, including but not limited to a maximum $2,000 penalty per violation. ALA. CODE § 8-19-11(b)

163. Purdue aimed the following deceptive practices, among others, at both prescribing physicians and consumers:

a. Denying that pain patients would become addicted to opioids;

b. Omitting that opioids are highly addictive and may result in overdose or death;

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

d. Claiming that the risk of addiction to opioids could be managed and avoided through risk screening tools and other strategies;

e. Claiming that opioid doses can be increased, without disclosing the greater risks of addiction, other injury, or death at higher doses;

f. Misleadingly comparing opioids and NSAIDs, including overstating the risks of NSAIDs and citing risks of NSAIDs without disclosing risks of opioids;

g. Claiming that opioids are an appropriate treatment for chronic pain, and failing to disclose the lack of long-term evidence for their use;

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

i. Promoting OxyContin as providing a full 12 hours of pain relief, and failing to disclose that it does not provide such relief for many patients;

j. Claiming abuse-deterrent opioids reduce addiction and abuse and are safer than other opioids, and failing to disclose that they do not limit oral abuse, can be defeated with relative ease, and may increase overall abuse;

k. Promoting itself as a company that encourages and assists law enforcement while not reporting suspicious prescribing to law enforcement;

l. Promoting opioids as superior to other competing analgesics, such as NSAIDs, and exaggerating the risks of NSAIDs while ignoring risks of adverse effects of opioids; and

m. Omitting other material facts that deceived consumers by Purdue's other representations to Alabama Consumers, including other adverse effects from opioid use.

164. Purdue's acts and practices were willful and knowingly directed toward a population that included numerous older persons and other vulnerable consumers.

COUNT II – PUBLIC NUISANCE

165. The State incorporates the preceding paragraphs as if fully set forth herein.

166. Under Alabama Law, a nuisance "is anything that works hurt, inconvenience, or damage to another." ALA. CODE § 6-5-120 (1975). "A public nuisance is one which damages all persons who come within the sphere of its operation, though it may vary in its effects on individuals." ALA. CODE § 6-5-121 (1975).

167. Under Alabama law, a public nuisance is abated by the filing of an action in the name of the State of Alabama. ALA. CODE § 6-5-121.

168. Purdue's actions described in this Complaint have worked and continue to work to hurt, inconvenience, and/or damage to the sovereign State and many of its individual citizens.

169. The residents of the State of Alabama have a common right to be free from conduct that creates an unreasonable jeopardy to the public health, welfare, and safety, and to be free from conduct that creates a disturbance and reasonable apprehension of danger to person and property.

170. Stemming the flow of illegally distributed prescription opioids, and abating the nuisance caused by the illegal flow of opioids, will help alleviate this problem, save lives, prevent injuries, and make the State of Alabama a safer place to live.

171. Purdue's conduct constitutes a public nuisance and, if unabated, will continue to threaten the health, safety, and welfare of the residents of the State of Alabama, creating an atmosphere of fear and addiction that tears at the residents' sense of well-being and security.

172. Purdue acted with actual malice because Purdue acted with a conscious disregard for the rights and safety of other persons, and said actions have a great probability of causing substantial harm.

173. The damages available to the State of Alabama include, *inter alia*, recoupment of governmental costs, flowing from an ongoing and persistent public nuisance which the government seeks to abate. Purdue's conduct is ongoing and persistent, and the State of Alabama seeks all damages flowing from Purdue's conduct. The State of Alabama further seeks to abate the nuisance and harm created by Purdue's conduct.

174. As a direct result of Purdue's conduct, the State of Alabama and the State of Alabama's residents have suffered actual injury and damages including, but not limited to, addiction and abuse, loss of productivity, loss of tax revenues for the State of Alabama, an

elevated level of crime, death and injuries to the residents of the State of Alabama, a higher level of fear, discomfort and inconvenience to the residents of the State of Alabama and direct costs to the State of Alabama. The State of Alabama hereby seeks recovery for its own harm.

175. The State of Alabama and the residents of the State of Alabama have sustained specific and special injuries because their damages include, *inter alia*, health services, law enforcement expenditures, costs related to opioid addiction treatment and overdose prevention, loss of productivity of Alabama's workforce, and loss of tax revenue for the State of Alabama.

176. The State of Alabama further seeks to abate the nuisance created by the Purdue's unreasonable, unlawful, intentional, ongoing, continuing, and persistent actions and omissions and interference with a right common to the public.

177. The State of Alabama seeks all legal and equitable relief as allowed by law, including, *inter alia,* abatement, compensatory damages, and punitive damages from the Defendants for the creation of a public nuisance, attorney fees and costs, and pre- and post-judgment interest.

178. The State of Alabama seeks economic losses (direct, incidental, or consequential pecuniary losses) resulting from Purdue's fraudulent activity and fraudulent misrepresentations.

179. The State of Alabama seeks all legal and equitable relief as allowed by law, other than such damages disavowed herein, including *inter alia* injunctive relief, restitution, disgorgement of profits, compensatory and punitive damages, and all damages allowed by law to be paid by Purdue, attorney fees and costs, and pre- and post-judgment interest.

COUNT III – DRUG RELATED NUSIANCE ALABAMA CODE § 6-5-155, *et seq.*

180. The State of Alabama incorporates the preceding paragraphs as if fully set forth herein.

181. "Drug-Related Nuisance" is defined under Alabama law as "[t]he use, sale, distribution, possession, storage, transportation, or manufacture of any controlled substances in violation of the controlled substance acts, or similar act of the United States or any other state." ALA. CODE § 6-5-155.1(3)(b).

182. For purposes of the Drug-Related Nuisance statute, "controlled substance acts" as defined as "[t]he provisions of Sections 20-2-1 *et seq.*, known as the "Alabama Uniform Controlled Substance Act," and Sections 13A-12-201 *et seq.*, known as "The Drug Predator Control Act of 1987," and Sections 13A-12-210 *et seq.*, known as "The Drug Crimes Amendments Act of 1987." ALA. CODE § 6-5-155.1.

183. Purdue's distribution of opioids while failing to maintain effective controls against diversion was proscribed by the Alabama Uniform Controlled Substance Act, the US Controlled Substances Act and regulations promulgated by the Alabama State Board of Pharmacy. *See, e.g.,* 21 CFR § 1301.74(b); ALA CODE §§ 20-2-56 and 57; ALA ADMIN. CODE § 680-X-3-.05. This distribution in violation of the controlled substance acts, or similar act of the United States, constitutes a Drug-Related Nuisance.

184. "Wherever there is reason to believe that a drug-related nuisance exists, the Attorney General ... may file an action ... to abate, enjoin, and prevent the drug-related nuisance." ALA CODE § 6-5-155.2.

185. Purdue's ongoing conduct produces an ongoing nuisance, as the prescription opioids that they allow and/or cause to be illegally distributed and possessed in the State of Alabama will be diverted, leading to abuse, addiction, crime, death, and public health and safety costs.

186. As a result of the Drug-Related Nuisance caused by Purdue, the State of Alabama has suffered numerous adverse impacts, including *inter alia*, an increase in the number of ambulance and police calls related to the use of opioids, violence stemming from drug-related activity, and/or the sickness and deaths of Alabama citizens. In addition, the staggering rates of prescription opioid abuse and heroin use resulting from Purdue's abdication of its gate-keeping duties has caused harm to the entire community, as set out in previous allegations, which are incorporated herein.

187. The notice provisions of ALA. CODE § 6-5-155.3 are inapplicable here, as the drug related nuisance is not confined to any single property, rather the drug-related nuisance is situated throughout the State of Alabama.

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

189. The State of Alabama requests, pursuant to ALA. CODE § 6-5-155.7, that the Court order the maximum per day civil penalty for each day the nuisance exists.

190. The State of Alabama seeks economic loss (direct, incidental, or consequential pecuniary losses) resulting from Purdue's fraudulent activity and fraudulent misrepresentations.

191. The State of Alabama seeks all legal and equitable relief as allowed by law, including *inter alia* abatement, compensatory damages, and punitive damages, from Purdue for the creation of a drug-related nuisance, attorney fees and costs, and pre- and post-judgment interest, as well as any and all civil remedies specifically enumerated in ALA CODE § 6-5-155.7.

COUNT IV – NEGLIGENCE

192. The State of Alabama incorporates the preceding paragraphs as if fully set forth herein.

193. The State of Alabama seeks economic damages which were the foreseeable result of Purdue's negligent and/or unlawful actions and omissions.

194. Under State law, to establish actionable negligence, one must show in addition to the existence of a duty, a breach of that duty, and injury resulting proximately therefrom and/or that was substantially caused thereby. All such essential elements exist here.

195. In Alabama, the "key factor" for determining whether a duty should be imposed as a matter of law is the "foreseeability" of the harm that might result if care is not exercised. *See also, e.g.*, *Taylor v. Smith*, 892 So.2d 887, 892 (Ala. 2004) (quoting *Key v. Compass Bank, Inc.*, 826 So.2d 159, 170 (Ala. Civ. App. 2001) (in turn quoting *Patrick v. Union State Bank*, 681 So.2d 1364, 1368 (Ala. 1996)).

196. Purdue owed a duty to the State of Alabama, and to the public health and safety in the State of Alabama, because the injury was foreseeable, and in fact foreseen, by Purdue. If a course of action creates a foreseeable risk of injury, the individual engaged in that course of action has a duty to protect others from such injury. Purdue owed a duty to the State of Alabama, and to the public in the State of Alabama, because the injury was foreseeable, and in fact foreseen, by Purdue.

197. In Alabama, a legal duty to "exercise care...arises where the parties are bound by contract, ... or where the obligations are expressly or impliedly imposed by statute, municipal ordinance, or by administrative rules or regulations, or by judicial decisions." *King v. National*

Spa & Pool Institute, 570 So.2d 612, 614 (Ala. 1990) (citations and internal quotation marks omitted).

198. Further, as Section 302B of the Restatement of Torts provides: "An act or an omission may be negligent if the actor realizes or should realize that it involves an unreasonable risk of harm to another through the conduct of the other or a third person which is intended to cause harm, even though such conduct is criminal."

199. Purdue had an obligation to exercise reasonable care in manufacturing, marketing, selling, and distributing highly dangerous opioid drugs to the State of Alabama.

200. Purdue had an obligation to exercise due care in manufacturing, marketing, selling, and distributing highly dangerous opioid drugs in the State of Alabama.

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

202. Reasonably prudent manufacturers of pharmaceutical products would know that aggressively pushing highly addictive opioids for chronic pain would result in the severe harm of addiction, foreseeably causing patients to seek increasing levels of opioids, frequently turning to the illegal drug market as a result of a drug addiction that was foreseeable to Purdue.

203. Moreover, Purdue was repeatedly warned by law enforcement of the unlawfulness and consequences of their actions and omissions.

204. The escalating amounts of addictive drugs flowing through Purdue's business, and the sheer volume of these prescription opioids, further alerted Purdue that addiction was fueling increased consumption and that legitimate medical purposes were not being served.

205. As described elsewhere in the Complaint in allegations expressly incorporated herein, Purdue breached its duties to exercise due care in the business of pharmaceutical manufacturing and distribution of dangerous opioids, which are Schedule II Controlled Substances, and by failing to inform physicians and consumers nature of the drugs and aggressively promoting them for chronic pain for which it knew the drugs were not safe or suitable.

206. Purdue's warnings to prescribing physicians were inadequate and its actions ensured that prescribing physicians were unaware of the risks posed their products, and the prescribing physicians would not have prescribed the products had Purdue informed them of the risks.

207. Purdue breached its duty to prevent diversion and report and halt suspicious orders thereby failing to comply with its legal duties.

208. The causal connection between Purdue's breaches of duties and the ensuing harm was entirely foreseeable and proximately resulted in the damages sought herein.

209. Purdue was selling dangerous drugs statutorily categorized as posing a high potential for abuse and severe dependence. Purdue knowingly traded in drugs that presented a high degree of danger if prescribed incorrectly or diverted to other than medical, scientific, or industrial channels. However, Purdue breached its duties to monitor for, report, and halt suspicious orders, breached its duties to prevent diversion.

210. Purdue's unlawful and/or negligent actions create a rebuttable presumption of negligence under State law.

211. The State of Alabama seeks economic losses (direct, incidental, or consequential pecuniary losses) resulting from Purdue's actions and omissions.

212. The State of Alabama seeks all legal and equitable relief as allowed by law, other than such damages disavowed herein, including *inter alia* injunctive relief, restitution, disgorgement of profits, compensatory and punitive damages, and all damages allowed by law to be paid by Purdue, attorney fees and costs, and pre- and post-judgment interest.

COUNT V - UNJUST ENRICHMENT

213. The State of Alabama incorporates the preceding paragraphs as if fully set forth herein.

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

215. As alleged herein, the State of Alabama has used public funds to reimburse opioid prescriptions covered by the State of Alabama's employee health plan and Medicaid Program. Due to Purdue's deceptive and illegal conduct in promoting opioids to treat chronic pain, the State of Alabama reimbursed prescriptions for opioids for chronic pain that otherwise would not have been written or reimbursed. Further, the State of Alabama has suffered, and continues to cope with, a crisis of opioid addiction, overdose, injury, and death that Purdue helped create and perpetuate.

216. Purdue has reaped revenues and profits from the State of Alabama's payments, enriching itself at the State of Alabama's expense. This enrichment was without justification, and the State of Alabama lacks an adequate remedy provided by law.

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

COUNT VI – WANTONNESS

218. The State of Alabama incorporates the preceding paragraphs as if fully set forth herein.

219. Purdue consciously, recklessly, and willfully failed to inform prescribing physicians and the general public of the addictive nature of prescription opioids and its lack of suitability for chronic pain. Purdue also failed to maintain a system to prevent diversion of its opioids by failing to monitor, report, halt, and divert suspicious orders. Purdue was fully aware these activities and omissions violated applicable laws and breached duties it owed under common law, yet acted consciously, recklessly, and willfully to increase its prescription opioid sales.

220. By engaging in the above-described intentional and/or unlawful acts or practices, Purdue acted with actual malice, wantonly, and oppressively. Purdue acted with conscious disregard to the rights of others and/or in a reckless, wanton, willful, or grossly negligent manner. Purdue acted with a prolonged indifference to the adverse consequences of their actions and/or omissions. Purdue acted with a conscious disregard for the rights and safety of others in a manner that had a great probability of causing substantial harm. Purdue acted toward the State of Alabama with oppression, and/or malice, and/or was grossly negligent in failing to perform the duties and obligations imposed upon it under applicable federal and state statutes, and common law.

221. Purdue was manufacturing and selling dangerous drugs statutorily categorized as posing a high potential for abuse and severe dependence. Thus, Purdue knowingly traded in drugs that presented a high degree of danger if prescribed incorrectly or diverted to other than legitimate medical, scientific, or industrial channels. Because of the severe level of danger posed

by, and indeed visited upon the State of Alabama by, these dangerous drugs, Purdue owed a high duty of care to ensure that these drugs were only used for proper medical purposes. Purdue chose profit over prudence, and the safety of the State of Alabama.

222. By engaging in the above-described wrongful conduct, Purdue also engaged in willful misconduct and gross negligence, and exhibited an entire want of care that would raise the presumption of a conscious indifference to consequences.

223. This heightened-level of misconduct warrants an award of punitive damages, in addition to the compensatory damages and other relief sought herein.

PRAYER FOR RELIEF

WHEREFORE, the State of Alabama prays for judgment against Purdue, as permitted by Alabama law, as follows:

224. For a declaration that Purdue has violated Alabama's Deceptive Trade Practices Act;

225. For injunctions enjoining Purdue from engaging in any acts that violate Alabama's Deceptive Trade Practices Act, including, but not limited to, the unfair and deceptive acts and practices alleged in this Complaint;

226. For restoration of money Purdue obtained from the State, as well as other equitable relief;

227. For civil penalties in the amount of $2,000 for each violation of Alabama's Deceptive Trade Practices Act under ALA. CODE § 8-19-11;

228. For an injunction permanently enjoining Purdue from engaging the acts and practices that caused the public nuisance under ALA CODE § 6-5-155.2;

229. For an order directing Purdue to pay compensatory and punitive damages to the State for its violations of the Deceptive Trade Practices Act, the public nuisance it created, the drug-related nuisance it created, its negligence, gross negligence, and/or negligent misrepresentation.

230. For restitution and/or disgorgement of Purdue's unjust enrichment and ill-gotten gains, plus interest, acquired because of the unlawful or wrongful conduct alleged herein;

231. For expenses, costs, attorneys' fees, and interest thereon; and

232. For all other relief deemed just and proper by the Court.

JURY DEMAND

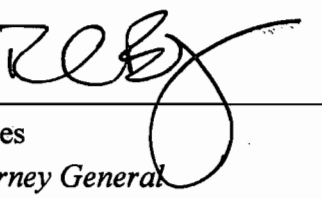
Plaintiff hereby demands a trial by jury on all issues of this cause. Should this action be transferred to MDL 2084, the State reserves the right to seek a remand of any and all issues and claims not resolved in the Transferee Court back to this Court for a jury trial.

Dated this 2nd day of February, 2018.

Respectfully submitted,

Steve Marshall
Attorney General

By:



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