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CIRCUIT COURT OF
MONTGOMERY COUNTY, ALABAMA
GINA J. ISHMAN, CLERK

REDACTED VERSION

IN THE CIRCUIT COURT FOR MONTGOMERY COUNTY, ALABAMA

THE STATE OF ALABAMA,	§	
	§	
Plaintiff,	§	
	§	
v.	§	
	§	
PURDUE PHARMA L.P.; PURDUE PHARMA, INC.; THE PURDUE FREDERICK COMPANY, INC.; RHODES PHARMACEUTICALS, L.P; ENDO HEALTH SOLUTIONS, INC.; ENDO PHARMACEUTICALS, INC.; MCKESSON CORPORATION;	§	**CIVIL ACTION NO.:**
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	§	***TRIAL BY JURY REQUESTED***
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	§	
	§	
Defendants.		

COMPLAINT

The State of Alabama ("Plaintiff") hereby files this complaint against Defendants Purdue Pharma L.P., Purdue Pharma, Inc.; The Purdue Frederick Company, Inc.; Rhodes Pharmaceuticals, L.P. (collectively "Purdue"); Defendants Endo Health Solutions Inc. and Endo Pharmaceuticals, Inc. (collectively "Endo"); and McKesson Corporation ("McKesson"), (collectively "Defendants") in this action. In further support, the State of Alabama alleges as follows:

PRELIMINARY STATEMENT

1. "It is accurate to describe the opioid epidemic as a man-made plague, twenty years in the making. The pain, death, and heartache it has wrought cannot be overstated."[1] As the Director of the Centers for Disease Control and Prevention ("CDC") has noted: "We know of no

[1] *In re: National Prescription Opiate Litigation*, No. 1:17-md-02804-DAH, Doc. 1203, at *38 (N.D. Ohio Dec. 19, 2018).

other medication routinely used for a nonfatal condition that kills patients so frequently."[2]

2. 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 as well as the failure to prevent the diversion of opioids into the State's communities, burdening the State with increasing monetary and societal costs, and fueling an ever-growing crisis in Alabama.

3. 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[.]"[3] The Centers for Disease Control and Prevention ("CDC") declared that "[o]pioid pain medication use presents serious risks, including overdose and opioid use disorder" (a diagnostic term for addiction).[4] Opioids are categorized as Schedule II controlled substances.

4. Alabama's opioid crisis has been, and is still being, fueled by the Defendants which have deceptively and illegally marketed opioids and failed to prevent their diversion into the State of Alabama in order to generate billions of dollars in sales. Defendants include Purdue and Endo ("collectively Manufacturer Defendants"), which are manufacturers of prescription opioids who aggressively advertised to, and persuaded doctors to, prescribe highly addictive, dangerous opioids and turned patients into drug addicts for the Manufacturer Defendants' own profit. Defendants also include McKesson, which is a distributor of these highly addictive drugs who intentionally and/or unlawfully breached its legal duties under federal and state law to monitor,

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

[3] DEA / Drug Scheduling, https://www.dea.gov/drug-scheduling (last visited June 17, 2019).

[4] 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.

detect, investigate, refuse, and report suspicious orders of prescription opioids.

5. As discussed below, the Manufacturer Defendants' 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.[5] As a direct consequence, the rampant use, overuse, and abuse of opioids is devastating both the citizens and the State of Alabama.

6. During the 1990s, the opioid market was small due to physicians prescribing opioids conservatively. 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.

7. Defendants knew, and have known for years, that, except as a last resort, opioids were addictive and subject to abuse – particularly when used long-term for chronic pain. Defendants further knew, and have 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.[6]

8. In order to expand the market for opioids, and thereby increase profits, the Manufacturer Defendants 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.

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

[6] *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).

9. The Manufacturer Defendants 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. The Manufacturer Defendants 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. The Manufacturer Defendants 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 scripted talks, but to draft misleading studies, conduct "continuing medical education programs" (CMEs) that were deceptive and lacked balance, and to 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. The Manufacturer Defendants 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 indeed contrary to, the evidence available to them. The Manufacturer Defendants' promotional claims were dangerously, and too often fatally, false.

12. In truth, roughly one in four patients who receive prescription opioids 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.[7] 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. The Manufacturer Defendants' marketing campaign has been extremely effective for increasing the prescribing, distribution and sale of opioids in Alabama.

14. As a wholesale distributor, McKesson shipped prescription opioids throughout the United States and in Alabama. It is required by law to ensure that these opioids would not be diverted for illicit purposes. McKesson has failed in that duty, however, by disregarding its statutory duty to report, investigate, and halt suspicious orders. As a result, McKesson has oversaturated Alabama's market and contributed to the ongoing crisis.

15. While the Defendants 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.[8]

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[7] 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 June 17, 2019).

[8] 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).

16. 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.[9] Moreover, 6.5% of BlueCross BlueShield of Alabama members were on a long-duration opioid regiment in 2015, compared to 3.8% nationwide.

17. The State of Alabama and its citizens have borne the costs, both in money and heartache, of Defendants' deceptive marketing and failure to prevent diversion of opioids. Defendants' actions combined and concurred in causing Plaintiff's injuries and damages and, as a result, are jointly and severally liable for these damages. Accordingly, the State of Alabama seeks: (a) injunctive relief to stop the Manufacturer Defendants' deceptive marketing; (b) damages for the loss of tax revenue for the State; (c) damages for, and abatement of, the public health epidemic that Defendants have 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 Defendants' conduct; (f) disgorgement of Defendants' 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

A. Plaintiff

18. 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 his constitutional, statutory, and common law authority, including the authority granted to him by

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

ALA. CODE § 36-15-12. The Attorney General further brings this action pursuant to his statutory authority, under ALA. CODE §§ 8-19-1 *et seq.*, to enjoin and penalize violations of the Alabama Deceptive Trade Practices Act.

B. Defendants

a. Manufacturer Defendants

19. The Manufacturer Defendants are defined below. At all relevant times, the Manufacturer Defendants have packaged, distributed, supplied, sold, placed into the stream of commerce, labeled, described, marketed, advertised, promoted, and purported to warn or purported to inform prescribers and users regarding the benefits and risks associated with the use of the prescription opioid drugs. The Manufacturer Defendants, at all times, have manufactured and sold prescription opioids without fulfilling their legal duty to prevent diversion and report suspicious orders.

20. 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."

21. 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).

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

23. Endo develops, markets, and sells prescription drugs, including the opioids Opana/Opana ER, Percodan, Percocet, and Zydone, in the United States. Opioids made up roughly $403 million of Endo's overall revenues of $3 billion in 2012. Opana ER yielded $1.15 billion in revenue from 2010 and 2013, and it accounted for 10% of Endo's total revenue in 2012. Endo also manufactures and sells generic opioids such as oxycodone, oxymorphone, hydromorphone, and hydrocodone products in the United States, by itself and through its subsidiary, Qualitest Pharmaceuticals, Inc. (also known as, *inter alia*, Generics International, Inc., (the U.S. parent)), now part of PAR Pharmaceuticals, a wholly owned subsidiary of Endo.

b. McKesson

24. McKesson Corporation ("McKesson"), is a Delaware corporation engaged in "wholesale distribution" as defined under state and federal law. McKesson has its principal place of business located in San Francisco, California. McKesson operates distribution centers in Alabama, including in McCalla, Alabama.

25. McKesson is engaged in "wholesale distribution," as defined under state and federal law, and it has, at all relevant times, operated as a licensed pharmacy wholesaler in Alabama. At all relevant times, McKesson has distributed, supplied, sold, and placed into the stream of commerce prescription opioids, without fulfilling the fundamental duty of wholesale

drug distributors to detect and warn of the diversion of dangerous drugs for non-medical purposes. Through its inaction, McKesson universally failed to comply with federal and/or state law.

26. McKesson has been investigated and/or fined by the Drug Enforcement Administration ("DEA") for its failure to report suspicious orders. Plaintiff has reason to believe that McKesson has engaged in unlawful conduct which resulted in the diversion of prescription opioids in the State of Alabama.

JURISDICTION AND VENUE

27. This Court has personal jurisdiction over Defendants because they conduct business in the State, purposefully direct or directed their actions toward the State, some or all consented to be sued in the State by registering an agent for service of process, because they consensually submitted to the jurisdiction of the State when obtaining a manufacturer or distributor license, and because they have the requisite minimum contacts with the State necessary to constitutionally permit the Court to exercise jurisdiction.

28. The State brings this action exclusively under Alabama law. No federal claims are being asserted, and to the extent that any claim or factual assertion set forth herein may be construed as to have stated any claim for relief arising under federal law, such claim is expressly and undeniably disavowed.

29. Because the State of Alabama is not a citizen for purposes of diversity jurisdiction, no federal court can exercise subject matter jurisdiction over this case based on diversity of citizenship between the parties.

30. Federal question subject matter jurisdiction pursuant to 28 U.S.C. § 1331 is not invoked by the State or its Complaint, as it exclusively sets forth herein viable state law claims against Defendants. No federal issue is important to the federal system as a whole under the

criteria set by the Supreme Court in *Gunn v. Minton*, 568 U.S. 251 (2013).

31. Specifically, the causes of action asserted, and the remedies sought herein, are founded upon the statutory, common, and decisional laws of the State of Alabama. Accordingly, any exercise of federal jurisdiction is without basis in law or fact. Further, the assertion of federal jurisdiction over the claims made herein would improperly disturb the congressionally approved balance of federal and state responsibilities. To be plain, the State cites federal statutes and federal regulations in its Complaint to define the contours of the duty owed by Defendants under Alabama law, not to allege an independent federal cause of action or to create a substantial federal question. Even where a federal regulation informs some part of the case, that does not convert any state legal cause of action into any federal question, substantial or otherwise, because it is Alabama law, and not any federal authority, that establishes the existence of the duties owed.

32. Venue in Montgomery County is appropriate pursuant to ALA. CODE § 6-3-7 as events giving rise to the causes of action alleged herein occurred in this county, and the Defendants transacted business in this county.

REDACTED VERSION

FACTUAL ALLEGATIONS[10]

I. The Manufacturer Defendants' False, Deceptive, and Unfair Marketing of Opioids

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

33. 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.

34. 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.

35. 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.

36. 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

[10] The allegations in this complaint are made upon information and belief, including upon information immediately available to Plaintiff from the ARCOS database upon their initial and intensive review. Plaintiff reserves the right to seek leave to amend or correct this Complaint based upon further analysis of the ARCOS, IMS, and other data upon further investigation and discovery.

opioids, and from 1999 to 2015, 183,000 deaths involved prescription opioids.[11] Overdose deaths directly correlate with the prescription rates of opioids.[12]

37. Both opioid use disorder and overdose risk are present even when opioids are taken as prescribed.[13] Therefore, the opioid epidemic is not a crisis of abuse – it is a crisis of use.

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

38. Central to the Manufacturer Defendants' marketing efforts is the claim that reliable evidence supports their representations that opioids either relieve pain or improve function when taken long-term for chronic pain and pose little or no risk of addiction. Those claims, however, are unsupported by any evidence.

39. 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,[14] determined that no study exists showing that opioids are effective for outcomes related to pain, function, and quality of life.[15]

40. 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

[11] Rose A. Rudd *et al*., *Increases in Drug and Opioid-Involved Overdose Deaths – United States, 2010 – 2015*, 65 Morbidity and Mortality Weekly Report 1145 (December 30, 2016), https://www.cdc.gov/mmwr/volumes/65/wr/mm655051e1.htm.

[12] *Id*.

[13] 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).

[14] Dowell, *supra* note 4.

[15] *Id*.

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."[16]

41. 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.[17] 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.[18] 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).

42. 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-

[16] Frieden, *supra* note 2.

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

[18] 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).

addicting treatments.[19] Most notably, it stated: "For functional outcomes, the other analgesics were significantly more effective than were opioids."[20] Another review of evidence relating to 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.[21]

43. 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.[22] 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.[23] A prescription for opioids as the first treatment for a workplace injury doubled the average length

[19] 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).

[20] *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 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).

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

[22] 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).

[23] 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).

of the claim.[24]

44. Despite the ever-increasing amount of evidence debunking the Manufacturer Defendants' claims, they continued to market drugs for which there was no evidence of effectiveness.

ii. Evidence confirms that opioids are highly addictive.

45. Opioids are extremely addictive. Studies have found diagnosed addiction rates in primary care settings as high as 26%.[25] Among opioid users who received four prescriptions in a year, 41.3% meet diagnostic criteria for a lifetime opioid-abuse disorder.[26]

46. 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.[27] A patient initially prescribed one month of opioids has a 29.9% chance of still using at one year.[28] In one study, almost 60% of patients who used opioids for 90 days were still using them five years later.[29]

47. Patients first prescribed extended release opioids have significant difficulty in stopping their use. Patients who initiated treatment on an extended release opioid such as

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

[25] Dowell, *supra* note 4.

[26] 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).

[27] 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).

[28] *Id.*

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

OxyContin have a 27.3% likelihood to be using them one year later and a 20.5% likelihood of using them three years later.[30]

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

49. Most patients receiving more than a few weeks of opioid therapy will experience withdrawal symptoms if opioids are discontinued (commonly referred to as "dependence").[31] 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.[32]

50. 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."[33] A patient's fear of the unpleasant effects of discontinuing opioids combined with

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[30] Shah, *supra*.

[31] 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).

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

[33] David Montero, *Actor's Death Sows Doubt Among O.C.'s Recovering Opioid Addicts*, The Orange Cnty. Regi.

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.[34]

51. 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."[35] 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.[36]

52. 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.[37] 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

(Feb. 3, 2014), http://www.ocregister.com/articles/heroin-600148-shaffer-hoffman.html.

[34] *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.").

[35] 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).

[36] Letter from Janet Woodcock, *supra* note 13.

[37] 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.

pain tolerance can, in fact, lead to overdose even where opioids are taken as recommended.[38]

53. 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."[39] It is very difficult to tell whether a patient is physically 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.[40]

54. Studies have shown that between 30% and 40% of long-term users of opioids experience problems with opioid use disorders.[41]

55. Each of these risks and adverse effects – dependence, tolerance, and addiction – is disclosed in the labels for the Manufacturer Defendants' opioids, but not, as described below, in their marketing and outreach.[42]

56. Prior to the Manufacturer 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, the Manufacturer Defendants misled doctors about the addictive nature of prescription opioids and

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

[39] Wilson M. Compton & Nora D. Volkow, *Major Increases in Opioid Analgesic Abuse in the United States: Concerns and Strategies*, 81(2) Drug & Alcohol Dependence 103, 106 (Feb. 1, 2006).

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

[41] 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).

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

its lack of suitability for chronic pain. Thus, were it not for the Manufacturer 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.

57. 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. Purdue's OxyContin 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." 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."[43]

58. 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."[44] The FDA further warned that "[e]ven proper use of opioids under medical supervision can result in life-threatening respiratory depression, coma, and death."[45] 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

[43] 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.

[44] Letter from Janet Woodcock, *supra* note 13.

[45] *Id*.

"should be used ***only when alternative treatments are inadequate***."[46]

59. 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.

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

60. The risk of addiction and negative consequences increases when opioids are administered long-term.[47] In 2013, the FDA noted that the data show that the risk of misuse and abuse is greatest for extended release opioids and observed that these drugs are often used chronically.[48]

61. 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.[49] In fact, a study published in 2015 found that 20% of patients on long-term opioid treatment will develop opioid use disorder.[50]

62. 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.[51] Another study found that higher daily doses and possible opioid misuse were

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

[47] Compton, *supra* note 39.

[48] Letter from Janet Woodcock, *supra* note 13.

[49] 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).

[50] 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).

[51] Dowell, *supra* note 4.

also strong predictors of continued use, and associated with increased risk of overdoses, fractures, dependence, and death.[52]

63. Accordingly, the CDC recommended that physicians carefully reassess increasing opioid doses beyond 50 morphine milligram equivalents (MMEs), and avoid exceeding 90 MMEs/day.[53]

64. 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.[54]

65. 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. Each Manufacturer Defendant Engaged in Deceptive Marketing, Both Branded and Unbranded, that Targeted and Reached Alabama Prescribers.

66. The Manufacturer Defendants, and the Front Groups and KOLs who depended on and worked alongside them, successfully changed the longstanding medical opinion regarding the prescription of opioids. Originally, opioids were prescribed to treat cancer-related pain and for end of life care; however, the Manufacturer Defendants successfully sought to influence and change medical opinion beyond the prescription of opioids for the treatment of long-term treatment for chronic pain, which resulted in the explosion of their use. The Manufacturer Defendants' contributed to this result through a combination of both direct and indirect marketing efforts over which the Manufacturer Defendants exercised editorial control. This deceptive marketing reached

[52] Edlund, *supra*.

[53] Dowell, *supra* note 4.

[54] Frieden, *supra* note 2.

Alabama prescribers and patients with the intent of distorting their views on the risks, benefits, and superiority of opioids for treatment of chronic pain.

a. Purdue

67. 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.[55]

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.

68. 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

[55] Portenoy, *supra* note 6.

about the risk of turning their patients into addicts to prescribe its opioids for chronic pain.

69. 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.

70. 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.

71. 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.

72. 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."[56] 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.

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

i. Purdue Continued to Aggressively and Deceptively Market its Opioids for Chronic Pain Despite Prior Reprimands.

74. 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

[56] 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.

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.

75. The 2007 settlements, however, did not mark a change in Purdue's culture or conduct. Because what doctors told Purdue in the mid-1990s remains true – 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.

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

77. 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.

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

79. 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."[57]

80. 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.

81. 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 citation to the prestigious *New England Journal of Medicine*, but failed to disclose its source was a letter to the editor.[58] 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.[59] A recent analysis in the *Journal* in June 2017 found that citation of

[57] 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.

[58] The letter cited is: Jane Porter & Herschel Jick, M.D., *Addiction Rare in Patients Treated with Narcotics*, 302(2) New Engl. J. Med. 123 (Jan. 10, 1980).

[59] Taylor Haney and Andrea Hsu, *Doctor Who Wrote 1980 Letter on Painkillers Regrets That It Fed The Opioid*

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."[60] It has continued to be widely cited in literature and materials available until the present. As of May 31, 2017, the New England Journal of Medicine added a disclaimer on the online archive of this letter, stating: "For reasons of public health, readers should be aware that this letter has been "heavily and uncritically cited" as evidence that addiction is rare with opioid therapy. Leung et al. describe its history."[61]

82. 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.

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

83. Purdue misrepresented, and continues to misrepresent even to this day, 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,

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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.

[60] *Id.*

[61] Archived at: https://www.nejm.org/doi/full/10.1056/NEJM198001103020221 (last visited June 17, 2019).

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.

84. 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.

85. 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, when used properly, were safe.

86. 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 was still available to Alabama prescribers online until recently.

87. 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.

88. 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.

89. 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."[62]

[62] Patrick R. Keefe, *The Family That Built an Empire of Pain*, The New Yorker (Oct. 30, 2017),

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

90. 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.

91. 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.

92. 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.[63] The CME has been and will continue to be viewed by additional Alabama prescribers.

93. Another Purdue-funded CME, *Chronic Pain Management and Opioid Use: Easing Fears, Managing Risks, and Improving Outcomes*, deceptively instructs doctors that, through the

https://www.newyorker.com/magazine/2017/10/30/the-family-that-built-an-empire-of-pain. (emphasis in original).

[63] 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 June 17, 2019).

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 was, as recently as May 2018, 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.

94. 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 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."

95. Purdue promoted pseudoaddiction through at least 2013 on its website, *Partners Against Pain*.[64]

96. Purdue also sponsored the publication *Responsible Opioid Prescribing* (2007),

[64] *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."

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.

97. 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.

98. 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.

99. 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.

100. 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.[65] 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.

101. 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 heroin."[66] Studies have shown that at least 8-12%, and as many as 30-40%, of long-term users of opioids experience problems with addiction.

102. Purdue's own evidence bears that out.

103. 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."[67] The CDC also emphasized that "continuing opioid therapy for 3 months substantially increases risk for opioid use disorder."[68]

104. 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

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[65] 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 June 17, 2019).

[66] Frieden, *supra* note 2.

[67] Dowell, *supra* note 4, at 2.

[68] *Id.* at 21.

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.

105. 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 misuse" and counsels that doctors "should not overestimate the ability of these tools to rule out risks from long-term opioid therapy."[69]

106. 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."[70]

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

107. 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.

[69] Dowell, *supra* note 4, at 28.

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

But as the CDC Guideline makes clear, there is "*insufficient evidence* to determine the long-term benefits of opioid therapy for chronic pain."[71] 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.[72] 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 . . . ."[73] As a result, the CDC recommends that 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.

108. 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.

109. 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.

[71] *Id.* at 10.

[72] *Id.* at 9.

[73] Frieden, *supra* note 2.

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.

110. 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.

111. 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.

112. 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.

113. 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]."[74] 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."[75] 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.[76]

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

114. 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'

[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).

[75] *Id.*

[76] 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.

function and quality of life and get them back to work and to their lives.

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

116. 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.

117. 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.

118. 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."[77] 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.

119. 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"[78] and advised that "there is no good evidence that opioids improve pain or function with long-term use."[79] Similarly, the FDA has warned other opioid product manufacturers that claims of improved function and quality of life were misleading.[80] The CDC also noted that the risks of addiction and death "can cause distress and inability to fulfill major role obligations."[81] Along those lines, a 2017 study by Princeton

[77] 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

[78] Dowell, *supra* note 4, at 15.

[79] *Id.* at 20.

[80] *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.

[81] Dowell, *supra* note 4, at 2.

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.[82]

120. 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."[83] 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]."[84]

c. Omitting or mischaracterizing adverse effects of opioids.

121. 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.

122. 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

[82] 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).

[83] Dowell, *supra* note 4, at 18.

[84] Frieden, *supra* note 2.

(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.

123. 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.

124. 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.

125. 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.[85] 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.[86]

[85] Noble, *supra* note 21.

[86] Frieden, *supra* note 2.

126. 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 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%.[87]

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

127. 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.

128. 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.

129. *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.

130. 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

[87] 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.

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.

131. 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.[88]

132. The CDC Guideline concludes that the "[b]enefits of high-dose opioids for chronic pain are not established"[89] while "[o]verdose risk increases in a dose-response manner . . . ."[90] That is why the CDC advises doctors to "avoid increasing doses" above 90 mg MED.[91]

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

133. 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

[88] Dunn, *supra* note 37. Most overdoses were medically serious and 12% were fatal.

[89] Dowell, *supra* note 4, 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."

[90] *Id*.

[91] *Id*. at 16.

disclose that OxyContin fails to provide 12 hours of pain relief to many patients.

134. 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 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.

135. 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.

136. 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.

137. 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."[92] 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.

138. 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.

139. 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.

[92] 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/.

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

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

141. 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.

142. A purported Abuse Deterrent Formula ("ADF") of OxyContin was passed through the FDA New Drug Application process in April 2010, but it was not until 2013 that the FDA, in response to a Citizen Petition filed by Purdue, permitted some reference to the abuse-deterrent properties in the label, with some caveats. When Purdue launched Hysingla ER, extended-release hydrocodone, in 2014, the product included similar abuse-deterrent properties.

143. 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.

144. Nevertheless, Purdue's national marketing campaign touted OxyContin's tamper-resistant properties as a primary message.[93]

145. 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,"[94] and, in fact, is still regularly tampered with and abused.

146. 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.

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

[94] *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.

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.

147. *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.

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

149. 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."[95] 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.[96] 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.

150. 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

[95] Dowell, *supra* note 4, at 22 (emphasis added).

[96] 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.

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

151. Purdue itself knew that claiming ADF formulations reduce abuse was not supported by evidence.

152. 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 their 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."[97] 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.

153. 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

[97] 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.

opioids did not carry that risk.

154. 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 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.

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

156. 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.

b. Endo

157. Endo marketed its opioids utilizing a wide array of marketing methods. It deployed its sales representatives, paid physician speakers, journal supplements, and advertising in support of its branded opioids, principally Opana and Opana ER. These deceptive messages addressed functional improvement, addiction risk, pseudoaddiction, addiction screening tools, and the safety of alternatives to opioids.

158. Simultaneously, Endo utilized third-party partners to promote its products through a combination of CMEs, websites, patient education pamphlets, and other publications. These materials echoed the misrepresentations described above, and also made deceptive statements

about withdrawal symptoms and the safety of opioids at higher doses.

159. Like Purdue, Endo engaged in the deceptive marketing of its opioids with the intent that Alabama prescribers and/or consumers would rely on them in choosing to use Endo's opioids to treat chronic pain.

i. Endo's Sales Force and Deceptive Sales Training

160. Endo's promotion of Opana ER relied heavily on in-person marketing, including marketing to Alabama prescribers. Endo had an aggressive detailing program, with its sales representatives making nearly 72,000 visits to prescribers nationwide to detail Opana ER in the first quarter of 2010 alone. Between 2007 and 2014, Endo spent between $3 million and $10 million each quarter promoting opioids through its sales force.

161. Endo's sales representatives, like those of Purdue, targeted physicians to deliver sales messages that were developed centrally and deployed uniformly across the country. These sales representatives were critical in transmitting Endo's marketing strategies and talking points to individual prescribers.

162. Endo directed its sales force to target physicians who would prescribe its drugs to treat chronic pain. For example, an Opana Brand Tactical Plan dated August 2007 aimed to increase "Opana ER business from [the Primary Care Physician] community" more than 45% by the end of that year. Indeed, Endo sought to develop strategies that would be most persuasive to primary care doctors—strategies that sought to influence the prescribing behavior of primary care physicians through the use of subject matter experts. A February 2011 Final Report on Opana ER Growth Trends, for example, predicted that Endo's planned "[u]se of Pain Specialists as local thought leaders should affect increased primary care adoption."

163. Endo trained its sales force to make a number of misrepresentations to physicians

nationwide, including physicians in Alabama. Endo's sales representatives were trained to represent to these prescribers that Opana ER would help patients regain function they had lost to chronic pain; that Endo's opioids had a lower potential for abuse because they were "designed to be crush resistant," even though the "clinical significance of INTAC Technology or its impact on abuse/misuse has not been established for Opana ER;" and that drug seeking behavior was a sign of undertreated pain rather than addiction.

164. Endo knew that its marketing reached physicians because it tracked their exposure. Internal documents dated August 23, 2006, show that the following percentages of physicians would view an Endo journal insert (or paid supplement) at least three times in an eight-month period: 86% of neurologists; 86% of rheumatologists; 85% of oncologists; 85% of anesthesiologists; 70% of targeted primary care physicians; and 76% of OBGYNs.

165. Further, Endo found that its promotional materials tripled prescribers' ability to recall the sales messages and doubled their willingness to prescribe Opana ER in the future. This was true of marketing that contained its deceptions. For example, according to internal documents, up to 10% of physicians Endo detailed were able to recall without assistance the message that Opana ER had "Minimal/less abuse/misuse" potential than other drugs. The Endo message that prescribers retained was a plain misrepresentation: that use of Opana ER was unlikely to lead to abuse and addiction. Although Opana ER has always been classified as a Schedule II drug with a "high potential for abuse," the largest single perceived advantage of Opana ER, according to a survey of 187 physicians who reported familiarity with the drug was "perceived low abuse potential," which 15% of doctors cited as an advantage.

166. Endo's own internal documents, however, acknowledged the misleading nature of these statements, conceding that "Opana ER has an abuse liability similar to other opioid

analgesics as stated in the [FDA-mandated] box warning."

167. Nevertheless, Endo knew that its marketing was extremely effective in turning physicians into prescribers. Nationally, the physicians Endo targeted for in-person marketing represented approximately 84% of all prescriptions for Opana ER in the first quarter of 2010. Endo also observed that the prescribers its sales representatives visited wrote nearly three times as many prescriptions per month for Opana ER as those physicians who were not targeted for Endo's marketing—7.4 prescriptions per month versus 2.5. The most heavily targeted prescribers wrote nearly 30 prescriptions per month. Internal Endo documents from May 2008 indicate that Endo expected that each of its sales representatives would generate 19.6 prescriptions per week by the end of 2008. As summarized by a February 2011 report on Opana ER growth trends, Endo's "[a]ggressive detailing [is] having an impact."

168. Broadly put, Endo's sales training and marketing plans demonstrate that its sales force was trained to provide prescribers with misleading information regarding the risks of opioids when used to treat chronic pain. Foremost among these messages were misleading claims that the risks of addiction, diversion, and abuse were low, and that the risks for Opana ER were certainly lower than the risks posed by other opioids.

ii. Endo's Misrepresentations Regarding the Risk of Addiction.

169. Until 2012, Endo's website for Opana ER, www.opana.com, stated that "[m]ost healthcare providers who treat patients with pain agree that patients treated with prolonged opioid medicines usually do not become addicted."

170. Upon information and belief, Endo improperly instructed its sales representatives to diminish and distort the risk of addiction associated with Opana ER. In 2011, Endo's training materials for its sales representatives also prompted sales representatives to answer "true" to the

statement that addiction to opioids is not common.

171. One of the Front Groups with which Endo worked most closely was the American Pain Foundation ("APF"), which is described more fully below. Endo provided substantial assistance to, and exercised editorial control over, the deceptive and misleading messages that APF conveyed through its National Initiative on Pain Control ("NIPC"), as well as its website Painknowledge.com, which claimed that "[p]eople who take opioids as prescribed usually do not become addicted."[98]

172. Another Endo website, *PainAction.com*, stated: "Did you know? Most chronic pain patients do not become addicted to the opioid medications that are prescribed for them."

173. In a brochure available on *Painknowledge.com* titled "*Pain: Opioid Facts*," Endo-sponsored NIPC stated that "people who have no history of drug abuse, including tobacco, and use their opioid medication as directed will probably not become addicted." In numerous patient education pamphlets, Endo repeated this deceptive message:

> In a patient education pamphlet titled "*Understanding Your Pain: Taking Oral Opioid Analgesics*," Endo answers the hypothetical patient question – "What should I know about opioids and addiction?" – by focusing on explaining what addiction is ("a chronic brain disease") and is not ("Taking opioids for pain relief"). It goes on to explain that "[a]ddicts take opioids for other reasons, such as unbearable emotional problems. Taking opioids as prescribed for pain relief is not addiction."

174. An Endo publication, *Living with Someone with Chronic Pain*, stated, "Most health care providers who treat people with pain agree that most people do not develop an addiction

[98] Endo was one of the APF's biggest financial supporters, providing more than half of the $10 million it received from opioid manufacturers during its lifespan. Endo was the sole funder of the NIPC and selected APF to manage NIPC. Internal Endo documents indicate that Endo was responsible for NIPC curriculum development, web posting, and workshops, developed and reviewed NIPC content, and took a substantial role in distributing NIPC and APF materials. Endo projected that it would be able to reach tens of thousands of prescribers nationwide through the distribution of NIPC materials.

problem." A similar statement appeared on the Endo website, www.opana.com, until at least April 2012.

175. In addition, a 2009 patient education publication, *Pain: Opioid Therapy*, funded by Endo and posted on *Painknowledge.com*, omitted addiction from the "common risks" of opioids.

iii. Endo's Deceptive Marketing of Opana ER

176. Similar to Purdue, Endo sought to make abuse-deterrence a key to its marketing strategy as the expiration of its patent exclusivity for Opana ER neared. By July 2011, Endo knew that "some newer statistics around abuse and diversion are not favorable to our product."

177. In December 2011, Endo obtained approval for a new formulation of Opana ER that added a hard coating that the company claimed made it crush-resistant. Even prior to its approval, the FDA advised Endo that it could not market the new Opana ER as abuse-deterrent, finding that such promotional claims "may provide a false sense of security since the product may be chewed and ground for subsequent abuse." In other words, Opana ER was still crushable. Indeed, Endo's own studies from 2009 and 2010 showed that Opana ER could still be crushed and ground, and, in correspondence with the FDA, Endo admitted that "[i]t has not been established that this new formulation of Opana ER is less subject to misuse, abuse, diversion, overdose, or addiction."

178. Further, a January 4, 2011, FDA Discipline Review letter made clear to Endo that:

> "[t]he totality of these claims and presentations suggest that, as a result of its new formulation, Opana ER offers a therapeutic advantage over the original formulation when this has not been demonstrated by substantial evidence or substantial clinical experience. In addition, these claims misleadingly minimize the risks associated with Opana ER by suggesting that the new formulation's '"INTAC'" technology confers some form of abuse-deterrence properties when this has not been demonstrated by substantial evidence."

The FDA acknowledged that there is "evidence to support some limited improvement" provided

by the new coating, but it would not let Endo promote any benefit because "there are several limitations to this data." Also, Endo was required to add language to its label specifically indicating that "Opana ER tablets may be abused by crushing, chewing, snorting, or injecting the product. These practices will result in less controlled delivery of the opioid and pose a significant risk to the abuse that could result in overdose and death."

179. The FDA expressed similar concerns, using nearly identical language, in a May 7, 2012, letter to Endo responding to a February 2, 2012, "request … for comments on a launch Draft Professional Detail Aid … for Opana ER." The FDA's May 2012 letter also includes a full two pages of comments regarding "Omissions of material facts" that Endo left out of the promotional materials.

180. Endo consciously chose not to do any post-approval studies that might have satisfied the FDA. According to internal documents, the company decided, by the time its studies would be done, generics would be on the market and "any advantages for commercials will have disappeared." However, this lack of evidence did not deter Endo from marketing Opana ER as ADF while its commercial window remained open.

181. Nonetheless, in August of 2012, Endo submitted a citizen petition asking the FDA for permission to change its label to indicate that Opana ER was abuse-resistant, both in that it was less able to be crushed and snorted and that it was resistant to injection by syringe. Similar to Purdue, Endo announced it would withdraw the original Opana ER formulation from the market and sought a determination that its decision was made for safety reasons which would prevent generic copies of original Opana ER.

182. Endo then sued the FDA, seeking to force expedited consideration of its citizen petition. The court filings confirmed Endo's true motives: in a declaration submitted with its

lawsuit, Endo's chief operating officer indicated that a generic version of Opana ER would decrease the company's revenue by up to $135 million per year. Endo also claimed that if the FDA did not block generic competition, $125 million, which Endo spent on developing the reformulated drug to "promote the public welfare" would be lost. The FDA responded that: "Endo's true interest in expedited FDA consideration stems from business concerns rather than the protection of the public health."[99]

183. Despite Endo's purported concern with public safety, it not only continued to distribute original, admittedly unsafe Opana ER for nine months after the reformulated version became available, but it also declined to recall original Opana ER despite the dangers Endo knew it presented. In fact, Endo claimed in September 2012 to be "proud" that "almost all remaining inventory" of the original Opana ER had "been utilized."[100]

184. In its citizen petition, Endo asserted that redesigned Opana ER had "safety advantages." Endo even relied on its rejected assertion that Opana ER was less crushable to argue that it developed Opana ER for patient safety reasons and that the new formulation would help, for example, "where children unintentionally chew the tablets prior to an accidental ingestion."[101]

185. However, in rejecting the petition in a 2013 decision, the FDA found that "study data show that the reformulated version's extended-release features can be compromised when subjected to … cutting, grinding, or chewing." Also troubling, the FDA noted that Opana ER could be "readily prepared for injections and more easily injected." In fact, the FDA warned the

[99] Defendants' Response to the Court's November 30, 2012 Order, *Endo Pharmaceuticals, Inc. v. U.S. Food and Drug Administration, et al.*, No. 1:12-cv-01936, Doc. 9 at 6 (D.D.C. Dec. 3, 2012).

[100] *Id*.; Endo News Release, Sept. 6, 2012 *Endo Pharmaceuticals, Inc. v. U.S. Food and Drug Administration, et al.*, No. 1:12-cv-01936, Doc. 18-4 (D.D.C. Dec. 9 2012).

[101] CP, FDA Docket 2012-8-0895, at 2.

preliminary data, including Endo's own studies, suggested that a higher percentage of reformulated Opana ER abuse is via injection than was the case with the original formulation.

186. Meanwhile, in 2012, an internal memorandum to Endo account executives noted that abuse of Opana ER had "increased significantly" in the wake of the purportedly abuse-deterrent formulation. In February 2013, Endo received abuse data regarding Opana ER from Inflexxion, Inc., which gathers information from substance abusers entering treatment and reviews abuse-focused internet discussions, which confirmed continued abuse, particularly by injection.

187. In 2009, only 3% of Opana ER abuse was by intravenous means. Since the reformulation, injection of Opana ER increased by more than 500%. Endo's own data, presented in 2014, found between October 2012 and March 2014, 64% of abusers of Opana ER did so by injection, compared with 36% for the old formulation.[102] The transition into injection of Opana ER made the drug even less safe than the original formulation because injection carries risks of HIV, Hepatitis C, and, in reformulated Opana ER's specific case, the blood-clotting disorder thrombotic thrombocytopenic purpura (TTP), which can cause kidney failure.

188. Despite its knowledge that Opana ER was widely abused and injected, Endo marketed the drug as tamper-resistant and abuse-deterrent. Upon information and belief, based on the company's detailing elsewhere, Endo sales representatives informed doctors that Opana ER was abuse-deterrent, could not be tampered with, and was safe. In addition, sales representatives did not disclose evidence that Opana ER was easier to abuse intravenously and, if pressed by prescribers, claimed that while outlier patients might find a way to abuse the drug, most would be protected.

[102] Theresa Cassity, *The Changing Abuse Ecology: Implications for Evaluating the Abuse Pattern of Extended-Release Oxymorphone and Abuse-Deterrent Opioid Formulations*, Pain Week Abstract 2014, available at: https://ibhsolutions.com/blog/changing-abuse-ecology-extended-release-oxymorphone. (last visited June 17, 2019).

189. A review of national surveys of prescribers regarding their "take-aways" from pharmaceutical detailing confirms that prescribers remember being told Opana ER was tamper-resistant. Endo also tracked messages that doctors took from its in-person marketing. Among the advantages of Opana ER, according to participating doctors, was its "low abuse potential." An internal Endo Document also notes that market research showed that, "[l]ow abuse potential continues as the primary factor influencing physicians' anticipated increase in use of Opana ER over the next 6 months."

190. In its written materials, Endo marketed Opana ER has having been designed to be crush-resistant, knowing that this would (falsely) imply that Opana ER actually was crush-resistant and that this implied crush-resistant quality would make Opana ER less likely to be abused. For example, a June 14, 2012 Endo press release announced, "the completion of the company's transition of its Opana ER franchise to the new formulation designed to be crush resistant."

191. The press release further stated that: "We firmly believe that the new formulation of Opana ER, coupled with our long-term commitment to awareness and education around appropriate use of opioids will benefit patients, physicians, and payers." The press release described the old formulation of Opana ER as subject to abuse and misuse but failed to disclose the absence of evidence that reformulation Opana ER was any better. In September 2012, another Endo press release stressed that reformulated Opana ER employed "INTAC Technology" and continued to describe the drug as "designed to be crush-resistant."

192. Similarly, journal advertisements that appeared in April 2013 stated Opana ER was "designed to be crush resistant." A January 2013 article in Pain Medicine News, based in part on an Endo press release, described Opana ER as "crush resistant." This article was posted on the *Pain Medicine News* website, which was accessible to patients and prescribers.

193. Endo, upon information and belief, targeted particular geographies for the redesigned Opana ER where abuse was most rampant.

194. In March 2017, an FDA advisory committee recommended that Opana be withdrawn from the market after being linked to outbreaks of HIV and TTP. The FDA adopted this recommendation on June 8, 2017.[103] Endo announced on July 6, 2017, that it would agree to stop marketing and selling Opana ER.[104] The damage, however, had already been done. Even then, Endo continued to insist, falsely, that it "has taken significant steps over the years to combat misuse and abuse."

iv. Endo's Misrepresentations about the Risks and Benefits of Opioids

195. Endo further misled patients and prescribers by downplaying the risk of opioids in comparison to other pain relievers. For example, it distributed nationally a presentation titled *Case Challenges in Pain Management: Opioid Therapy for Chronic Pain*. This study held out as a representative example one patient who had taken NSAIDs for more than eight years and, as a result, developed a "massive upper gastrointestinal bleed." The presentation recommended treating this patient with opioids instead. By focusing on the adverse side effects of NSAIDs, while omitting discussion of serious side effects associated with opioids, this presentation misleadingly portrayed the comparative risks and benefits of these drugs.

196. Endo distributed *Case Challenges in Pain Management: Opioid Therapy for Chronic Pain* to 116,000 prescribers in 2007, including primary care physicians.

iv. Endo's Misrepresentations that Chronic Opioid Therapy Would Improve Patients' Ability to Function.

[103] Press Release, "FDA requests removal of Opana ER for risks related to abuse," June 8, 2017, available at https://www.fda.gov/news-events/press-announcements/fda-requests-removal-opana-er-risks-related-abuse. (last visited June 17, 2019).

[104] Press Release, "Endo Provides Update on Opana ER," July 6, 2017, available at: http://investor.endo.com/news-releases/news-release-details/endo-provides-update-opanar-er. (last visited June 17, 2019).

197. In addition to their deceptive messages regarding addiction, Endo's promotional materials and sales trainings also misleadingly claimed that patients using opioids for the long-term treatment of chronic pain would experience improvements in their daily function. In reality, long-term opioid use has not been shown to and does not improve patients' function, and in fact, often is accompanied by serious side effects that degrade function. Endo's own internal documents acknowledged that claims about improved quality of life were unsubstantiated "off label claims."

198. Nevertheless, Endo distributed product advertisements that suggested that using Opana ER to treat chronic pain would allow patients to perform demanding tasks like work as a chef. One such advertisement states prominently on the front: "Janice is a 46-year-old chef with chronic low back pain. She needs a treatment option with true 12-hour dosing." The advertisement does not mention the "moderate to severe pain" qualification in Opana ER's indication, except in the fine print. These advertisements were mailed to prescribers and distributed by Endo's sales force in detailing visits which would have included visits to prescribers in Alabama.

199. In a 2007 Sales Tool that was intended to be shown by Endo sales personnel to physicians during their detailing visits, Endo highlighted a hypothetical patient named "Bill," a 40-year-old construction worker who was reported to suffer from chronic low back pain. According to the Sales Tool, Opana ER will make it more likely that Bill can return to work and support his family.

200. A sales training video dated March 8, 2012, which Endo produced and used to train its sales force makes the same types of claims. A patient named "Jeffrey" explains in the video that he suffers from chronic pain and that "chronic pain […] reduces your functional level." Jeffrey claims that after taking Opana ER, he "can go out and do things" like attend his son's basketball games and "[t]here's no substitute for that." This video was shown to Endo's sales force, which

adopted its misleading messaging in its nationwide sales approach, including the approach used in Alabama.

201. Claims of improved functionality were central to Endo's marketing efforts for years. A 2012 Endo Business Plan lists ways to better position Opana ER in the market, and among them is the claim that Opana ER will help patients "[m]aintain[] normal functionality, sleep, [and] work/life/performance productivity" and have a positive "[e]ffect on social relationships." Indeed, that business plan describes the "Opana ER Vision" as "[t]o make the Opana franchise (Opana ER, Opana, Opana Injection) the choice that maximizes improvement in functionality and freedom from the burden of moderate-to-severe pain."

vi. Endo's Use of Third Parties to Advance its Deceptive Marketing.

202. In addition to engaging in deceptive direct marketing, Endo sought to enlist the support of third party group advocacy groups and professional organizations to promote the sale of its opioids.

a. **The APF**

203. As explained above, Endo worked closely with the APF. It provided substantial assistance to, and exercised editorial control over, the deceptive and misleading messages that APF conveyed through its NIPC. In 2008 alone, Endo spent $1.1 million on the NIPC program, funding earmarked, in part, for the creation of the CME materials that were intended to be used over and over again.

204. Endo's influence over APF's activities was so pervasive that APF President Will Rowe even reached out to the Defendants, including Endo, rather than his own staff to identify potential authors to answer an article critical of opioids that appeared in the *Archive of Internal Medicine* in 2011. Personnel from multiple opioid manufacturers, including Purdue and Endo,

worked with Rowe to formulate APF's response. The response suggested by the Manufacturer Defendants was the one that APF ultimately published.

205. Documents also indicate that Endo personnel were given advance notice of materials APF planned to publish on its website and provided an opportunity to comment on the content of those materials before they were published. For example, in early July 2009, APF's Director of Strategic Development wrote to Endo personnel to give them advance notice of content that APF planned to be "putting…up on the website but it's not up yet." This Endo employee also reassured the sender that she "will not forward it to anyone at all" and promised that she would "'double delete' from [her] inbox." In response, APF's Director of Strategic Development replied internally with only four words: "And where's the money?"

206. Endo's sponsorship of NIPC was the strongest relationship it had with APF. An August 2009 document titled "A Proposal for the American Pain Foundation to Assume Sponsorship of the National Initiative on Pain Control," pointed out that "[f]or the past 9 years, the NIPC has been supported by unrestricted annual grants from Endo Pharmaceuticals, Inc." According to this document, APF's sponsorship of the NIPC "[o]ffers the APF a likely opportunity to generate new revenue, as Endo has earmarked substantial funding: $1.2 million in net revenue for 2010 to continue the NIPC." Further, sponsorship of the APF would "[p]rovide[] numerous synergies to disseminate patient education materials," including "[h]andouts to attendees at all live events to encourage physicians to drive their patients to a trusted source for pain education – the APF website."

207. Internal Endo scheduling documents indicate that "NIPC module curriculum development, web posting, and live regional interactive workshops" were Endo promotional tasks in 2010. Endo emails further indicate that Endo personnel reviewed the content created by NIPC

and provided feedback.

208. Behind the scenes, Endo exercised substantial control over NIPC's work. Endo exerted its control over NIPC by funding NIPC and APF projects; developing, specifying, and reviewing content; and taking a substantial role in distribution of NIPC and APF materials, which, in effect, determined which messages were actually delivered to prescribers and consumers. Endo projected that it would be able to reach tens of thousands of prescribers nationwide through the distribution of NIPC materials.

209. Endo worked diligently to ensure that the NIPC materials it helped to develop would have the broadest possible distribution. Endo's 2008 to 2012 Opana Brand Tactical Plan indicates that it sought to reach 1,000 prescribers in 2008 through live NIPC events, and also to "[l]everage live programs via enduring materials and web posting." Endo also planned to disseminate NIPC's work by distributing two accredited newsletters to 60,000 doctors nationwide for continuing education credit and sponsoring a series of 18 NIPC regional case-based interactive workshops.

210. In sum, NIPC was a centerpiece of Endo's marketing strategy. Indeed, internal APF emails question whether it was worthwhile for APF to continue operating NIPC given the NIPC's work was producing far more financial benefit for Endo than for APF. APF's commitment to NIPC's "educational" mission did not figure at all in APF's consideration of the value of its work, nor was Endo's motive or benefit in doubt.

b. Misleading Medical Education.

211. NIPC distributed a series of eNewsletter CMEs focused on "key topic[s] surrounding the use of opioid therapy" and sponsored by Endo. These newsletters were edited by KOL Dr. Perry Fine and also listed several industry-backed KOLs, including Dr. Webster, as

individual authors. Endo estimated that approximately 60,000 prescribers viewed each newsletter, all of which were available to and would have included prescribers in the State of Alabama. Before-and-after surveys showed that prescriber comfort with prescribing opioids ranged from 27% to 62% before exposure to the CME, and from 76% to 92% afterwards.

212. Endo documents made clear that the persuasive power of NIPC speakers was directly proportional to their perceived objectivity. Accordingly, Endo personnel directed that, when giving Endo-sponsored talks, NIPC faculty would not appear to be "Endo Speakers." Nevertheless, the two parties understood that Endo and NIPC shared a common "mission to educate physicians" and working "through the APF … [wa]s a great way to work out…problems that could have been there without the APF's participation and support."

213. The materials made available on and through NIPC included misrepresentations. For example, Endo worked with NIPC to sponsor a series of CMEs titled *Persistent Pain in the Older Patient* and *Persistent Pain in the Older Adult.* These CMEs misrepresented the prevalence of addiction by stating that opioids have "possibly less potential for abuse" in elderly patients than in younger patients, even though there is no evidence to support such an assertion. Moreover, whereas withdrawal symptoms are always a factor in discontinuing long-term opioid therapy, *Persistent Pain in the Older Adult* also misleadingly indicated that such symptoms can be avoided entirely by tapering the patient's doses by 10-20% per day for ten days. *Persistent Pain in the Older Patient*, for its part, made misleading claims that opioid therapy has been "shown to reduce pain and improve depressive symptoms and cognitive functioning." NIPC webcast these CMEs from its own website, where they were available to, and were intended to reach, Alabama prescribers.

c. Painknowledge.com

214. Endo also made a number of misleading statements through the NIPC's website, painknowledge.com. Endo tracked visitors to the website and used it to broadcast notifications about additional NIPC programming Endo helped to create.

215. APF made a grant request to Endo to create an online opioid "tool-kit" for NIPC and to promote NIPC's website, painknowledge.com. In doing so, APF made clear that it planned to disseminate Defendants' misleading advertising. The grant request expressly indicated APF's intent to make misleading claims about functionality, noting: "Some of these people [in chronic pain] may be potential candidates for opioid analgesics, which can improve pain, function, and quality of life." Endo provided $747,517 to fund the project.

216. True to APF's word, painknowledge.com misrepresented that opioid therapy for chronic pain would lead to improvements in patients' ability to function. Specifically, in 2009 the website instructed patients and prescribers that, with opioids, a patient's "level of function should improve" and that patients "may find [they] are now able to participate in activities of daily living, such as work and hobbies, that [they] were not able to enjoy when [their] pain was worse."

217. As explained above, painknowledge.com also deceptively minimized the risk of addiction by claiming that [p]eople who take opioids as prescribed usually do not become addicted." Even worse, the website deceptively portrayed opioids as safe at high doses and also misleadingly omitted serious risks, including the risks of addiction and death, from its description of the risks associated with the use of opioids to treat chronic pain.

218. Endo was the sole funder of painknowledge.com, and it continued providing funding even though it was aware of the website's misleading contents.

REDACTED VERSION

d. Key Opinion Leaders and Misleading Science

219. Similar to Purdue, Endo used key opinion leaders and misleading science to promote using opioids to treat chronic pain.

220. Endo's 2010 publication plan for Opana ER identified a corporate goal of making Opana ER the second-leading branded product for the treatment of moderate-to-severe chronic pain (after OxyContin). Endo sought to achieve this goal by providing "clinical evidence for the use of Opana ER in chronic low back pain and osteoarthritis," and it succeeded in having articles published on this topic.[105]

221. Endo's reliance on flawed, biased research is also evident in its 2012 marketing materials and strategic plans. A 2012 Opana ER slide deck for Endo's speakers' bureaus, on which these recruited physician speakers were trained and to which they were required to adhere, misrepresented that the drug had low abuse potential and suggested that as many as 25% of the adult population could be candidates for opioid therapy. Although the FDA requires such speaker slide decks to reflect a fair balancing of information on benefits and risks, Endo's slides reflected one-sided and deeply biased information. The presentation's 28 literature citations were largely to "data on file" with the company, posters, and research funded by or otherwise connected to Endo. Endo's speakers carried the information in these slides to audiences that were unaware of the skewed science on which the information was based.

222. A 2012 Opana ER Strategic Platform Review suffered from similar defects. Only a small number of the endnote references in that document, which it cites to indicate "no gap" in

[105] These studies suffered from the same limitations common to the opioid literature. None of the comparison trials lasted longer than three weeks. Endo also commissioned a six-month, open label trial during which a full quarter of the patients failed to find a stable dose, and 17% of patients discontinued, citing intolerable effects. In open label trials, subjects know which drug they are taking; such trials are not as rigorous as double-blind, controlled studies in which neither the patients nor the examiners know which drugs the patients are taking.

scientific evidence for particular claims, were to national-level journals. Many were published in lesser or dated journals, and written or directly financially supported by opioid manufacturers. Where the strategy document did cite independent, peer-reviewed research, it did so out of context. For example, it cited a 2008 review article on opioid efficacy for several claims, including that "treatment of chronic pain reduces pain and improves functionality," but it ignores that article's overall focus on "the lack of consistent effectiveness of opioids in reducing pain and improving functional status."[106]

223. Notwithstanding Endo's reliance upon dubious or cherry-picked science, in an Opana ER brand strategy plan, it internally acknowledged the continuing need for a significant investment in clinical data to support comparative effectiveness. Endo also cited a lack of "head-to-head data" as a barrier to greater share acquisition and the "lack of differential data" as a challenge to addressing the "#1 Key Issue" of product differentiation. Nor did this acknowledged lack of support stop Endo from directing its sales representatives to tell prescribers that its drugs were less likely to be abused or less addictive than other opioids.

224. Endo also worked with various KOLs to disseminate various misleading statements about chronic opioid therapy. For example, Endo distributed a patient education pamphlet edited by KOL Dr. Russell Portenoy titled *Understanding Your Pain: Taking Oral Opioid Analgesics*. This pamphlet deceptively minimized the risks of addiction by stating that "[a]ddicts take opioids for other reasons [besides pain relief], such as unbearable emotional problems," implying that patients who are taking opioids for pain are not at risk of addiction.

[106] Andrea M. Trescot, *et al.*, *Opioids in the management of non-cancer pain: an update of American Society of the International Pain Physicians*, Pain Physicians 2008 Opioids Special Issue, S5-S2.

225. *Understanding Your Pain: Taking Oral Opioid Analgesics* also misleadingly omitted any description of the increased risks posed by higher doses of opioid medication. Instead, in a Q&A format, the pamphlet asked "[i]f I take the opioid now, will it work later when I really need it?" and responded that "[t]he dose can be increased…[y]ou won't 'run out' of pain relief."

226. Dr. Portenoy received research support, consulting fees, and honoraria from Endo for editing *Understanding Your Pain* and other projects.

227. Endo similarly distributed a book written by Dr. Lynn Webster titled *Avoiding Opioid Abuse While Managing Pain*, which stated that in the face of signs of aberrant behavior, increasing the dose "in most cases … should be the clinician's first response."

228. A slide from an Opana ER business plan contemplated distribution of the book as part of Endo's efforts to "[i]ncrease the breadth and depth of the Opana ER prescriber base via targeted promotion and educational programs." The slide indicates that the book would be particularly effective "for [the] PCP audience" and instructed "[s]ales representatives [to] deliver [the book] to participating health care professionals." The slide demonstrates Endo's express incorporation of this book by a KOL into its marketing strategy.

229. Endo documents indicate that, around 2007, the company purchased at least 50,000 copies of the book for distribution. Internal Endo documents demonstrate that the book had been approved for distribution by Endo's sales force, and Endo had fewer than 8,000 copies on hand in March of 2013. Based on the nationwide and uniform character of Endo's marketing, and the book's approval for distribution, this book was available to and was intended to reach Alabama prescribers.

REDACTED VERSION

III. Although the Manufacturer Defendants Knew that their Marketing of Opioids was False and Misleading, the Companies Fraudulently Concealed their Misconduct.

230. The Manufacturer Defendants have made, promoted, and profited from their misrepresentations about the risks and benefits of opioids for chronic pain even though they have known that their marketing was false and misleading. The history of opioids, as well as research and clinical experience over the last 20 years, established that opioids were highly addictive and responsible for a long list of very serious adverse outcomes. The FDA and other regulators warned the Manufacturer Defendants of this, and accordingly, they have paid millions of dollars to address similar misconduct that occurred before. The Manufacturer Defendants had access to scientific studies, detailed prescription data, and reports of adverse events, including reports of addiction, hospitalization, and deaths – all of which made clear to them 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 the Manufacturer Defendants' misrepresentations.

231. Notwithstanding this knowledge, at all times relevant to this Complaint, the Manufacturer Defendants have taken steps to avoid detection of, and to fraudulently conceal, their unlawful, unfair, and deceptive conduct. The Manufacturer Defendants disguised their own role in the deceptive marketing of chronic opioid therapy by funding and working through biased science, unbranded marketing, third party advocates, and professional associations. The Manufacturer Defendants have purposely hidden behind the assumed credibility of these sources and relied on them to establish the accuracy and integrity of their false and misleading messages about the risks and benefits of long-term opioid use for chronic pain. The Manufacturer Defendants have masked, or never bothered to disclose, their role in shaping, editing, and approving the content of this

information. The Manufacturer Defendants have also distorted the meaning or import of studies it cited and offered them as evidence for propositions the studies did not support. The Manufacturer Defendants have 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 the Manufacturer Defendants' deception and could not have acquired such knowledge earlier through the exercise of reasonable diligence.

IV. McKesson's Unlawful Distribution of Opioids.

232. McKesson owes a duty under both federal law and Alabama law to monitor, detect, investigate, refuse to fill, and report suspicious orders of prescription opioids originating in the State of Alabama as well as those orders which McKesson knew or should have known were likely to be diverted into Alabama.

233. The foreseeable harm from a breach of these duties is the diversion of prescription opioids for non-medical purposes.

234. McKesson repeatedly and purposefully breached its duties under state and federal law. Such breaches are direct and proximate causes of the widespread diversion of prescription opioids for non-medical purposes into the State.

235. The unlawful diversion of prescription opioids is a direct and proximate cause and/or substantial contributing factor to the opioid epidemic and particularly to prescription opioid abuse, addiction, morbidity, and mortality in the State. This diversion and the epidemic are direct causes of the harms for which Plaintiff seeks to recover here.

236. The opioid epidemic in the State remains an immediate hazard to public health and safety.

237. The opioid epidemic in the State is a temporary and continuous public nuisance and remains unabated.

238. McKesson intentionally continued its conduct, as alleged herein, with knowledge that such conduct was creating the opioid nuisance and causing the harms and damages alleged herein.

a. Wholesale Drug Distributors Have a Duty under State and Federal Law to Guard Against, and Report, Unlawful Diversion and to Report and Prevent Suspicious Orders.

239. The Alabama Legislature has found that "the diversion, abuse, and misuse of prescription medications classified as controlled substances under the Alabama Uniform Controlled Substances Act constitutes a serious threat to the health and welfare of the citizens of the State of Alabama." ALA. CODE § 20-2-210. *See also* ALA. ADMIN. CODE § 680-X-2-.23(2)(k) ("It shall be a violation of these rules for a wholesale drug distributor to . . . operate in such a manner as to endanger the public health."). The Legislature has further termed this diversion constitutes a "drug crisis in the State of Alabama which is plaguing our neighborhoods." ALA. CODE § 6-5-155(1).

240. Opioids are a controlled substance and are categorized as having a "high potential for abuse" under Alabama law. *See* ALA. CODE § 20-2-24. Likewise, federal law also classifies opioids as Schedule II drugs which carry a "high potential for abuse." 21 U.S.C. §§ 812(b), 812(2)(A)-(C). The diversion of these drugs, as the Alabama Legislature has recognized, has caused – and continues to cause – "a serious threat to the health and welfare of the citizens of the State of Alabama." ALA. CODE § 20-2-210.

241. Each Defendant was required under Alabama law to first be registered with and permitted by the Alabama State Board of Pharmacy. ALA. CODE §§ 20-2-51; 34-23-32; and ALA. ADMIN. CODE §§ 680-X-2-.25; 680-X-3-.01; 680-X-3-.05.

242. Alabama's Pharmacy Board Regulations predicate such registration for both manufacturers and distributors upon, *inter alia*, "[m]aintenance of effective controls against diversion of controlled substances into other than legitimate medical, scientific, or industrial channels" and "[p]ast experience in the manufacture or distribution of controlled substances and the existence in the applicant's establishment of effective controls against diversion." ALA. CODE § 20-2-52(a)(1) and (4).

243. Alabama Pharmacy Board Regulations also require manufacturers and distributors of controlled substances doing business in Alabama to "submit to the Alabama State Board of Pharmacy legible copies of records and reports required by the Drug Enforcement Administration concerning increases in purchases or high or unusual volumes purchased by pharmacies within 30 days." ALA. ADMIN. CODE § 680-X-3-.05. *See also* ALA. CODE § 20-2-56 ("Persons registered to manufacture, distribute, or dispense controlled substances under this article shall keep records and maintain inventories in conformance with the record keeping and inventory requirements of federal law and with any additional rules issued by the State Board of Medical Examiners, the State Board of Health, or the State Board of Pharmacy"); ALA. CODE § 20-2-71(a)(3) ("It is unlawful for any person: . . . To refuse or fail to make, keep or furnish any record, notification, order form, statement, invoice, or information required under this chapter"); ALA. CODE § 20-2-72(a)(4) ("It is unlawful for any person: . . . To furnish false or fraudulent material information in or omit any material information from any application, report, or other document required to be kept or filed under [the Alabama Uniform Controlled Substances Act] or any record required to be

kept by [the Alabama Uniform Controlled Substances Act]; . . .); ALA. ADMIN. CODE § 680-X-2-.23(2)(e) (requiring wholesale distributors to forward all "records and reports required by the Drug Enforcement Administration concerning increases in purchases or high or unusual volumes purchased by pharmacies. . . to the Board of Pharmacy.").

244. Furthermore, Alabama law incorporates federal requirements set out under the Controlled Substances Act and related controlled substance laws and regulations. *See* ALA. CODE § 20-2-52(d) (each manufacturer and distributor, was required to "compl[y] . . . with the provisions of the federal law respecting registration . . . ."); ALA. CODE § 20-2-56 ("Persons registered to manufacture, distribute, or dispense controlled substances under [Article 3 of the Alabama Uniform Controlled Substances Act] shall keep records and maintain inventories in conformance with the record keeping and inventory requirements of federal law and with any additional rules issued by the State Board of Medical Examiners, the State Board of Health, or the State Board of Pharmacy."); ALA. ADMIN. CODE § 680-X-2-.23(2)(k) ("Wholesale drug distributors shall operate in compliance with applicable Federal, State and Municipal laws and regulations.").

245. McKesson was further required to register with the DEA, pursuant to the federal Controlled Substances Act. *See* 21 U.S.C. § 823(b), (e); 28 C.F.R. § 0.100. McKesson is a "registrant" as a wholesale distributor in the chain of distribution of Schedule II controlled substances with a duty to comply with all security requirements imposed under that statutory scheme. Those requirements are adopted and incorporated into Alabama law, as set out above. *See, e.g.*, ALA. CODE § 20-2-52(d).

246. McKesson has an affirmative duty under federal and Alabama law to act as a gatekeeper guarding against the diversion of the highly addictive, dangerous opioid drugs. Federal law requires that Distributors of Schedule II drugs, including opioids, must maintain "effective

control against diversion of particular controlled substances into other than legitimate medical, scientific, and industrial channels." 21 U.S.C. § 823(b)(1). Those requirements are adopted and incorporated into Alabama law, as set out above.

247. Federal regulations, incorporated by Alabama law, impose a non-delegable duty upon wholesale drug distributors to "design and operate a system to disclose to the registrant suspicious orders of controlled substances. The registrant [distributor] shall inform the Field Division Office of the Administration in his area of suspicious orders when discovered by the registrant. Suspicious orders include orders of unusual size, orders deviating substantially from a normal pattern, and orders of unusual frequency." 21 C.F.R. § 1301.74(b).

248. "Suspicious orders" include orders of an unusual size, orders of unusual frequency or orders deviating substantially from a normal pattern. *See* 21 C.F.R. § 1301.74(b). These criteria are disjunctive and are not all inclusive. For example, if an order deviates substantially from a normal pattern, the size of the order does not matter, and the order should be reported as suspicious. Likewise, a wholesale distributor need not wait for a normal pattern to develop over time before determining whether an order is suspicious. The size of an order alone, regardless of whether it deviates from a normal pattern, is enough to trigger the wholesale distributor's responsibility to report the order as suspicious. The determination of whether an order is suspicious depends not only on the ordering patterns of the customer but also on the patterns of the entirety of the wholesale distributor's customer base and the patterns throughout the relevant segment of the wholesale distributor industry.

249. In addition to reporting all suspicious orders, distributors must also stop shipment on any order which is flagged as suspicious and only ship orders which were flagged as potentially suspicious if, after conducting due diligence, the distributor can determine that the order is not

likely to be diverted into illegal channels. *See Southwood Pharm., Inc.*, 72 Fed. Reg. 36487-01, 36501 (Drug Enf't Admin. July 3, 2007); *Masters Pharmaceutical, Inc. v. Drug Enforcement Administration*, 861 F.3d 206 (D.C. Cir. June 30, 2017). Regardless, all flagged orders must be reported. *Id*.

250. These prescription drugs are regulated to provide a "closed" system intended to reduce the widespread diversion of these drugs out of legitimate channels into the illicit market, while at the same time providing the legitimate drug industry with a unified approach to narcotic and dangerous drug control.[107]

251. Different entities supervise the discrete links in the chain that separate a consumer from a controlled substance. Statutes and regulations define each participant's role and responsibilities.[108]

252. As the DEA advised all registrants, including each of the Defendants, in a letter to them dated September 27, 2006, wholesale distributors are "one of the key components of the distribution chain. If the closed system is to function properly … distributors must be vigilant in deciding whether a prospective customer can be trusted to deliver controlled substances only for lawful purposes. This responsibility is critical, as … the illegal distribution of controlled

[107] *See* 1970 U.S.C.C.A.N. 4566, 4571-72.

[108]Brief for Healthcare Distribution Management Association and National Association of Chain Drug Stores as Amici Curiae in Support of Neither Party, *Masters Pharm., Inc. v. U.S. Drug Enf't Admin.* (No.15-1335) (D.C. Cir. Apr. 4, 2016), 2016 WL 1321983, at *22 [hereinafter Brief for HDMA and NACDS]. The Healthcare Distribution Management Association (HDMA or HMA)— now known as the Healthcare Distribution Alliance (HDA)— is a national, not-for-profit trade association that represents the nation's primary, full-service healthcare distributors whose membership includes, among others: AmerisourceBergen Drug Corporation, Cardinal Health, Inc., and McKesson Corporation. *See generally* HDA, *About* https://www.hda.org/about/membership/distributor (last visited June 17, 2019). The National Association of Chain Drug Stores (NACDS) is a national, not-for-profit trade association that represents traditional drug stores and supermarkets and mass merchants with pharmacies whose membership includes, among others: Walgreen Company, CVS Health, Rite Aid Corporation and Walmart. *See generally* NACDS, *Mission*, https://www.nacds.org/about/mission/ (last visited June 17, 2019), https://www.nacds.org/membership/directories/chain-companies/ (last visited June 17, 2019).

substances has a substantial and detrimental effect on the health and general welfare of the American people."[109]

253. McKesson has admitted that it is responsible for reporting suspicious orders.[110]

254. The DEA's September 27, 2006, letter also warned that it would use its authority to revoke and suspend registrations when appropriate. The letter expressly states that a distributor, in addition to reporting suspicious orders, has a "statutory responsibility to exercise due diligence to avoid filling suspicious orders that might be diverted into other than legitimate medical, scientific, and industrial channels."[111] The letter also instructs that "distributors must be vigilant in deciding whether a prospective customer can be trusted to deliver controlled substances only for lawful purposes."[112] The DEA warns that "even just one distributor that uses its DEA registration to facilitate diversion can cause enormous harm."[113]

255. The DEA sent a second letter to all DEA registrants, including each of the Defendants, on December 27, 2007.[114] This letter reminds the Defendants of their statutory and

[109] *See* Letter from Joseph T. Rannazzisi, Deputy Assistant Adm'r, Office of Diversion Control, Drug. Enf't Admin., U.S. Dep't of Justice, to Cardinal Health (Sept. 27, 2006) [hereinafter Rannazzisi Letter] ("This letter is being sent to every commercial entity in the United States registered with the Drug Enforcement Agency (DEA) to distribute controlled substances. The purpose of this letter is to reiterate the responsibilities of controlled substance distributors in view of the prescription drug abuse problem our nation currently faces."), *filed in Cardinal Health, Inc. v. Holder*, No. 1:12-cv-00185-RBW (D.D.C. Feb. 10, 2012), ECF No. 14-51

[110] *See* Brief for HDMA and NACDS, *supra* note 108, 2016 WL 1321983, at *4 ("[R]egulations...in place for more than 40 years require distributors to report suspicious orders of controlled substances to DEA based on information readily available to them (e.g., a pharmacy's placement of unusually frequent or large orders).").

[111] Rannazzisi Letter, *supra* note 109, at 2.

[112] *Id.* at 1.

[113] *Id.* at 2.

[114] *See* Letter from Joseph T. Rannazzisi, Deputy Assistant Adm'r, Office of Diversion Control, Drug. Enf't Admin., U.S. Dep't of Justice, to Cardinal Health (Dec. 27, 2007), filed in *Cardinal Health, Inc. v. Holder*, No.1:12-cv-00185-RBW (D.D.C. Feb.10, 2012), ECF No.14-8.

regulatory duties to "maintain effective controls against diversion" and "design and operate a system to disclose to the registrant suspicious orders of controlled substances."[115] The letter further explains:

> The regulation also requires that the registrant inform the local DEA Division Office of suspicious orders when discovered by the registrant. Filing a monthly report of completed transactions (e.g., "excessive purchase report" or "high unity purchases") does not meet the regulatory requirement to report suspicious orders. Registrants are reminded that their responsibility does not end merely with the filing of a suspicious order report. Registrants must conduct an independent analysis of suspicious orders prior to completing a sale to determine whether the controlled substances are likely to be diverted from legitimate channels. Reporting an order as suspicious will not absolve the registrant of responsibility if the registrant knew, or should have known, that the controlled substances were being diverted.
>
> The regulation specifically states that suspicious orders include orders of unusual size, orders deviating substantially from a normal pattern, and orders of an unusual frequency. These criteria are disjunctive and are not all inclusive. For example, if an order deviates substantially from a normal pattern, the size of the order does not matter and the order should be reported as suspicious. Likewise, a registrant need not wait for a "normal pattern" to develop overtime before determining whether a particular order is suspicious. The size of an order alone, whether or not it deviates from a normal pattern, is enough to trigger the registrant's responsibility to report the order as suspicious. The determination of whether an order is suspicious depends not only on the ordering patterns of the particular customer, but also on the patterns of the registrant's customer base and the patterns throughout the segment of the regulated industry.
>
> Registrants that rely on rigid formulas to define whether an order is suspicious may be failing to detect suspicious orders. For example, a system that identifies orders as suspicious only if the total amount of a controlled substance ordered during one month exceeds the amount ordered the previous month by a certain percentage or more is insufficient. This system fails to identify orders placed by a pharmacy if the pharmacy placed unusually large orders from the beginning of its relationship with the distributor. Also, this system would not identify orders as suspicious if the order were solely for one highly abused controlled substance if the orders never grew substantially. Nevertheless, ordering one highly abused controlled substance and little or nothing else deviates from the normal pattern of what pharmacies generally order.
>
> When reporting an order as suspicious, registrants must be clear in their

[115] *Id.*

> communication with DEA that the registrant is actually characterizing an order as suspicious. Daily, weekly, or monthly reports submitted by registrant indicating "excessive purchases" do not comply with the requirement to report suspicious orders, even if the registrant calls such reports "suspicious order reports."
>
> Lastly, registrants that routinely report suspicious orders, yet fill these orders without first determining that order is not being diverted into other than legitimate medical, scientific, and industrial channels, may be failing to maintain effective controls against diversion. Failure to maintain effective controls against diversion is inconsistent with the public interest as that term is used in 21 U.S.C. 823 and 824, and may result in the revocation of the registrant's DEA Certificate of Registration.[116]

256. Finally, the DEA letter references the Revocation of Registration issued in *Southwood Pharmaceuticals, Inc.*, 72 Fed. Reg. 36487-01 (July 3, 2007), which discusses the obligation to report suspicious orders and "some criteria to use when determining whether an order is suspicious."[117]

257. McKesson has "statutory and regulatory responsibilities to detect and prevent diversion of controlled prescription drugs," as well as a responsibility to "undertake such efforts as responsible members of society."[118]

258. McKesson knew it was required to monitor, detect, and halt suspicious orders. Industry compliance guidelines established by the Healthcare Distribution Management Association, the trade association of pharmaceutical distributors, explain that distributors are "[a]t the center of a sophisticated supply chain" and therefore "are uniquely situated to perform due diligence to help support the security of the controlled substances they deliver to their customers."

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[116] *Id*.

[117] *Id*.

[118] *See Brief for Healthcare Distribution Management Association and National Association of Chain Drug Stores as Amici Curiae in Support of Appellant Cardinal Health, Inc., filed in Cardinal Health, Inc. v. United States Dep't of Justice*, 2012 WL 1637016, at *2 (D.C. Cir. May 9, 2012).

The guidelines set forth recommended steps in the "due diligence" process, and note in particular: If an order meets or exceeds a distributor's threshold, as defined in the distributor's monitoring system, or is otherwise characterized by the distributor as an order of interest, the distributor should not ship to the customer, in fulfillment of that order, any units of the specific drug code product as to which the order met or exceeded a threshold or as to which the order was otherwise characterized as an order of interest.[119]

259. McKesson sold prescription opioids, including hydrocodone and/or oxycodone, to retailers in the State of Alabama and/or to retailers from which Defendants knew prescription opioids were likely to be diverted to the State of Alabama.

260. McKesson owes a duty to monitor and detect suspicious orders of prescription opioids.

261. McKesson owes a duty under federal and state law to investigate and refuse suspicious orders of prescription opioids.

262. McKesson owes a duty under federal and state law to report suspicious orders of prescription opioids.

263. McKesson owes a duty under federal and state law to prevent the diversion of prescription opioids into illicit markets in the State.

264. The foreseeable harm resulting from a breach of these duties is the diversion of prescription opioids for non-medical purposes and subsequent plague of opioid addiction.

[119] Healthcare Distribution Management Association (HDMA) *Industry Compliance Guidelines: Reporting Suspicious Orders and Preventing Diversion of Controlled Substances, filed in Cardinal Health, Inc. v. Holder*, No. 12-5061 (D.C. Cir. Mar.7, 2012), Doc. No. 1362415 (App'x B).

265. The foreseeable harm resulting from the diversion of prescription opioids for non-medical purposes is abuse, addiction, morbidity and mortality in the State and the damages caused thereby.

b. McKesson Breached its Duties.

266. Because McKesson handles such large volumes of controlled substances, and is the first major line of defense in the movement of legal pharmaceutical controlled substances from legitimate channels into the illicit market, it is incumbent on McKesson to maintain effective controls to prevent diversion of controlled substances. Should a distributor deviate from these checks and balances, the closed system collapses.[120]

267. The sheer volume of prescription opioids distributed to pharmacies in the State of Alabama, and/or to pharmacies from which McKesson knew the opioids were likely to be diverted into the State, is excessive for the medical need of the community and facially suspicious. Some red flags are so obvious that no one who engages in the legitimate distribution of controlled substances can reasonably claim ignorance of them.[121]

i. McKesson Failed to Report Suspicious Orders it Shipped to Alabama Opioid Dispensers.

268. McKesson operates a distribution facility in McCalla, Alabama.

[redacted] substantial quantities of prescription opioids in other states, and these drugs were diverted from

[120] *See* Rannazzisi Decl.¶ 10, filed in *Cardinal Health, Inc. v. Holder*, No. 1:12-cv-00185-RBW (D.D.C. Feb.10, 2012), ECF No. 14-2.

[121] *Masters Pharmaceuticals, Inc.*, 80 Fed. Reg. 55418-01, 55482 (Sept. 15, 2015) (citing *Holiday CVS, L.L.C., d/b/a CVS/Pharmacy Nos. 219 and 5195*, 77 Fed. Reg. 62316-01, 62322 (2012)).

these other states to Alabama. McKesson failed to take meaningful action to stop this diversion, despite its knowledge that diversion was occurring, and it contributed substantially to the diversion problem.

270. McKesson developed and maintained extensive data on opioids it distributed and dispensed. Through this data, McKesson had direct knowledge of patterns and instances of improper distribution, prescribing, and use of prescription opioids in communities throughout the United States, and in Alabama in particular. It then used that data to evaluate its own sales activities and workforce. On information and belief, McKesson also provided the Defendants with data regarding, *inter alia*, individual doctors in exchange for rebates or other forms of consideration. This data is a valuable resource that it could have used to help stop diversion but failed to do so.

[redacted]

[122] On information and belief, the ARCOS data disclosed to date in the Ohio Multi-district Litigation only contains data for four opioid-related DEA drug codes: oxycodone (DEA Drug Code 9143); hydrocodone (DEA Drug Code 9193); hydromorphone (DEA Drug Code 9150); and fentanyl (DEA Drug Code 9801). The ARCOS data disclosed to date does not include morphine (DEA Drug Code 9300); oxymorphone (DEA Drug Code 9652); carfentanil (DEA Drug Code 9743); tapentadol (DEA Drug Code 9780); or Buprenorphine (DEA Drug Code 9064). The charts contained herein contain the distribution data for oxycodone (DEA Drug Code 9143), hydrocodone (DEA Drug Code 9193), hydromorphone (DEA Drug Code 9150), but do not include fentanyl (DEA Drug Code 9801), which, on information and belief, is not typically distributed as a pill.

[redacted]

REDACTED VERSION

[redacted]

273. This volume of opioids reported in the ARCOS data currently available, however, appears to understate the scope of the problem because it only accounts for four opioid-related DEA drug codes. Therefore, the total number of opioids dispensed and distributed in the State of Alabama is likely even higher than the above figures.

274. This high volume of opioids alone should have alerted McKesson that it was filling suspicious orders. Yet it failed to halt those orders, instead increasing the number of pills distributed and market share each year.

[redacted]

[redacted]

REDACTED VERSION

276. Upon information and belief, Plaintiff expects other egregious examples of McKesson failing to fulfill its statutory duty to prevent diversion will be discovered as additional ARCOS data and other relevant information is obtained as the litigation progresses.

277. As these statistics show, McKesson failed to report "suspicious orders" originating from the State, or which McKesson knew were likely to be diverted to the State, to the federal and state authorities, including the DEA and/or the state Board of Pharmacy.

278. McKesson unlawfully filled suspicious orders of unusual size, orders deviating substantially from a normal pattern and/or orders of unusual frequency in the State, and/or in areas from which McKesson knew opioids were likely to be diverted to the State.

279. McKesson breached its duty to monitor, detect, investigate, refuse, and report suspicious orders of prescription opiates originating from the State, and/or in areas from which McKesson knew opioids were likely to be diverted to the State.

280. McKesson breached its duty to maintain effective controls against diversion of prescription opiates into other than legitimate medical, scientific, and industrial channels.

281. McKesson breached its duty to "design and operate a system to disclose to the registrant suspicious orders of controlled substances" and failed to inform the authorities including the DEA of suspicious orders when discovered, in violation of their duties under federal and state law.

282. McKesson breached its duty to exercise due diligence to avoid filling suspicious orders that might be diverted into channels other than legitimate medical, scientific, and industrial channels.[126]

283. The federal and state laws at issue here are public safety laws.

284. McKesson's violations of public safety statutes constitute prima facie evidence of negligence under State law.

285. McKesson supplied prescription opioids to obviously suspicious physicians and pharmacies, enabled the illegal diversion of opioids, aided criminal activity, and disseminated massive quantities of prescription opioids into the black market.

286. The unlawful conduct by McKesson is purposeful and intentional. McKesson refused to abide by the duties imposed by federal and state law which are required to legally acquire and maintain a license to distribute prescription opiates.

287. McKesson acted with actual malice in breaching their duties, i.e., they have acted with a conscious disregard for the rights and safety of other persons, and said actions have a great probability of causing substantial harm.

288. McKesson's repeated shipments of suspicious orders, over an extended period, in violation of public safety statutes, and without reporting the suspicious orders to the relevant authorities demonstrates wanton, willful, or reckless conduct or criminal indifference to civil obligations affecting the rights of others and justifies an award of punitive damages.

[126] *See Cardinal Health, Inc. v. Holder*, 846 F.Supp. 2d 203, 206 (D.D.C. 2012).

c. McKesson Sought to Avoid and Misrepresented its Compliance with its Legal Duties.

289. McKesson has repeatedly misrepresented its compliance with its legal duties under state and federal law and has wrongfully and repeatedly disavowed those duties to mislead regulators and the public regarding McKesson's compliance with its legal duties.

290. McKesson has refused to recognize any duty beyond reporting suspicious orders. In *Masters Pharmaceuticals*, the HDMA, a trade association run by distributors, including McKesson, and the NACDS submitted amicus briefs regarding the legal duty of wholesale distributors. Inaccurately denying the legal duties that the wholesale drug industry has been tragically recalcitrant in performing, they argued as follows:

a. The Associations complained that the "DEA has required distributors not only to report suspicious orders, but to investigate orders (e.g., by interrogating pharmacies and physicians) and take action to halt suspicious orders before they are filled."[127]

b. The Associations argued that, "DEA now appears to have changed its position to require that distributors not only report suspicious orders, but investigate and halt suspicious orders. Such a change in agency position must be accompanied by an acknowledgment of the change and a reasoned explanation for it. In other words, an agency must display awareness that it is changing position and show that there are good reasons for the new policy. This is especially important here, because

[127] Brief for HDMA and NACDS, *supra* note 108, 2016 WL 1321983, at *4–5.

imposing intrusive obligation on distributors threatens to disrupt patient access to needed prescription medications."[128]

c. The Associations alleged (inaccurately) that nothing "requires distributors to investigate the legitimacy of orders, or to halt shipment of any orders deemed to be suspicious."[129]

d. The Association complained that the purported "practical infeasibility of requiring distributors to investigate and halt suspicious orders (as well as report them) underscores the importance of ensuring that DEA has complied with the APA before attempting to impose such duties."[130]

e. The Associations alleged (inaccurately) that "DEA's regulations [] sensibly impose[] a duty on distributors simply to report suspicious orders, but left it to DEA and its agents to investigate and halt suspicious orders."[131]

f. Also, inaccurately, the Associations argued that, "[i]mposing a duty on distributors – which lack the patient information and the necessary medical expertise – to investigate and halt orders may force distributors to take a shot-in-the-dark approach to complying with DEA's demands."[132]

[128] *Id.* at *8 (citations and quotation marks omitted).

[129] *Id.* at *14.

[130] *Id.* at *22.

[131] *Id.* at *24–25.

[132] *Id.* at 26.

291. The positions taken by the trade groups are emblematic of the positions taken by McKesson in its futile attempt to deny its legal obligations to prevent diversion of the dangerous drugs.[133]

292. Despite the positions taken by McKesson, the Court of Appeals for the District of Columbia recently issued its opinion affirming that a wholesale drug distributor does, in fact, have duties beyond simply reporting. *Masters Pharm., Inc. v. Drug Enf't Admin*., 861 F.3d 206 (D.C. Cir. 2017). The D.C. Circuit Court upheld the revocation of Masters Pharmaceutical's license and determined that DEA regulations require that in addition to reporting suspicious orders, a distributor must "decline to ship the order, or conduct some 'due diligence' and—if it is able to determine that the order is not likely to be diverted into illegal channels—ship the order." *Id*. at 212. Masters Pharmaceutical was in violation of legal requirements because it failed to conduct necessary investigations and filled suspicious orders. *Id*. at 218–19, 226. A distributor's investigation must dispel all the red flags giving rise to suspicious circumstance prior to shipping a suspicious order. *Id*. at 226. The Circuit Court also rejected the argument made by the HDMA and NACDS (quoted above), that, allegedly, the DEA had created or imposed new duties. *Id*. at 220.

d. Enforcement Actions Brought Against McKesson for Failure to Adhere to its Duties.

293. McKesson has recently been forced to specifically admit to breach of its duties to monitor, report, and prevent suspicious orders. Pursuant to an Administrative Memorandum of Agreement ("2017 Agreement") entered into between McKesson and the DEA in January 2017, McKesson admitted that, at various times during the period from January 1, 2009 through the

[133] *See* Brief of HDMA, *supra* note 118, 2012 WL 1637016, at *3 (arguing the wholesale distributor industry "does not know the rules of the road because" they claim (inaccurately) that the "DEA has not adequately explained them").

effective date of the Agreement (January 17, 2017) it "did not identify or report to [the] DEA certain orders placed by certain pharmacies which should have been detected by McKesson as suspicious based on the guidance contained in the DEA Letters."[134] Further, the 2017 Agreement specifically finds that McKesson "distributed controlled substances to pharmacies even though those McKesson Distribution Centers should have known that the pharmacists practicing within those pharmacies had failed to fulfill their corresponding responsibility to ensure that controlled substances were dispensed pursuant to prescriptions issued for legitimate medical purposes by practitioners acting in the usual course of their professional practice, as required by 21 C.F.R. § 1306.04(a)."[135] McKesson admitted that, during this time period, it "failed to maintain effective controls against diversion of particular controlled substances into other than legitimate medical, scientific and industrial channels by sales to certain of its customers in violation of the CSA and the CSA's implementing regulations, 21 C.F.R. Part 1300 *et seq*., at the McKesson Distribution Centers" including the McKesson Distribution Center located in "Washington Courthouse, Ohio."[136] Due to these violations, McKesson agreed that its authority to distribute controlled substances from the Washington Courthouse, Ohio facility (among other facilities) would be partially suspended.[137]

294. The 2017 Memorandum of Agreement followed a 2008 Settlement Agreement in which McKesson also admitted failure to report suspicious orders of controlled substances to the

[134] *See* Administrative Memorandum of Agreement between the U.S. Dep't of Justice, the Drug Enf't Admin., and the McKesson Corp. (Jan. 17, 2017), https://www.justice.gov/opa/press-release/file/928476/download.

[135] *Id.* at 4.

[136] *Id.*

[137] *Id.* at 6.

DEA.[138] In the 2008 Settlement Agreement, McKesson "recognized that it had a duty to monitor its sales of all controlled substances and report suspicious orders to DEA," but had failed to do so.[139] The 2017 Memorandum of Agreement documents that McKesson continued to breach its admitted duties by "fail[ing] to properly monitor its sales of controlled substances and/or report suspicious orders to DEA, in accordance with McKesson's obligations."[140] As a result of these violations, McKesson was fined and required to pay to the United States $150 million.[141] The MOA also stated that McKesson would "maintain a compliance program designed to detect and prevent the diversion of controlled substances, inform DEA of suspicious orders required by 21 C.F.R. § 1301.74(b), and follow the procedures established by its Controlled Substance Monitoring Program."

295. Even though McKesson had been sanctioned in 2008 for failure to comply with its legal obligations regarding controlling diversion and reporting suspicious orders, and even though McKesson had specifically agreed in 2008 that it would no longer violate those obligations, McKesson continued to violate the laws in contrast to its written agreement not to do so.

296. Rather than abide by its non-delegable duties under public safety laws, wholesale pharmaceutical distributors, including McKesson, individually and collectively through trade groups in the industry, pressured the U.S. Department of Justice to "halt" prosecutions and lobbied

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[138] *Id.* at 4.

[139] *Id.*

[140] *Id.*; *see also* Settlement Agreement and Release between the U.S. and McKesson Corp., at 5 (Jan.17, 2017) [hereinafter 2017 Settlement Agreement and Release] ("McKesson acknowledges that, at various times during the Covered Time Period [2009-2017], it did not identify or report to DEA certain orders placed by certain pharmacies, Which should have been detected by McKesson as suspicious, in a manner fully consistent with the requirements set forth in the 2008 MOA."), https://www.justice.gov/opa/press-release/file/928471/download.

[141] *See* 2017 Settlement Agreement and Release, *supra* note 121, at 6.

Congress to strip the DEA of its ability to immediately suspend distributor registrations. The result was a "sharp drop in enforcement actions" and the passage of the "Ensuring Patient Access and Effective Drug Enforcement Act" which, ironically, raised the burden for the DEA to revoke a distributor's license from "imminent harm" to "immediate harm" and provided the industry the right to "cure" any violations of law before a suspension order can be issued.[142]

297. In addition to taking actions to limit regulatory prosecutions and suspensions, McKesson undertook to fraudulently convince the public that it was complying with its legal obligations, including those imposed by licensing regulations. Through such statements, McKesson attempted to assure the public it was working to curb the opioid epidemic.

298. For example, McKesson publicly stated that it has a "best-in-class controlled substance monitoring program to help identify suspicious orders," and claimed it is "deeply passionate about curbing the opioid epidemic in our country."[143] Again, given McKesson's historical conduct, this statement is either false, or the company ignored outputs of the monitoring program.

299. By misleading the public about the effectiveness of its controlled substance monitoring programs, McKesson successfully concealed the facts sufficient to arouse suspicion of

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[142] *See* Lenny Bernstein & Scott Higham, *Investigation: The DEA Slowed Enforcement While the Opioid Epidemic Grew Out of Control*, Wash. Post, Oct. 22, 2016, https://www.washingtonpost.com/investigations/the-dea-slowed-enforcement-while-the-opioid-epidemic-grew-out-of-control/2016/10/22/aea2bf8e-7f71-11e6-8d13-d7c704ef9fd9_story.html?utm_term=.e2d89d4ccd07; Lenny Bernstein & Scott Higham, *Investigation: U.S. Senator Calls for Investigation of DEA Enforcement Slowdown Amid Opioid Crisis*, Wash. Post, Mar. 6, 2017, https://www.washingtonpost.com/investigations/us-senator-calls-for-investigation-of-dea-enforcement-slowdown/2017/03/06/5846ee60-028b-11e7-b1e9-a05d3c21f7cf_story.html?utm_term=.bf8b934d4329; Eric Eyre, *DEA Agent: "We Had No Leadership" in WV Amid Flood of Pain Pills*, Charleston Gazette-Mail, Feb. 18, 2017,https://www.wvgazettemail.com/news/health/dea-agent-we-had-no-leadership-in-wv-amid-flood/article_928e9bcd-e28e-58b1-8e3f-f08288f539fd.html.

[143] Scott Higham *et al*., *Drug Industry Hired Dozens of Officials from the DEA as the Agency Tried to Curb Opioid Abuse*, Wash. Post, Dec. 22, 2016, https://www.washingtonpost.com/investigations/key-officials-switch-sides-from-dea-to-pharmaceutical-industry/2016/12/22/55d2e938-c07b-11e6-b527-949c5893595e_ story.html? utm_term=. fd9df7d2e66a.

the claims that the Plaintiff now asserts. The Plaintiff did not know of the existence or scope of McKesson's industry-wide fraud and could not have acquired such knowledge earlier through the exercise of reasonable diligence.

300. Meanwhile, the opioid epidemic rages unabated in the Nation and in the State of Alabama.

301. The epidemic still rages because the fines and suspensions imposed by the DEA do not change the conduct of the industry. The distributors, including McKesson, pay fines as a cost of doing business in an industry that generates billions of dollars in annual revenue. It holds multiple DEA registration numbers and when one facility is suspended, it simply ships from another facility.

302. The wrongful actions and omissions of McKesson which have caused the diversion of opioids and which have been a substantial contributing factor to and/or proximate cause of the opioid crisis.

303. McKesson has abandoned its duties imposed under federal and state law, taken advantage of a lack of DEA law enforcement, and abused the privilege of distributing controlled substances in the State.

V. The Manufacturer Defendants' Unlawful Failure to Prevent Diversion and Monitor, Report, and Prevent Suspicious Orders.

304. The same legal duties to prevent diversion, and to monitor, report, and prevent suspicious orders of prescription opioids that were incumbent upon McKesson were also legally required of the Manufacturer Defendants under federal and Alabama law.

305. Under Alabama and federal law, the Manufacturer Defendants were required to comply with substantially the same licensing and permitting requirements as McKesson, and same rules regarding prevention of diversion and reporting suspicious orders, as set out above.

306. Like McKesson, the Manufacturer Defendants were required to register with the DEA and with the Alabama Board of Pharmacy to manufacture schedule II controlled substances, like prescription opioids. *See* 21 U.S.C. § 823(a); ALA. CODE §§ 20-2-51; 34-23-32; and ALA. ADMIN. CODE §§ 680-X-2-.25; 680-X-3-.01; 680-X-3-.05. A requirement of such registration is the:

> maintenance of effective controls against diversion of particular controlled substances and any controlled substance in schedule I or II compounded therefrom into other than legitimate medical, scientific, research, or industrial channels, by limiting the importation and bulk manufacture of such controlled substances to a number of establishments which can produce an adequate and uninterrupted supply of these substances under adequately competitive conditions for legitimate medical, scientific, research, and industrial purposes . . .

21 U.S.C. § 823(a)(1).

307. Alabama predicates such registration for manufacturers upon, *inter alia*, "[m]aintenance of effective controls against diversion of controlled substances into other than legitimate medical, scientific, or industrial channels" ALA. Code § 20-2-52(a)(1).

308. Additionally, as "registrants" under 21 U.S.C. § 823(a) and pursuant to Alabama law, the Manufacturer Defendants were also required to monitor, report, and prevent suspicious orders of controlled substances:

> The registrant shall design and operate a system to disclose to the registrant suspicious orders of controlled substances. The registrant shall inform the Field Division Office of the Administration in his area of suspicious orders when discovered by the registrant. Suspicious orders include orders of unusual size, orders deviating substantially from a normal pattern, and orders of unusual frequency.

21 C.F.R. § 1301.74. *See also* 21 C.F.R. § 1301.02 ("Any term used in this part shall have the definition set forth in section 102 of the Act (21 U.S.C. 802) or part 1300 of this chapter."); 21 C.F.R. § 1300.01 ("Registrant means any person who is registered pursuant to either section 303 or section 1008 of the Act (21 U.S.C. §§ 823 or 958)." Like McKesson, the Manufacture Defendants

breached these duties.

309. Alabama Pharmacy Board Regulations require manufacturers of controlled substances doing business in Alabama to "submit to the Alabama State Board of Pharmacy legible copies of records and reports required by the Drug Enforcement Administration concerning increases in purchases or high or unusual volumes purchased by pharmacies within 30 days." ALA. ADMIN. CODE § 680-X-3-.05. *See also* ALA. CODE § 20-2-56

310. The Manufacturer Defendants had access to and possession of the information necessary to monitor, report, and prevent suspicious orders and to prevent diversion. The Manufacturer Defendants engaged in the practice of paying "chargebacks" to opioid distributors. A chargeback is a payment made by a manufacturer to a distributor after the distributor sells the manufacturer's product at a price below a specified rate. After a distributor sells a manufacturer's product to a pharmacy, for example, the distributor requests a chargeback from the manufacturer and, in exchange for the payment, the distributor identifies to the manufacturer the product, volume and the pharmacy to which it sold the product. Thus, the Manufacturer Defendants knew – just as McKesson knew – the volume, frequency, and pattern of opioid orders being placed and filled. The Manufacturer Defendants built receipt of this information into the payment structure for the opioids provided to the opioid distributors.

311. Federal statutes and regulations, and Alabama law incorporating those requirements, are clear: just like opioid distributors, opioid manufacturers are required to "design and operate a system to disclose . . . suspicious orders of controlled substances" and to maintain "effective controls against diversion." 21 C.F.R. § 1301.74; 21 USCA § 823(a)(1).

312. The Department of Justice has recently confirmed the suspicious order obligations clearly imposed by federal law upon opioid manufacturers, fining opioid manufacturer

Mallinckrodt $35 million for failure to report suspicious orders of controlled substances, including opioids, and for violating recordkeeping requirements.[144]

313. In the press release accompanying the settlement, the Department of Justice stated: "[Mallinckrodt] did not meet its obligations to detect and notify DEA of suspicious orders of controlled substances such as oxycodone, the abuse of which is part of the current opioid epidemic. These suspicious order monitoring requirements exist to prevent excessive sales of controlled substances, like oxycodone . . . Mallinckrodt's actions and omissions formed a link in the chain of supply that resulted in millions of oxycodone pills being sold on the street. . . Manufacturers and distributors have a crucial responsibility to ensure that controlled substances do not get into the wrong hands. . . ."[145]

314. Among the allegations resolved by the settlement, the government alleged "Mallinckrodt failed to design and implement an effective system to detect and report 'suspicious orders' for controlled substances – orders that are unusual in their frequency, size , or other patterns . . . [and] Mallinckrodt supplied distributors, and the distributors then supplied various U.S. pharmacies and pain clinics, an increasingly excessive quantity of Oxycodone pills without notifying DEA of these suspicious orders."[146]

315. The Memorandum of Agreement entered into by Mallinckrodt ("2017 Mallinckrodt MOA") avers "[a]s a registrant under the CSA, Mallinckrodt had a responsibility to maintain

[144] *See* Press Release, U.S. Dep't of Justice, Mallinckrodt Agrees to Pay Record $35 Million Settlement for Failure to Report Suspicious Orders of Pharmaceutical Drugs and for Record keeping Violations (July 11, 2017), https://www.justice.gov/opa/pr/mallinckrodt-agrees-pay-record-35-million-settlement-failure-report-suspicious-orders.

[145] *Id*.

[146] *Id*.

effective controls against diversion, including a requirement that it review and monitor these sales and report suspicious orders to DEA."[147]

316. The 2017 Mallinckrodt MOA further details the DEA's allegations regarding Mallinckrodt's failures to fulfill its legal duties as an opioid manufacturer:

> With respect to its distribution of oxycodone and hydrocodone products, Mallinckrodt's alleged failure to distribute these controlled substances in a manner authorized by its registration and Mallinckrodt's alleged failure to operate an effective suspicious order monitoring system and to report suspicious orders to the DEA when discovered as required by and in violation of 21 C.F.R. § 1301.74(b). The above includes, but is not limited to Mallinckrodt's alleged failure to:
>
> **i.** conduct adequate due diligence of its customers;
>
> **ii.** detect and report to the DEA orders of unusual size and frequency;
>
> **iii.** detect and report to the DEA orders deviating substantially from normal patterns including, but not limited to, those identified in letters from the DEA Deputy Assistant Administrator, Office of Diversion Control, to registrants dated September 27, 2006 and December 27, 2007:
>
> 1. orders that resulted in a disproportionate amount of a substance which is most often abused going to a particular geographic region where there was known diversion,
>
> 2. orders that purchased a disproportionate amount of a substance which is most often abused compared to other products, and
>
> 3. orders from downstream customers to distributors who were purchasing from multiple different distributors, of which Mallinckrodt was aware;
>
> **iv.** use "chargeback " information from its distributors to evaluate suspicious orders. Chargebacks include downstream purchasing information tied to certain discounts, providing Mallinckrodt with data on buying patterns for Mallinckrodt products; and

[147] Administrative Memorandum of Agreement between the United States Department of Justice, the Drug Enforcement Agency, and Mallinckrodt, PLC. and its subsidiary Mallinckrodt, LLC (July 10, 2017), https://www.justice.gov/usao-edmi/press-release/file/986026/download. ("2017 Mallinckrodt MOA").

> **v.** take sufficient action to prevent recurrence of diversion by downstream customers after receiving concrete information of diversion of Mallinckrodt product by those downstream customers.[148]

317. Mallinckrodt agreed that its "system to monitor and detect suspicious orders did not meet the standards outlined in letters from the DEA Deputy Administrator, Office of Diversion Control, to registrants dated September 27, 2006 and December 27, 2007." Mallinckrodt further agreed that it "recognizes the importance of the prevention of diversion of the controlled substances they manufacture" and would "design and operate a system that meets the requirements of 21 CFR 1301.74(b) . . . [such that it would] utilize all available transaction information to identify suspicious orders of any Mallinckrodt product. Further, Mallinckrodt agrees to notify DEA of any diversion and/or suspicious circumstances involving any Mallinckrodt controlled substances that Mallinckrodt discovers."[149]

318. Mallinckrodt acknowledged that "[a]s part of their business model Mallinckrodt collects transaction information, referred to as chargeback data, from their direct customers (distributors). The transaction information contains data relating to the direct customer sales of controlled substances to downstream registrants. Mallinckrodt agreed that, from this data, it would "report to the DEA when Mallinckrodt concludes that the chargeback data or other information indicates that a downstream registrant poses a risk of diversion."[150]

319. The same duties imposed by federal law on Mallinckrodt were imposed upon all manufacturers, including Purdue and Endo.

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[148] 2017 Mallinckrodt MOA at p. 2-3.

[149] *Id.* at 3-4.

[150] *Id.* at p. 5.

320. The same business practices utilized by Mallinckrodt regarding "chargebacks" and receipt and review of data from opioid distributors regarding orders of opioids were utilized industry-wide among opioid manufacturers and distributors, including, upon information and belief, the other Manufacturer Defendants.

321. Through, *inter alia*, the chargeback data, the Manufacturer Defendants could monitor suspicious orders of opioids.

322. The Manufacturer Defendants failed to monitor, report, and halt suspicious orders of opioids as required by federal law.

323. The Manufacturer Defendants' failures to monitor, report, and halt suspicious orders of opioids were intentional and unlawful.

324. The Manufacturer Defendants have misrepresented their compliance with federal law.

325. The Manufacturer Defendants enabled the supply of prescription opioids to obviously suspicious physicians and pharmacies, enabled the illegal diversion of opioids, aided criminal activity, and disseminated massive quantities of prescription opioids into the black market.

326. The Manufacturer Defendants' actions and omissions in failing to effective prevent diversion and failing to monitor, report, and prevent suspicious orders have enabled the unlawful diversion of opioids into the State of Alabama.

VI. The Manufacturer Defendants' Unlawful Conduct and Breaches of Legal Duties Caused the Alleged Harm and Substantial Damages.

327. As the Manufacturer Defendants' efforts to expand the market for opioids increased so have the rates of prescription and sale of their products – and the rates of opioid-related substance abuse, hospitalization, and death among the people of the State of Alabama. In addition,

McKesson has continued to unlawfully ship these massive quantities of opioids into the State of Alabama, fueling the epidemic.

328. There is a "parallel relationship between the availability of prescription opioid analgesics through legitimate pharmacy channels and the diversion and abuse of these drugs and associated adverse outcomes."[151]

329. Opioid analgesics are widely diverted and improperly used, and the widespread use of the drugs has resulted in a national epidemic of opioid overdose deaths and addictions.[152]

330. The epidemic is "directly related to the increasingly widespread misuse of powerful opioid pain medications."[153]

331. The increased abuse of prescription painkillers along with growing sales has contributed to many overdoses and deaths.[154]

332. As shown above, the opioid epidemic has escalated in the State of Alabama with devastating effects. Substantial opiate-related substance abuse, hospitalization, and death that mirrors Defendants' increased manufacture and distribution of opiates.

333. Because of the well-established relationship between the use of prescription opiates and the use of non-prescription opioids, like heroin, the massive distribution of opioids to the State of Alabama and areas from which such opioids are being diverted into the state, has caused the Defendant-caused opioid epidemic to include heroin addiction, abuse, and death.

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[151] Richard C. Dart, *et al.*, *Trends in Opioid Analgesic Abuse and Mortality in the United States*, 372 N. Eng. J. Med. 241, (January 15, 2015), https://www.nejm.org/doi/full/10.1056/NEJMsa1406143.

[152] Nora D. Volkow and A. Thomas McLellan, *Opioid Abuse in Chronic Pain – Misconceptions and Mitigation Strategies*, 374 N. Eng. J. Med. 1253, (March 31, 2016), https://www.nejm.org/doi/full/10.1056/NEJMra1507771.

[153] Robert M. Califf, *et al.*, *A Proactive Response to Prescription Opioid Abuse*, 374 N. Eng. J. 1480 (April 14, 2016), https://www.nejm.org/doi/full/10.1056/NEJMsr1601307.

[154] *See* Press Release, Ctrs. For Disease Control and Prevention, U.S. Dep't of Health and Human Servs., *supra* note 13.

334. Prescription opioid abuse, addiction, morbidity, and mortality are hazards to public health and safety in the State of Alabama.

335. Heroin abuse, addiction, morbidity, and mortality are hazards to public health and safety in the State of Alabama.

336. Defendants repeatedly and purposefully breached their duties under state and federal law, and such breaches are direct and proximate causes of, and/or substantial factors leading to, the widespread diversion of prescription opioids for non-medical purposes into the State of Alabama.

337. The unlawful diversion of prescription opioids is a direct and proximate cause of, and/or substantial factor leading to, the opioid epidemic, prescription opioid abuse, addiction, morbidity and mortality in the State of Alabama. This diversion and the epidemic are direct causes of foreseeable harms incurred by the Plaintiff.

338. Defendants' intentional and/or unlawful conduct resulted in direct and foreseeable, past and continuing, economic damages for which Plaintiff seeks relief, as alleged herein. Plaintiff also seeks the means to abate the epidemic created by Defendants' wrongful and/or unlawful conduct.

339. Plaintiff seeks economic damages from the Defendants as reimbursement for the costs association with past efforts to eliminate the hazards to public health and safety.

340. Plaintiff seeks economic damages from the Defendants to pay for the cost to permanently eliminate the hazards to public health and safety and abate the temporary public nuisance.

341. To eliminate the hazard to public health and safety, and abate the public nuisance, a "multifaceted, collaborative public health and law enforcement approach is urgently needed."[155]

342. A comprehensive response to this crisis must focus on preventing new cases of opioid addiction, identifying early opioid-addicted individuals, and ensuring access to effective opioid addiction treatment while safely meeting the needs of patients experiencing pain.[156]

343. These community-based problems require community-based solutions that have been limited by "budgetary constraints at the state and Federal levels."[157]

344. Having profited enormously through the aggressive sale, misleading promotion, and irresponsible distribution of opiates, Defendants should be required to take responsibility for the financial burdens their conduct has inflicted upon the State of Alabama.

VII. Statutes of Limitations are tolled, and Defendants are estopped from asserting statutes of limitations as defenses.

a. Continuing Conduct

345. Plaintiff contends it continues to suffer harm from the unlawful actions by the Defendants.

346. The continued tortious and unlawful conduct by the Defendants causes a repeated or continuous injury. The damages have not occurred all at once but have continued to occur and have increased as time progresses. The tort is not completed nor have all the damages been incurred

[155] *See* Rudd *et al*., *supra* note 10, at 1145.

[156] *See* Johns Hopkins Bloomberg School of Public Health, *The Prescription Opioid Epidemic: An Evidence-Based Approach* (G. Caleb Alexander *et al*. eds., 2015 https://www.jhsph.edu/research/centers-and-institutes/center-for-drug-safety-and-effectiveness/research/prescription-opioids/JHSPH_OPIOID_EPIDEMIC_REPORT.pdf.

[157] *See* Office of Nat'l Drug Control Policy, Exec. Office of the President, *Epidemic: Responding to America's Prescription Drug Abuse Crisis* (2011), https://www.ncjrs.gov/pdffiles1/ondcp/rx_abuse_plan.pdf.

until the wrongdoing ceases. The wrongdoing and unlawful activity by Defendants has not ceased. The public nuisance remains unabated.

b. Equitable Estoppel

347. Defendants are equitably estopped from relying upon a statute of limitations defense because they undertook efforts to purposefully conceal their unlawful conduct and fraudulently assure the public, including the State of Alabama, that they were undertaking efforts to comply with their obligations under the state and federal controlled substances laws, all with the goal of protecting their registered manufacturer or distributor status in the State and to continue generating profits. Notwithstanding the allegations set forth above, the Defendants affirmatively assured the public, including the State of Alabama, that they are working to curb the opioid epidemic.

348. For example, McKesson publicly stated that it has a "best-in-class controlled substance monitoring program to help identify suspicious orders," and claimed it is "deeply passionate about curbing the opioid epidemic in our country."[158]

349. Moreover, in furtherance of their effort to affirmatively conceal their conduct and avoid detection, pharmaceutical distributors, including McKesson, through their trade associations, HDMA and NACDS, filed an amicus brief in *Masters Pharmaceuticals*, which made the following statements:[159]

a. "HDMA and NACDS members not only have statutory and regulatory responsibilities to guard against diversion of controlled prescription drugs but undertake such efforts as responsible members of society."

[158] Higham *et al*., *supra* note 143.

[159] Brief for HDMA and NACDS, *supra* note 93, 2016 WL 1321983, at *3-4, *25.

b. "DEA regulations that have been in place for more than 40 years require distributors to report suspicious orders of controlled substances to DEA based on information readily available to them (e.g., a pharmacy's placement of unusually frequent or large orders)."

c. "Distributors take seriously their duty to report suspicious orders, utilizing both computer algorithms and human review to detect suspicious orders based on the generalized information that is available to them in the ordering process."

d. "A particular order or series of orders can raise red flags because of its unusual size, frequency, or departure from typical patterns with a given pharmacy."

e. "Distributors also monitor for and report abnormal behavior by pharmacies placing orders, such as refusing to provide business contact information or insisting on paying in cash."

350. Through the above statements made on their behalf by their trade associations, and other similar statements assuring their continued compliance with their legal obligations, McKesson not only acknowledged that it understood its obligations under the law, but it further affirmed that its conduct complied those obligations.

351. Until the Ohio Federal District Court overseeing the Opioid MDL issued its April 11, 2018, order requiring the release of the DEA's ARCOS data to limited recipients, including Plaintiff, Defendants concealed and prevented discovery of information, including data from the ARCOS database, that confirmed their identities, along with other manufacturers and distributors, and the extent of their wrongful and illegal activities.

352. The Manufacturer Defendants distorted the meaning or import of studies they cited and offered them as evidence for propositions the studies did not support. The Manufacturer

Defendants invented "pseudoaddiction" and promoted it to an unsuspecting medical community. The Manufacturer Defendants provided the medical community with false and misleading information about ineffectual strategies to avoid or control opioid addiction. The Manufacturer Defendants recommended to the medical community that dosages be increased, without disclosing the risks. The Manufacturer Defendants spent millions of dollars over a period of years on a misinformation campaign aimed at highlighting opioids' alleged benefits, disguising the risks, and promoting sales. The Manufacturer Defendants duped the medical community, consumers, and the State of Alabama through their campaign to misrepresent and conceal the truth about the opioid drugs that they were aggressively pushing in the State.

353. Defendants intended that their actions and omissions would be relied upon by the State of Alabama, yet the State of Alabama did not have the means to know the truth precisely because of the Defendants' actions and omissions.

354. Plaintiff reasonably relied on Defendants' affirmative statements regarding their purported compliance with their obligations under the law and consent orders.

c. Fraudulent Concealment.

355. The Plaintiff's claims are further subject to equitable tolling, stemming from Defendants' knowingly and fraudulently concealing the facts alleged herein. As alleged herein, Defendants knew of the wrongful acts set forth above, and had material information pertinent to their discovery, and concealed them from Plaintiff. Plaintiff did not know, or could not have known through the exercise of reasonable diligence, of its cause of action because of Defendants' conduct.

356. The purposes of the statutes of limitations period are satisfied because Defendants cannot claim prejudice due to a late filing where the Plaintiff filed suit promptly upon discovering the facts essential to its claims, described herein, which Defendants knowingly concealed.

357. Considering their statements to the media, in legal filings, and settlements, Defendants had actual or constructive knowledge that their conduct was deceptive, in that they consciously concealed the schemes set forth herein

358. Defendants continually and secretly engaged in their scheme to avoid compliance with their legal obligations. Only Defendants and their agents knew or could have known about Defendants' unlawful actions because Defendants made deliberate efforts to conceal their conduct. Because of the above, the Plaintiff was unable to obtain vital information bearing on its claim absent any fault or lack of diligence on its part.

VIII. The Defendants' Conduct Fueled the Opioid Epidemic and Significantly Harmed Alabama.

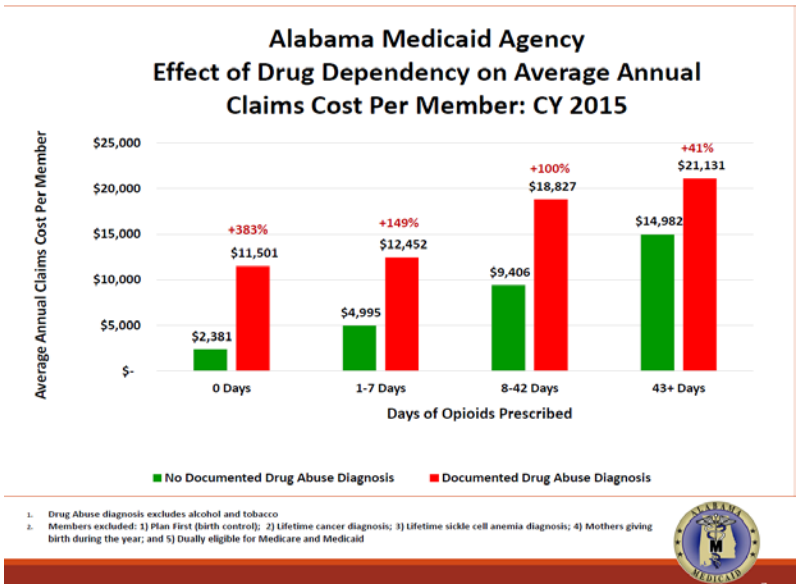
359. While the Defendants have profited greatly from increased sales of their opioids, Alabama and its taxpayers have borne its costs. These costs were imposed, in large measure, by the Defendants and should be borne by them.

360. 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)."[160]

361. 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.[161] In 2015, no fewer than 282 deaths were attributable to opioid overdoses in Alabama.[162]

362. 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 opioids increases.[163]



363. Indeed, the likelihood of continued opioid use correlates with the length of the first

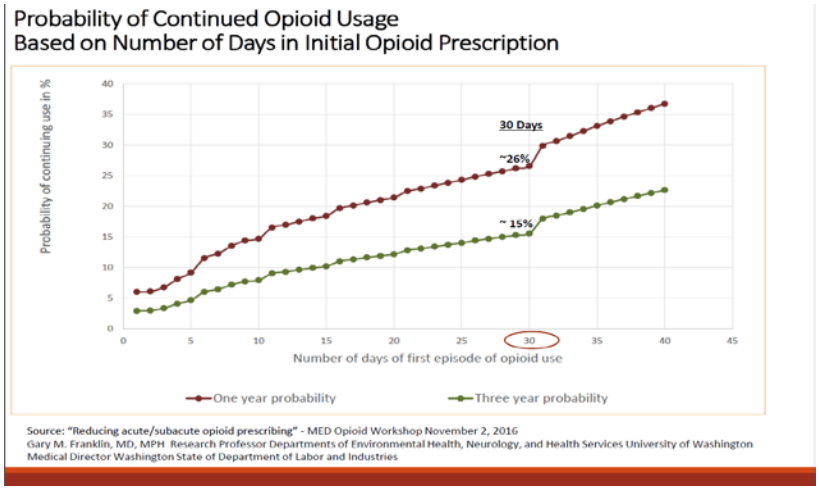
[160] U.S. Dept. of Ag., Economic Information Bulletin 182, Rural America at a Glance (Nov. 2017).

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

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

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

episode of opioid use.[164]



364. 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.

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

366. 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

[164] *Id. See also,* CDC, *Characteristics of Initial Prescription Episodes and Likelihood of Long-Term Opioid Use – United States, 2006-2015*, https://www.cdc.gov/mmwr/volumes/66/wr/pdfs/mm6610a1.pdf.

$234,480,306 in such costs, amounting to $48 per resident.[165]

367. 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.

368. Plaintiff will incur significant expenses in the future to abate the public nuisance caused by the Manufacturer Defendants' deceptive marketing and both their and McKesson's failure to report, investigate, and halt the shipment of suspicious orders as required under law. 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.

369. 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.[166]

370. 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

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

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

encourage the identification, intervention with and treatment of individuals addicted to controlled substances.

CLAIMS FOR RELIEF

COUNT I – PUBLIC NUISANCE
(Against All Defendants)

371. Plaintiff incorporates paragraphs 31-370 as if fully set forth herein.

372. 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).

373. 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.

374. Defendants' 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. Specifically, the Manufacturer Defendants' deceptive marketing of their opioids fueled the ongoing opioid crisis. The Manufacturer Defendants knew opioids were addictive, and the result of their deceptive marketing would lead to patients becoming addicted and those individuals receiving more opioids that furthered that addiction. All Defendants' failure to satisfy their statutory duty to report, investigate, and halt suspicious orders also contributed to the flood of opioids in the State of Alabama

375. 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.

376. 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.

377. Defendants' 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.

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

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

380. As a direct result of Defendants' conduct, Plaintiff and its 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. Plaintiff hereby seeks recovery for its own harm.

381. The State of Alabama and its residents 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.

382. Plaintiff further seeks to abate the nuisance created by Defendants' unreasonable, unlawful, intentional, ongoing, continuing, and persistent actions and omissions and interference with a right common to the public.

383. Plaintiff 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.

384. Plaintiff seeks economic losses (direct, incidental, or consequential pecuniary losses) resulting from Defendants' fraudulent activity and fraudulent misrepresentations.

385. Plaintiff 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 Defendants, attorney fees and costs, and pre- and post-judgment interest.

COUNT II – VIOLATION OF ALABAMA'S DECEPTIVE TRADE PRACTICES ACT (Against All Defendants)

386. Plaintiff incorporates paragraphs 31-370 as if fully set forth herein.

387. As described in those paragraphs, the Defendants engaged in trade or commerce in the State of Alabama.

388. 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.

389. Section 5 of the ADTPA declares certain acts and practices to be unlawful. ALA. CODE § 8-19-5. The Defendants 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).

390. 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)

391. The Manufacturer Defendants 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. Purdue 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. Endo promoting Opana ER as abuse deterrent and "crush-resistant" yet failing to disclose these claims were not supported by the evidence and contrary to FDA findings.

k. 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;

l. Promoting itself as companies that encourage and assist law enforcement while not reporting suspicious prescribing to law enforcement;

m. 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

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

392. McKesson likewise violated the ADTPA by engaging in the following deceptive

conduct:

a. Publicly representing that it was complying with its legal obligations to report, investigate, and halt suspicious orders.

b. Promoting itself as a company that encourages and assists law enforcement while it was actually disregarding its duty to report not reporting suspicious orders.

c. Publicly stating that it has a "best-in-class controlled substance monitoring program to help identify suspicious orders" when, in fact, it ignored outputs of the monitoring program.

d. Misleading the public about the effectiveness of its controlled substances monitoring program.

393. The Defendants' acts and practices were willful and knowingly directed toward a population that included numerous older persons and other vulnerable consumers.

COUNT III – VIOLATION OF THE ALABAMA UNIFORM CONTROLLED SUBSTANCES ACT (Against All Defendants)

394. Plaintiff incorporates paragraphs 31-370 as if fully set forth herein.

395. According to the Centers for Disease Control and Prevention (CDC), Alabama ranks highest in the nation as having more opioid prescriptions than people, with Alabama physicians writing an alarming 5.8 million prescriptions for opioids in 2015. Alabama also ranks as the highest prescribing state in the nation for opioid prescriptions, according to the CDC.

396. Defendant Endo's non-branded U.S. Generic Pharmaceuticals portfolio consists of products primarily focused in pain management through a differentiated portfolio of controlled substances and liquids. That portfolio accounted for 22%, 28%, and 40% of Endo's total revenues

in 2012, 2013, and 2014, respectively. Endo acquired Qualitest Pharmaceuticals, Inc. in 2010, a generic opioid distributor and manufacturer. [redacted] PAR Pharmaceutical manufactures generic Percocet, Roxicodone, Actiq (fentanyl patch), Opana, Norco, and others.

397. The "Alabama Uniform Controlled Substances Act," Ala. Code 1975 §§ 20-2-1 *et seq*, ("the Act" or "the Alabama Act") provides, *inter alia*, that anyone who "manufactures, distributes, or dispenses" any controlled substance in Alabama must obtain annually a registration issued by the certifying boards. ALA. CODE § 20-2-51(a). Such registrants must abide by the terms of their issued registration and act "in conformity with the other provisions of this article." ALA. CODE § 20-2-51(b). Purdue, Endo, and McKesson each are subject to the Act and its provisions and are obligated to comply with the Act's rules and regulations, and have been since the inception of the Act.

398. Specifically, Alabama's State Board of Health Regulation 680-X-3-.05 provides as follows:

> (1) Any manufacturer, wholesaler or distributor of controlled substances doing business in the State of Alabama or who proposes to do business in Alabama shall obtain annually a registration by the Alabama State Board of Pharmacy.
>
> (2) Such manufacturers, wholesalers, or distributors doing business in the State of Alabama who sell, furnish, give away, or otherwise dispose of controlled substances drugs enumerated in Schedule I, II, III, IV, or V or precursor agents used to manufacture such controlled substances to a registrant other than another manufacturer or wholesaler, shall submit to the Alabama State Board of Pharmacy legible copies of records and reports required by the Drug Enforcement Administration concerning increases in purchases or high or unusual volumes purchased by pharmacies within 30 days.

399. Section 20-2-56 of the Act requires registrants to maintain records in conformity

with requirements of federal law and "with any additional rules issued by the State Board of Medical Examiners, the State Board of Health, or the State Board of Pharmacy." Sections 20-2-210 thru 220 created the "Controlled Substances Prescription Database" and imposes mandatory reporting requirements on registrants. Regulation 680-X-3-.05 of the Alabama State Board of Health provides that:

> [M]anufacturers, wholesalers, or distributors doing business in the State of Alabama who sell, furnish, give away, or otherwise dispose of controlled substances . . . shall submit to the Alabama State Board of Pharmacy legible copies of records and reports required by the Drug Enforcement Administration concerning increases in purchases or high or unusual volumes purchased by pharmacies within 30 days.

400. Section 20-2-71(a)(3) provides that "It is unlawful for any person . . . [t]o refuse or fail to make, keep or furnish any record, notification, order form, statement, invoice, or information required under this chapter." Section 20-2-72 further provides as follows:

> (a) It is unlawful for any person:
>
> > (1) To distribute as a registrant a controlled substance classified in Schedules I or II, except pursuant to an order form as required by Section 20-2-57;
> >
> > . . .
> >
> > (4) To furnish false or fraudulent material information in or omit any material information from any application, report, or other document required to be kept or filed under this chapter or any record required to be kept by this chapter.

401. The Act further states "the following things, conditions and acts, among others, are hereby declared to be public nuisances per se, menacing public health and unlawful:

> . . .
>
> (5) Such … acts, things or conditions as may, from time to time, be by the rules and regulations of the State Board of Health declared to be public nuisances per se, menacing public health;

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. . .

> (7) The conducting of a business, trade, industry or occupation or the doing of a thing, not inherently insanitary or a menace to public health, in such a manner as to make it a menace, or likely to become a menace, to public health; and
>
> (8) The conducting of a business, trade or industry or occupation or the doing of a thing lawful, but inherently insanitary or a menace to public health, without complying with safeguards for the protection of health as may, from time to time, be prescribed by the rules and regulations of the State Board of Health.

402. Purdue, Endo, and McKesson have separately and severally combined and concurred in violating Alabama's Controlled Substances Act by, *inter alia*, failing to report suspicious orders of drugs classified as Schedule I and II, by failing to properly register in conformity with Section 20-2-51(b) of Alabama's Act and Alabama State Board of Health Regulation 680-X-3-.05(1), and by failure to report suspicious activity under Alabama's State Board of Health Regulation 680-X-3-.05(2). [redacted]

403. McKesson has a history of illegal conduct concerning the manufacturing and marketing of scheduled drugs in the United States. In January 2017, McKesson, paid a record $150 million to resolve an investigation by the U.S. Department of Justice ("DOJ") for failing to report suspicious orders of certain drugs, including opioids. In addition to the monetary penalty, the DOJ required McKesson to suspend sales of controlled substances from distribution centers in Ohio, Florida, Michigan, and Colorado. The DOJ described these "staged suspensions" as "among the most severe sanctions ever agreed to by a [Drug Enforcement Administration] registered

distributor."

404. As explained above in Section IV(b)(i), McKesson shipped high volumes of opioids throughout Alabama yet failed to comply with its statutory obligation to report and halt suspicious orders. These actions, along with those committed by Purdue and Endo alleged herein, combined and concurred in causing Plaintiff's injuries and damages and, as a result, all Defendants are jointly and severally liable for Plaintiff's damages.

406. Purdue's actions of excessively manufacturing and marketing opioids, as alleged herein, were corrupt because Purdue engaged in the felonious manufacture, buying, selling, or otherwise dealing in controlled substances in such a manner to be punishable by law in Alabama. Specifically, Purdue engaged in the manufacture, buying, selling, marketing, or otherwise dealing in controlled substances in violation of Alabama's Act because Purdue furnished false or fraudulent material information in, and omitted material information from, applications, reports, records, and other document they were required to make, keep, or file or required to be made, kept, or filed under Alabama's Act.

407. Purdue's actions in the excessive manufacture, sale and distribution of prescription

opioids, and in misrepresenting that it was complying with its duties under Alabama's Act, in furnishing false or fraudulent material information in, and omitting material information from, its applications, reports, records and other documents, and by engaging in unlawful sales of opioids that resulted in diversion of controlled substances through suspicious orders, and by refusing to identify or report suspicious orders of controlled substances sales to the DEA[167] and the State of Alabama's Board of Pharmacy, were violative of Alabama's Act.

408. Purdue's violations of law and its pattern of illegal activity directly and indirectly caused injury to the citizens of Alabama and caused the State of Alabama to incur exorbitant, and otherwise needless, extra medical and law enforcement expenses related to Purdue's conduct as specifically alleged in this count and by facts incorporated by reference into this count. Purdue's pattern of corrupt activity logically, substantially, and foreseeably caused and/or contributed in causing an opioid epidemic in Alabama. The injuries and damages, to which the State of Alabama and its citizens were subjected, as described herein, were not unexpected, unforeseen or independent. Rather, Purdue knew that the opioids it excessively manufactured and deceptively marketed would fuel an ever-increasing illicit prescription market, as well as increasing the addiction and death rate.

409. Similar to Endo and McKesson, Purdue has been fined for its illegal activity. 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. Although Purdue did

[167] 21 C.F.R. § 1303.11(b); 21 C.F.R. § 1303.23.

not comply with the terms, 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.

COUNT IV – NEGLIGENCE
(Against All Defendants)

410. Plaintiff incorporates paragraphs 31-370 as if fully set forth.

411. Plaintiff seeks economic damages which were the foreseeable result of Defendants' negligent and/or unlawful actions and omissions.

412. 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.

413. 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, 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)).

414. Defendants owed a duty to Plaintiff, and to the public health and safety in the State of Alabama, because the injury was foreseeable, and in fact foreseen, by Defendants. 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. Defendants owed Plaintiff, and to the public in the State of Alabama, because the injury was foreseeable, and in fact foreseen, by Defendants.

415. 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).

416. 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."

417. Defendants had an obligation to exercise reasonable care in manufacturing, marketing, selling, and distributing highly dangerous opioid drugs to Plaintiff and within the State of Alabama.

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

419. 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.

420. 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 Defendants.

421. Reasonably prudent manufacturers and distributors of pharmaceutical products would know that filling suspicious orders contrary to their enumerated duties under application laws and regulations to report, investigate, and halt such orders would foreseeably result in a flooding of opioids into the State of Alabama thereby causing the opioid epidemic.

422. Moreover, Defendants were repeatedly warned by law enforcement of the unlawfulness and consequences of their actions and omissions.

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

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

425. The Manufacturer Defendants' warnings to prescribing physicians were inadequate and their actions ensured that prescribing physicians were unaware of the risks posed their products, and the prescribing physicians would not have prescribed the products had they informed them of the risks.

426. Defendants breached their duty to prevent diversion and report and halt suspicious orders thereby failing to comply with its legal duties.

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

428. Defendants were selling dangerous drugs statutorily categorized as posing a high potential for abuse and severe dependence. Defendants 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, Defendants breached their duties to monitor for, report, and halt suspicious orders, breached their duties to prevent diversion.

429. Defendants' unlawful and/or negligent actions create a rebuttable presumption of negligence under State law.

430. Plaintiff seeks economic losses (direct, incidental, or consequential pecuniary losses) resulting from Defendants' actions and omissions.

431. Plaintiff 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 damages, and all damages allowed by law to be paid by Defendants, attorney fees and costs, and pre- and post-judgment interest.

COUNT V - UNJUST ENRICHMENT
(Against All Defendants)

432. Plaintiff incorporates paragraphs 31-370 as if fully set forth herein.

433. Defendants have unjustly retained a benefit to Plaintiff's detriment, and Defendants' retention of that benefit violates the fundamental principles of justice, equity, and good conscience.

434. As alleged herein, Plaintiff has used public funds to reimburse opioid prescriptions covered by the State of Alabama's employee health plan and state Medicaid Program. Due to Defendants' 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, Plaintiff has suffered, and continues to cope with, a crisis of opioid addiction, overdose, injury, and death that Defendants helped create and perpetuate.

435. Defendants have reaped revenues and profits from Plaintiff's payments, enriching themselves at Plaintiff's expense. This enrichment was without justification, and the State of

Alabama lacks an adequate remedy provided by law.

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

COUNT VI – WANTONNESS
(Against all Defendants)

437. Plaintiff incorporates paragraphs 31-370 as if fully set forth herein.

438. The Manufacturer Defendants consciously, recklessly, and willfully failed to inform prescribing physicians and the general public of the addictive nature of prescription opioids and their lack of suitability for chronic pain. Defendants also failed to maintain a system to prevent diversion of its opioids by failing to monitor, report, halt, and divert suspicious orders. Defendants were 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.

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

440. The Manufacturer Defendants were manufacturing and selling, and all Defendants were distributing, dangerous drugs statutorily categorized as posing a high potential for abuse and

severe dependence. Thus, Defendants 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, Defendants owed a high duty of care to ensure that these drugs were only used for proper medical purposes. Defendants chose profit over prudence and the safety of Plaintiff.

441. By engaging in the above-described wrongful conduct, Defendants 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.

442. 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, Plaintiff prays for judgment against Defendants, as permitted by Alabama law, as follows:

443. For a declaration that the Defendants have violated Alabama's Deceptive Trade Practices Act;

444. For injunctions enjoining the Defendants 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;

445. For a finding of a public nuisance and an order of abatement and permanent injunction against all Defendants prohibiting them from engaging in the unlawful conduct detailed herein, including the over-promotion and over-supply of opioids in and around Alabama, failure to monitor and prevent diversion of opioids in and around Alabama, the entry of any appropriate

orders and judgments imposing reasonable restrictions upon the future activities of Defendants, including, but not limited to, prohibiting any Defendant from engaging in the same type of endeavor(s) and, further, for injunctive relief to curtail Defendants' false advertising and marketing of opioids and failure to adequately monitor against the diversion of opioids.

446. For a declaration that all Defendants have violated the Alabama Uniform Controlled Substances Act;

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

448. 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; For an order directing the Defendants to pay compensatory and punitive damages to the State for their violations of the Alabama Deceptive Trade Practices Act, the public nuisance all Defendants created through their negligence and/or wantonness.

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

450. For all monetary damages recoverable under Alabama law for the claims brought by the State.

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

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

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JURY DEMAND

Plaintiff hereby demands a trial by jury on all issues of this cause.

Dated this 20th day of June, 2019.

Respectfully submitted,

Steve Marshall
Attorney General

By:

/s/ Rhon E. Jones
Rhon E. Jones
Deputy Attorney General

/s/ Joshua P. Hayes
Joshua P. Hayes
Deputy Attorney General

Attorneys for Plaintiff, State of Alabama

ADDRESS OF COUNSEL:

Steve Marshall
Attorney General

Michael G. Dean
Assistant Attorney General

Winfield J. Sinclair
Assistant Attorney General

Office of the Attorney General of Alabama
501 Washington Avenue
Montgomery, AL 36130
Phone: (334) 242-7300
Fax: (334) 242-4891
mdean@ago.state.al.us
wsinclair@ago.state.al.us

REDACTED VERSION

OF COUNSEL:

Jere L. Beasley – ASB 1981A35J
Rhon E. Jones – ASB 7747E52R
J. Parker Miller – ASB 7363H53M
Richard D. Stratton – ASB 3939T76R
William R. Sutton – ASB 3903L74S
J. Ryan Kral – ASB 9669N70K
Jeff Price – ASB 8190F60P

Beasley, Allen, Crow, Methvin, Portis & Miles, P.C.
218 Commerce Street
Post Office Box 4160 (36103-4160)
Montgomery, Alabama 36104
Telephone: (334) 269-2343
Fax: (334) 954-7555
Jere.Beasley@BeasleyAllen.com
Rhon.Jones@BeasleyAllen.com
Parker.Miller@BeasleyAllen.com
Rick.Stratton@BeasleyAllen.com
William.Sutton@BeasleyAllen.com
Ryan.Kral@BeasleyAllen.com
Jeff.Price@BeasleyAllen.com

Robert F. Prince – ASB-2570-C56R
Joshua P. Hayes – ASB-4868-H68H

Prince Glover Hayes
1 Cypress Point
701 Rice Mine Road North
Tuscaloosa, Alabama 35406
Telephone: (205) 345-1234
Fax: (205) 752-6313
rprince@princelaw.net
jhayes@princelaw.net