

NO. D-1-GN-18-002403

STATE OF TEXAS,	§	IN THE DISTRICT COURT OF
	§	
Plaintiff,	§	
	§	
v.	§	
	§	
PURDUE PHARMA L.P.; PURDUE	§	TRAVIS COUNTY, TEXAS
PHARMA INC.; THE PURDUE	§	
FREDERICK COMPANY, INC.; and	§	
PURDUE TRANSDERMAL	§	
TECHNOLOGIES L.P.,	§	
	§	
Defendants.	§	345TH
		_____ JUDICIAL DISTRICT

**STATE OF TEXAS’S ORIGINAL PETITION**

**TO THE HONORABLE JUDGE OF SAID COURT:**

Plaintiff, the STATE OF TEXAS (“Plaintiff” or “State”), acting by and through the Attorney General of Texas, KEN PAXTON, files this petition complaining of Defendants **PURDUE PHARMA L.P.; PURDUE PHARMA INC.; THE PURDUE FREDERICK COMPANY, INC.;** and **PURDUE TRANSDERMAL TECHNOLOGIES L.P.** (“Purdue” or “Defendants”) seeking civil penalties and injunctive relief to stop the deceptive marketing of prescription opioid drugs and the misrepresentation of the risk of addiction, potential benefits, effectiveness, and potential side effects associated with the use of these drugs in order to protect the public as follows:

**I. INTRODUCTION**

1.1 Addiction to opioids is a serious national public health crisis. More than three hundred fifty thousand (350,000) people have died from opioid-related overdoses in the United States since

1999; five times as many people died from opioid-related overdoses in 2016 as in 1999.<sup>1</sup> This startling rise in the number of deaths attributable to opioids did not occur by happenstance. It resulted in large measure from a company's decision to aggressively and deceptively market OxyContin and misrepresent the most serious side effect of opioids—addiction. That company is Purdue.

1.2 Once Purdue began its campaign to aggressively push a highly addictive drug to the masses as safe and effective for moderate to severe chronic pain—without adequately disclosing the high risk of addiction—other manufacturers followed suit. But Purdue dwarfed its competitors in sales volume and profits. Purdue's aggressive and deceptive marketing efforts yielded staggering profits, and OxyContin became one of the most prescribed narcotics in the country. Purdue has realized over \$35 billion in sales from OxyContin since it began marketing the drug in 1996. In 2015, Purdue's owners, the Sackler family, entered the Forbes' "Richest U.S. Families" list.<sup>2</sup>

1.3 The results of Purdue's widespread marketing campaign to push a highly addictive drug for a common health issue produced disastrous consequences. The explosion in availability of highly addictive prescription opioids has established the United States as a consumer of 99% of the world's supply of hydrocodone and 70% of the world's supply of oxycodone.<sup>3</sup> And prescription opioids are a driving factor behind the sixteen-year increase in opioid overdose deaths.

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<sup>1</sup> *Opioid Overdose—Understanding the Epidemic*, DIV. OF UNINTENTIONAL INJURY, CTRS. FOR DISEASE CONTROL & PREVENTION (Aug. 17, 2017), <https://www.cdc.gov/drugoverdose/epidemic/index.html> [hereinafter *CDC Opioid Overdose*].

<sup>2</sup> Alex Morrell, *The OxyContin Clan: The \$14 Billion Newcomer to Forbes 2015 List of Richest U.S. Families*, FORBES: LISTS (July 1, 2015, 10:17 AM), <https://www.forbes.com/sites/alexmorrell/2015/07/01/the-oxycontin-clan-the-14-billion-newcomer-to-forbes-2015-list-of-richest-u-s-families/#6d3667fc75e0>.

<sup>3</sup> U.N. INT'L NARCOTICS CONTROL BOARD, REPORT 2017, ESTIMATED WORLD REQUIREMENTS FOR 2018—STATISTICS FOR 2016, at 36–37, U.N. Doc. E/INCB/2017/2, U.N. Sales No. T.18.XI.5 (2017), [https://www.incb.org/documents/Narcotic-Drugs/Technical-Publications/2017/Narcotic\\_drugs\\_technical\\_publication\\_2017.pdf](https://www.incb.org/documents/Narcotic-Drugs/Technical-Publications/2017/Narcotic_drugs_technical_publication_2017.pdf).

1.4 Purdue's deceptive efforts to market long-acting opioids as routine treatment for moderate to severe chronic pain have exacted a devastating human toll in Texas. From 1999 to 2015, Texas experienced a 3.5-fold increase in the number of opioid-related deaths.<sup>4</sup> In 2017, the Texas legislature found that deaths resulting from the use of opioids constitute a public health crisis and confirmed the State's compelling interest in closely regulating the prescribing of these drugs.<sup>5</sup> Almost 17,000 Texans have died in opioid-involved deaths.<sup>6</sup> The casualties continue to mount.

1.5 This enforcement action, instituted by Attorney General Ken Paxton through the Consumer Protection Division, is directed at the primary actor involved in the manufacture, sale, and marketing of prescription opioids: Purdue. OxyContin, the first blockbuster extended-release formulation with an indication for moderate to severe chronic pain, was the brainchild of Purdue, and Purdue's deceptive marketing and promotion of OxyContin and other extended-release opioids, is a leading cause of the current crisis.

1.6 Since 1996, and continuing to the present, Purdue manufactured, sold, and marketed extended-release opioids, including its blockbuster opioid drug, OxyContin. In violation of Texas law, Purdue used false, misleading, and deceptive acts and practices to promote these products through a sophisticated and targeted marketing scheme aimed at consumers and health care providers alike.

1.7 In the course of promoting its array of opioid medications, Purdue materially misrepresented crucial information about these powerful drugs. As set forth below in the State of

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<sup>4</sup> *Texas Health Data: Opioid-Related Deaths in Texas*, CTR. FOR HEALTH STATISTICS, TEX. DEP'T OF ST. HEALTH SERVS., <http://healthdata.dshs.texas.gov/Opioids/Deaths> (last visited May 10, 2018) (hereinafter *Opioid-Related Deaths in Texas*).

<sup>5</sup> Tex. Occ. Code § 168.003.

<sup>6</sup> *Opioid-Related Deaths in Texas*, *supra* note 4.

Texas's Petition, through aggressive and sophisticated marketing, Purdue violated Texas consumer protection law by:

- misrepresenting or failing to adequately disclose the risk of addiction of opioids;
- misrepresenting the potential for abuse of opioids;
- misrepresenting the abuse-deterrent formulation properties of opioids;
- misrepresenting the therapeutic benefits of opioids;
- misrepresenting or failing to adequately disclose the material risks of opioids;
- making false, unsubstantiated representations about the concept of "pseudoaddiction";
- misrepresenting the signs of addiction to opioids;
- misrepresenting the ease of preventing addiction in patients taking opioids;
- misrepresenting the efficacy of opioids in treating long-term moderate to severe chronic pain; and
- misrepresenting the safety of treating pain with opioids.

1.8 Purdue's deceptive marketing campaign was fueled by greed and disregard for its consequences. Even as the opioid crisis reached its zenith, Purdue continued to deceptively market prescription opioid products. While this enforcement action cannot fully remedy the damage inflicted by Purdue, it is a first step towards holding a dominant and unrepentant actor in the prescription opioid crisis accountable for its deceptive conduct in Texas and the ruinous consequences that inevitably followed.

## **II. DISCOVERY**

2.1 Plaintiff intends to conduct discovery under Level 3 of Texas Rule of Civil Procedure 190.4 and affirmatively pleads that this case is not governed by the expedited-actions process in Texas Rule of Civil Procedure 169 for the following reasons:

- (a) The relief sought includes non-monetary injunctive relief; and
- (b) The claims for monetary relief—including penalties, costs, expenses, and attorneys’ fees—is in excess of \$100,000.

## **III. JURISDICTION AND STATUTORY AUTHORITY**

3.1 This enforcement action is brought by Attorney General Ken Paxton, through his Consumer Protection Division, in the name of the STATE OF TEXAS and in the public interest pursuant to the authority granted by § 17.47 of the Texas Deceptive Trade Practices—Consumer Protection Act, Tex. Bus. & Com. Code §§ 17.41–17.63 (“DTPA”), upon the ground that Defendants have engaged in false, deceptive, and misleading acts and practices in the course of trade and commerce as defined in, and declared unlawful by, § 17.46(a) and (b) of the DTPA.

## **IV. PUBLIC INTEREST AND NOTICE**

4.1 Plaintiff has reason to believe that Defendants have engaged in, and will continue to engage in, the unlawful practices set forth in this petition.

4.2 Plaintiff has reason to believe Defendants have caused and will cause immediate, irreparable injury, loss, and damage to the State of Texas by deceptively marketing prescription opioids to consumers while misrepresenting the risk of addiction, potential benefits, effectiveness, and potential side effects. Therefore, these proceedings are in the public interest. *See* DTPA § 17.47(a).

4.3 Plaintiff informed Defendants herein at least seven (7) days before instituting this action of the alleged unlawful conduct of which complaint is now made.

## V. VENUE

5.1 Venue of this suit lies in Travis County, Texas, under DTPA § 17.47(b), for the following reasons:

- (a) Transactions forming the basis of this suit occurred in Travis County, Texas; and
- (b) Defendants have done business in Travis County, Texas.

## VI. TRADE AND COMMERCE

6.1 At all times described below, Defendants and their agents have engaged in conduct constituting “trade” and “commerce,” defined in § 17.45(6) of the DTPA, as follows:

“Trade” and “commerce” mean the advertising, offering for sale, sale, lease, or distribution of any good or service, of any property, tangible or intangible, real, personal, or mixed, and any other article, commodity, or thing of value, wherever situated, and shall include any trade or commerce directly or indirectly affecting the people of this state.

## VII. CLAIM FOR RELIEF

7.1 The State’s claims for monetary relief including penalties and attorneys’ fees and costs are in excess of \$100,000 and could exceed \$1,000,000. The State also seeks nonmonetary, injunctive relief.

## VIII. DEFENDANTS

8.1 Defendant **Purdue Pharma L.P.** is a foreign limited partnership organized and existing under the laws of Delaware that engages in business in the State of Texas with its principal place of business in Connecticut. The registered agent for Purdue Pharma L.P. is Corporation Service Company dba CSC at 211 E. 7th St., Suite 620, Austin, Texas 78701-3218. Defendant Purdue

Pharma L.P. may be served with process by serving its Registered Agent, Corporation Service Company dba CSC at 211 E. 7th St., Suite 620, Austin, Texas 78701-3218.

8.2 Defendant **Purdue Pharma Inc.** is a foreign corporation organized and existing under the laws of the State of New York that engages in business in the State of Texas, but has not designated and does not maintain a resident agent within the State of Texas. Defendant Purdue Pharma Inc.'s principal office is One Stamford Forum, Stamford, Connecticut 06901. Defendant Purdue Pharma Inc. may be served with process by serving the Secretary of State for the State of Texas, 1019 Brazos Street, Austin, Texas 78701, as its agent for service of process because Purdue Pharma Inc. has not designated or maintained a resident agent for service of process in Texas, as required by statute. Tex. Civ. Prac. & Rem. Code Ann. §§ 17.044(a)(1) and 17.045.

8.3 Defendant **The Purdue Frederick Company, Inc.** is a foreign corporation organized and existing under the laws of New York that engages in business in the State of Texas, but has not designated and does not maintain a resident agent within the State of Texas. Defendant The Purdue Frederick Company Inc.'s principal office is One Stamford Forum, Stamford, Connecticut 06901. Defendant The Purdue Frederick Company Inc. may be served with process by serving the Secretary of State for the State of Texas, 1019 Brazos Street, Austin, Texas 78701, as its agent for service of process because The Purdue Frederick Company, Inc. has not designated or maintained a resident agent for service of process in Texas, as required by statute. Tex. Civ. Prac. & Rem. Code Ann. §§ 17.044(a)(1) and 17.045.

8.4 Defendant **Purdue Transdermal Technologies L.P.** is a foreign limited partnership organized and existing under the laws of Delaware that engages in business in the State of Texas, but has not designated and does not maintain a resident agent within the State of Texas. Purdue Transdermal Technologies L.P.'s principal place of business is One Stamford Forum, Stamford

CT 06901. Defendant Purdue Transdermal Technologies L.P. may be served with process by serving the Secretary of State for the State of Texas, 1019 Brazos Street, Austin, Texas 78701, as its agent for service of process because Purdue Transdermal Technologies L.P. has not designated or maintained a resident agent for service of process in Texas, as required by statute. Tex. Civ. Prac. & Rem. Code Ann. §§ 17.044(a)(1) and 17.045.

## **IX. ACTS OF AGENTS**

9.1 Whenever in this petition it is alleged that Purdue or Defendants did any act, it is meant that Purdue or Defendants:

- (a) Performed or participated in the act; or
- (b) Their officers, successors in interest, agents, partners, trustees, or employees performed or participated in the act on behalf of and under the authority of one or more of the Defendants.

## **X. FACTUAL BACKGROUND**

### ***The Prescription Opioid Epidemic: An Overview.***

10.1 The overprescribing of opioids—and the carefully-orchestrated marketing efforts to downplay their risks—has caused a serious national public health crisis. On average, 115 Americans die each day from an opioid overdose, and two-thirds of all drug overdose deaths in the United States involve an opioid.<sup>7</sup> Drug overdose deaths and opioid-involved deaths continue to increase in the United States.<sup>8</sup> In 2016, the number of overdose deaths involving opioids

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<sup>7</sup> *Opioid Overdose Crisis*, NAT'L INST. ON DRUG ABUSE, <https://www.drugabuse.gov/drugs-abuse/opioids/opioid-overdose-crisis> (last visited May 13, 2018); see Rose A. Rudd, Puja Seth, Felicita David & Lawrence Scholl, *Increases in Drug and Opioid-Involved Overdose Deaths—United States, 2010–2015*, 65 CDC MORBIDITY & MORTALITY WKLY REP. 1445–52 (2016), <https://www.cdc.gov/mmwr/volumes/65/wr/pdfs/mm655051.pdf>.

<sup>8</sup> *CDC Opioid Overdose*, *supra* note 1.

(including prescription opioids and heroin) was five times higher than in 1999.<sup>9</sup> From 2000 to 2016, more than 600,000 people died from drug overdoses.<sup>10</sup>

10.2 Prescription opioids are a driving factor in the 16-year increase in opioid overdose deaths. According to the Centers for Disease Control (“CDC”), the amount of prescription opioids sold by pharmacies, hospitals, and doctors’ offices nearly quadrupled between 1999 and 2010,<sup>11</sup> yet at the same time, there was no overall change in the amount of pain that Americans reported. Deaths from prescription opioids—drugs like oxycodone, hydrocodone, and methadone—have more than tripled since 1999.<sup>12</sup> The vast increases in prescription opioid availability have resulted in severe consequences related to their abuse.

10.3 Texas has not escaped the prescription opioid crisis. The use of prescription opioids in Texas has skyrocketed. In 2014, for every 100 Texas residents, 67 opioid prescriptions were dispensed.<sup>13</sup> And in some Texas counties, the number of opioid prescriptions substantially exceed the actual number of county residents.<sup>14</sup>

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<sup>9</sup> *Id.*

<sup>10</sup> *Id.*; Puja Seth, Lawrence Scholl, Rose A. Rudd & Sarah Bacon, *Vital Signs: Overdose Deaths Involving Opioids, Cocaine, and Psychostimulants—United States, 2015–2016*, 67 CDC MORBIDITY & MORTALITY WKLY REP. 349, 351 (2018), <https://www.cdc.gov/mmwr/volumes/67/wr/pdfs/mm6712a1-H.pdf>.

<sup>11</sup> Leonard J. Paulozzi, Christopher M. Jones, Karin A. Mack & Rose A. Rudd, *Vital Signs: Overdoses of Prescription Opioid Pain Relievers—United States, 1999–2008*, 60 CDC MORBIDITY & MORTALITY WKLY REP. 1487, 1489 (2011), <https://www.cdc.gov/mmwr/pdf/wk/mm6043.pdf>.

<sup>12</sup> *Id.* at 1487.

<sup>13</sup> *Opioid Overdose: U.S. State Prescribing Rates, 2014*, DIV. OF UNINTENTIONAL INJURY, CTRS. FOR DISEASE CONTROL & PREVENTION (July 31, 2017), <https://www.cdc.gov/drugoverdose/maps/rxstate2014.html>.

<sup>14</sup> *Opioid Overdose: U.S. County Prescribing Rates, 2014*, DIV. OF UNINTENTIONAL INJURY, CTRS. FOR DISEASE CONTROL & PREVENTION (July 31, 2017), <https://www.cdc.gov/drugoverdose/maps/rxcounty2014.html>.

10.4 Prescription opioids present a serious abuse and addiction risk. In 2013, the FDA found that most opioid drugs have a “high potential for abuse” and that opioids are associated with a substantial risk of misuse, addiction, overdose, neonatal complications, and death.<sup>15</sup>

10.5 A major cause of the increase in opioid availability is Purdue. In the 1980s, Purdue marketed the first long-acting opioid medication, MS Contin, in the United States.<sup>16</sup> MS Contin, which contains morphine, was primarily used for pain relief in patients that suffered from cancer and terminal illnesses.<sup>17</sup> In the early 1990s, Purdue used the same timed-release mechanism in MS Contin to create OxyContin, which contains oxycodone, an opioid that is twice the strength of morphine.<sup>18</sup> Purdue aimed to expand OxyContin’s market beyond cancer treatment and terminal illnesses.<sup>19</sup> Purdue then marketed OxyContin as an opioid that, according to its label, could be taken every twelve hours to treat moderate to severe chronic pain.<sup>20</sup> It was the first of the oral extended-release opioid drugs indicated for moderate to severe chronic pain and was soon a blockbuster for Purdue, generating over \$30 billion in revenue in the last twenty years.<sup>21</sup> As it launched OxyContin in the marketplace, Purdue ramped up marketing efforts to health care

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<sup>15</sup> Resp. to Physicians for Responsible Opioid Prescribing Citizen Pet., CTR. FOR DRUG EVALUATION & RES., U.S. FOOD & DRUG ADMIN., No. FDA-2012-P-0818, at 1, 8 (Sept. 10, 2013), <https://www.regulations.gov/document?D=FDA-2012-P-0818-0793>.

<sup>16</sup> Christopher Glazek, *The Secretive Family Making Billions from the Opioid Crisis*, ESQUIRE (Oct. 16, 2017), <https://www.esquire.com/news-politics/a12775932/sackler-family-oxycontin/>; Sam Quinones, *DREAMLAND: THE TRUE TALE OF AMERICA’S OPIOID EPIDEMIC* 155–59 (2015) (ebook).

<sup>17</sup> Glazek, *supra* note 16.

<sup>18</sup> *Id.*

<sup>19</sup> *Id.*

<sup>20</sup> *Id.*; 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>; Harriet Ryan, Lisa Girion & Scott Glover, ‘You Want a Description of Hell?’ *OxyContin’s 12-Hour Problem*, L.A. TIMES (May 5, 2016), <http://www.latimes.com/projects/oxycontin-part1/> [hereinafter *OxyContin’s 12-Hour Problem*].

<sup>21</sup> *OxyContin’s 12-Hour Problem*, *supra* note 20.

providers, disseminating the message that pain was undertreated; that opioids were non-addictive; that patients deserved to be pain free; and that its opioids were superior to non-opioids for pain relief. Prior to the release of OxyContin, prescription opioids had been used only to treat severe pain immediately after surgery and for end-of-life care because health care providers feared the risk of addiction resulting from prolonged use of opioid drugs.<sup>22</sup>

10.6 Following the successful release of OxyContin, Purdue developed and introduced other extended-release/long-acting opioid-containing prescription drugs to its formulary, including Butrans, Hysingla, Ryzolt, and Targiniq. Building off OxyContin’s success, Purdue followed the same playbook with these drugs—pushing the message that pain was undertreated, minimizing the risk of addiction, and claiming that addiction risk could be carefully screened. Purdue persisted in its effort to expand the market for its extended-release opioid drugs, misleadingly promoting benefits such as “no ceiling dose,” a lack of side effects as compared to nonsteroidal anti-inflammatory drugs (“NSAIDs”), and the ability to take fewer doses a day as compared to short-acting opioids—despite having little to no evidence to support these claims. Purdue made them available to health care providers and patients through its sales representatives, advertising campaigns conducted through third-parties, and unbranded promotional materials, fueling the opioid crisis in the United States and Texas.

***Purdue Deceptively Marketed Prescription Opioids in Texas.***

**Purdue Misrepresented the Risk of Addiction to Prescription Opioids.**

10.7 In promoting its long-acting opioids, Purdue minimized or omitted discussion with doctors of the risk of addiction and misrepresented the potential for abuse of its opioid prescription drugs with purportedly abuse-deterrent formulations. To promote OxyContin, Purdue trained its sales

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<sup>22</sup> Glazek, *supra* note 16.

representatives to carry the message that the risk of addiction was less than one percent and provided educational materials to physicians stating that the risk of addiction was extremely small, even though these claims were unsupported by scientific evidence.<sup>23</sup>

10.8 Purdue also funded or sponsored a variety of publications and third-party groups, like the American Pain Foundation (“APF”), as part of its aggressive campaign to push its highly addictive opioids to the masses while downplaying the risk of addiction.<sup>24</sup> APF was almost entirely funded by Purdue and other drug companies.<sup>25</sup> Purdue sponsored APF’s “Treatment Options: A Guide for People Living with Pain,” a publication that touted prescription opioids as under-used pain treatment options and omitted mention of the risk of addiction, even in instances when the drugs are used as directed under medical supervision. APF’s “A Policy Maker’s Guide to Understanding Pain & its Management” represents that “less than 1 percent of children treated with opioids become addicted” and that pain is undertreated due to “misconceptions about opioid addiction.” Both publications are still available on-line. Other APF publications misrepresented and downplayed addiction risks. For example, the publication “Getting the Help You Need” asserts: “studies and clinical practice have shown that the risk of addiction is small when [opioids] are appropriately prescribed and taken as directed” and “[the] chance of addiction is low when pain medicines are properly prescribed and taken as directed.” Another Purdue-sponsored publication,

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<sup>23</sup> Art Van Zee, *The Promotion and Marketing of OxyContin: Commercial Triumph, Public Health Tragedy*, 99 Am. J. Pub. Health 221 (2009), available at <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC2622774/>.

<sup>24</sup> Charles Ornstein & Tracy Weber, *American Pain Foundation Shuts Down as Senators Launch Investigation of Prescription Narcotics*, PROPUBLICA (May 8, 2012 at 8:57 AM), <https://www.propublica.org/article/senate-panel-investigates-drug-company-ties-to-pain-groups> [hereinafter *APF Shuts Down*]; Charles Ornstein & Tracy Weber, *The Champion of Painkillers*, PROPUBLICA (Dec. 23, 2011 at 9:15 AM), <https://www.propublica.org/article/the-champion-of-painkillers>.

<sup>25</sup> *APF Shuts Down*, *supra* note 24.

“Commonly Asked Questions and Answers,” tells providers to “[k]eep in mind, pain medicine in and of itself does not cause someone to become addicted.”

10.9 Purdue’s unbranded “In the Face of Pain” campaign promoted the concept of “undertreatment of pain,” and included on its website a “Pain Care Bill of Rights” that touted the following message to pain sufferers: “Knowledge is power. Many people living with pain and even some health care providers believe that opioid medications are addictive. The truth is that when properly prescribed by a health care professional and taken as directed, these medications give relief—not a ‘high.’” Purdue misled the public for years through this campaign’s website by failing to disclose that from 2008 to 2013, it provided financial compensation to the doctors and other health care professionals whose testimonials appeared on the site. On information and belief, this website was accessed by Texas residents thousands of times before Purdue removed the profiles of the paid “advocates” in 2015.<sup>26</sup>

**Purdue Promoted the Unsubstantiated Concept of “Pseudoaddiction” to Deceptively Market its Opioids.**

10.10 Purdue falsely represented that many individuals who exhibited signs of addiction to opioids were actually experiencing “pseudoaddiction.” The term “pseudoaddiction” was coined by Dr. David Haddox, who later became Purdue’s Vice President, to describe the purported inaccurate interpretation of drug-seeking behaviors in patients with ineffectively treated pain. This novel and unproven concept was advanced through published articles funded by opioid manufacturers, including Purdue. Despite abandonment of this concept by some of its proponents and a lack of empirical validation in scientific literature, Purdue persisted in its promotion of higher doses of opioids to treat patients with drug-seeking behaviors.

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<sup>26</sup> Pat Anson, *Purdue Pharma’s ‘Misleading’ Websites*, PAIN NEWS NETWORK (Aug. 21, 2015), <https://www.painnewsnetwork.org/stories/2015/8/21/purdue-pharmas-misleading-websites>.

10.11 As recently as 2011, Purdue published a pamphlet entitled “Providing Relief, Preventing Abuse,” which deceptively instructed health care providers to focus on less common manifestations of OxyContin addiction, while downplaying the more common signs of addiction associated with OxyContin. Purdue sought to create the false impression that addiction stemmed only from illicit use of opioid medications. On information and belief, Purdue sales representatives distributed thousands of these pamphlets to prescribers nationwide, including in Texas. Another publication sponsored by Purdue, titled “Responsible Opioid Prescribing,” asserts behaviors such as requesting drugs by name, being demanding or manipulative, seeing multiple doctors to obtain opioids, and hoarding drugs are all signs of “pseudoaddiction,” rather than true addiction. The 2012 edition of this publication remains accessible on-line.

10.12 Purdue also promoted the concept of “pseudoaddiction” through its Continuing Medical Education programs (“CME”). Through its CMEs, Purdue sought to downplay common, recognized clinical symptoms of opioid addiction, and substitute an alternative explanation: the unproven concept of “pseudoaddiction.”

10.13 Purdue also disseminated the concept of “pseudoaddiction” by providing doctors with CD-ROMs such as “Complexities of Caring for People in Pain.” Through its “Complexities” campaign, Purdue represented that untreated or undertreated pain reached epidemic proportions, comprising a serious problem in America, and described “pseudoaddiction” as a direct consequence of inadequate pain management. Purdue distributed copies of another CD-ROM, “Consensus Paper: Definitions Related to the Use of Opioids for the Treatment of Pain,” in which it defines “pseudoaddiction” as a “term to describe patient behaviors that may occur when a pain is undertreated” and “can be distinguished from true addiction in that the behaviors resolve when

pain is effectively treated.” Purdue disseminated the same definition of “pseudoaddiction” in its publication, “Clinical Issues in Opioid Prescribing.”

**Purdue Misrepresented the Signs of Addiction and the Ease of Preventing Addiction.**

10.14 Besides promoting the unproven concept of “pseudoaddiction” through webinars, publications, and CME programs, Purdue also downplayed the difficulties associated with addiction prevention. Purdue’s deceptive messaging misrepresented the true risk of addiction posed by long-term opioid use by *any* patient by falsely creating the impression that “problem” patients that were likely to become addicted could be accurately identified and screened out.<sup>27</sup> In 2011, Purdue sponsored a webinar, “Managing Patient’s Opioid Use: Balancing the Need and Risk,” in which it claimed that screening tools, urine tests, and patient agreements prevent “overuse of prescriptions” and “overdose deaths.”<sup>28</sup> But Purdue’s representations about the accuracy of patient screening were false. In fact, the CDC found that studies on the accuracy of screening tools and other mechanisms for identifying and predicting risk of addiction were “extremely inconsistent” and noted that “currently available tools do not allow clinicians to reliably identify patients who are at low risk for substance abuse disorder.”<sup>29</sup> Purdue also sponsored APF’s “A Policy Maker’s Guide to Understanding Pain & Its Management,” which claimed that “symptoms of physical dependence can often be ameliorated by gradually decreasing the dose of medication

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<sup>27</sup> Purdue falsely represented that a screening tool developed by Dr. Lynn Webster, a Purdue “Key Opinion Leader” (“KOL”), could effectively screen patients for their risk of addiction.

<sup>28</sup> MEDICOM WORLDWIDE, INC., *CE Education, Managing Patient’s Opioid Use: Balancing the Need and the Risk, EMERGING SOLUTIONS IN PAIN*, [http://www.emergingsolutionsinpain.com/ce-education/opioid-management?option=com\\_continued&view=frontmatter&Itemid=303&course=209](http://www.emergingsolutionsinpain.com/ce-education/opioid-management?option=com_continued&view=frontmatter&Itemid=303&course=209) (last visited May 10, 2018).

<sup>29</sup> Deborah Dowell, Tamara M. Haegerich & Roger Chou, *CDC Guideline for Prescribing Opioids for Chronic Pain—United States, 2016*, 65 CDC MORBIDITY & MORTALITY WKLY REP.: RECOMMENDATIONS & REPS., March 18, 2016, at 1, 10–11, 31, <https://www.cdc.gov/mmwr/volumes/65/rr/pdfs/rr6501e1.pdf> [hereinafter *CDC Guideline*].

during discontinuation,” while failing to mention common complications that might occur, such as withdrawal.

10.15 Purdue sponsored APF’s “Treatment Options: A Guide for People Living with Pain,” a publication that asserted that some patients “need” a larger dose of an opioid, regardless of the dose currently prescribed. Through this publication, Purdue disseminated the astounding claim that its powerful opioid medications have “no ceiling dose,” i.e., *there is no upper dosage of an opioid that is unsafe*, and that opioids are the most appropriate treatment for severe pain. APF’s “A Policy Maker’s Guide to Understanding Pain & Its Management” asserted dosage escalations are “sometimes necessary,” even unlimited ones, but failed to disclose the risks associated with the use of high-dose opioids. A Purdue-sponsored CME entitled “Overview of Management Options,” which was edited by a KOL, taught that competing NSAIDs such as Motrin, aspirin, and other drugs—but not opioids—are unsafe at high dosages. This CME is still available for credit.

**Purdue Falsely Represented the Abuse-Deterrent Properties of its Opioids.**

10.16 Purdue represented to health care providers that its abuse-deterrent formula (“ADF”) prevented abuse despite the lack of scientific evidence to support that claim.<sup>30</sup> Purdue KOLs gave presentations to providers claiming ADFs “make opioids [they] prescribe harder to abuse—and make all clinicians part of the solution to prescription opioid abuse.” Moreover, Dr. Gerald

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<sup>30</sup> *Strong Track Record of Addressing Prescription Drug Abuse and Diversion*, PURDUE PHARMA, [http://www.purduepharma.com/wp-content/pdfs/Purdue\\_Pharma\\_Strong\\_Track\\_Record\\_of\\_Addressing\\_Prescription\\_Drug\\_Abuse\\_and\\_Diversion.pdf](http://www.purduepharma.com/wp-content/pdfs/Purdue_Pharma_Strong_Track_Record_of_Addressing_Prescription_Drug_Abuse_and_Diversion.pdf) (last visited May 10, 2018); *Statement of Purdue Pharma L.P. Regarding FDA’s Approval of Reformulated OxyContin® (oxycodone HCl controlled-release) Tablets*, PURDUE PHARMA (April 15, 2010), <http://www.purduepharma.com/news-media/2010/04/statement-of-purdue-pharma-l-p-regarding-fdas-approval-of-reformulated-oxycontin-oxycodone-hcl-controlled-release-tablets/> [hereinafter *Statement of Purdue Pharma*].

Aranoff, a KOL for Purdue, wrote “sponsored content” in *The Atlantic*, claiming ADFs made “certain forms of abuse much more difficult.”<sup>31</sup>

10.17 There is no scientific evidence that supports Purdue’s claim that ADF opioids reduce the risk of abuse compared to other opioid medications. According to the CDC’s Guidance, no reliable studies have established that ADFs of Extended-Release/Long-Acting opioids, such as OxyContin, are effective at risk mitigation for deterring or preventing abuse.<sup>32</sup> Similarly, the CDC states ADFs “do not prevent opiate abuse through oral intake, the most common route of opioid abuse, and can still be abused by nonoral routes” and “do not prevent overdose through oral intake.”<sup>33</sup> And Purdue has acknowledged, “there is no evidence that the reformulation of OxyContin is less subject to misuse, abuse, diversion, overdose or addiction.”<sup>34</sup> In fact, Purdue identified 32 publicly-circulated “recipes” that effectively defeat ADFs.<sup>35</sup> Yet despite its own research findings and the dearth of scientific evidence, Purdue continued to misrepresent to health care providers and the public that abuse-deterrent properties of some of its opioids could curb addiction and abuse. Purdue’s misrepresentations about Oxycontin’s abuse deterrent properties were inaccurate, continuous, and effective. A 2014 survey of 1,000 primary care physicians revealed that nearly

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<sup>31</sup> Gerald Aronoff, *Take My Pain Away—A Physician’s Perspective of Prescription Opioids and Pain Management*, THE ATLANTIC (Jan. 9, 2015), <https://www.theatlantic.com/sponsored/purdue-health/take-my-pain-away/202/>.

<sup>32</sup> *CDC Guideline*, *supra* note 29, at 21–22.

<sup>33</sup> *Id.*

<sup>34</sup> *Statement of Purdue Pharma*, *supra* note 30.

<sup>35</sup> Emily C McNaughton et al., *Monitoring of Internet Forums to Evaluate Reactions to the Introduction of Reformulated OxyContin to Deter Abuse*, 16 J. OF MED. INTERNET RES. e119 (2014), [https://www.researchgate.net/profile/Paul\\_Coplan/publication/262109563\\_Monitoring\\_of\\_Internet\\_Forums\\_to\\_Evaluate\\_Reactions\\_to\\_the\\_Introduction\\_of\\_Reformulated\\_OxyContin\\_to\\_Deter\\_Abuse/links/00b49537d336751f8b000000/Monitoring-of-Internet-Forums-to-Evaluate-Reactions-to-the-Introduction-of-Reformulated-OxyContin-to-Deter-Abuse.pdf?origin=publication\\_detail](https://www.researchgate.net/profile/Paul_Coplan/publication/262109563_Monitoring_of_Internet_Forums_to_Evaluate_Reactions_to_the_Introduction_of_Reformulated_OxyContin_to_Deter_Abuse/links/00b49537d336751f8b000000/Monitoring-of-Internet-Forums-to-Evaluate-Reactions-to-the-Introduction-of-Reformulated-OxyContin-to-Deter-Abuse.pdf?origin=publication_detail).

one half of surveyed physicians erroneously reported that abuse-deterrent formulations were less addictive than their counterparts.

**Purdue Misrepresented that Doctors and Patients Could Increase the Dose of Opioids Indefinitely.**

10.18 Purdue falsely represented that doctors and patients could simply increase opioid dosages indefinitely without added risk. The Purdue-sponsored APF publication “Treatment Options: A Guide for People Living with Pain,” claimed some patients “needed” a higher dose of an opioid, regardless of the dose currently prescribed. Purdue also claims that opioids have “no ceiling dose” and are therefore the most appropriate treatment for severe pain. In addition, the Purdue-sponsored APF’s “A Policy Maker’s Guide to Understanding Pain & Its Management” taught that dosage escalations are “sometimes necessary,” even unlimited ones, but did not disclose the risk from high opioid dosages.

**Purdue Overstated the Benefits of Prescription Opioids.**

10.19 Through its sales representatives, promotional materials, websites, KOL presentations, webinars, and third-party publications, Purdue grossly overstated the benefits of its prescription opioid products to both health care providers and the public by claiming that Purdue’s extended-release opioids are superior to their immediate-release counterparts due to “convenience” of dosing, i.e., fewer pills; and Purdue’s opioids are superior to NSAIDs, acetaminophen, and combination-opioids due to a “lack of a ceiling dose.”

10.20 Purdue made false representations that extended-release opioids, such as OxyContin, were superior to immediate-release opioids due to “convenience” of fewer doses and reduced “pill burden.”<sup>36</sup> These claims were not based on substantial scientific evidence.<sup>37</sup>

10.21 Purdue misrepresented its opioids as superior to NSAIDs due to lack of a “dose ceiling” for opioids, though Purdue lacked scientific or clinical support for the claim that higher doses of opioids are more effective for treating pain. Purdue was aware this claim was dubious and that no “head-to-head” clinical studies substantiated it. Purdue also instructed its sales representatives: “while we can state that OxyContin is a single-entity opioid that doesn’t contain acetaminophen, aspirin, ibuprofen, or any other non-opioid component, we cannot discuss the ceiling doses of these agents. Any discussion about dosing limitations of another agent may lead to a claim of implied superiority.” Yet, despite their internal acknowledgments, Purdue falsely touted the absence of a dose ceiling for extended-release opioids. These pronouncements were made despite clear scientific evidence that higher opioid doses increase the risk of addiction, dependence, and overdose.<sup>38</sup> As the CDC states: Higher Doses, Higher Risk.

10.22 Purdue funded numerous third-party publications that stressed the existence of non-opioid dose ceilings, and even included detailed charts outlining the dosing limitations and potential drug interactions of NSAIDs and acetaminophen. For example, Purdue funded APF’s publication “Treatment Options,” which states that “[t]here is no ceiling dose as there is with NSAIDs. As

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<sup>36</sup> *OxyContin’s 12-Hour Problem*, *supra* note 20.

<sup>37</sup> L. Pedersen et al., *Abstract: A Randomized, Double-Blind, Double-Dummy Comparison of Short- and Long-Acting Dihydrocodeine in Chronic Non-Malignant Pain*, 155 PAIN 881 (2014), <https://www.ncbi.nlm.nih.gov/pubmed/24345428>; Charles E. Argoff & Daniel I. Silvershein, *A Comparison of Long- and Short-Acting Opioids for the Treatment of Chronic Noncancer Pain: Tailoring Therapy to Meet Patient Needs*, 84 Mayo Clinic Proceedings 602, 604 (2009), [https://www.ncbi.nlm.nih.gov/pmc/articles/PMC2704132/pdf/mayoclinproc\\_84\\_7\\_007.pdf](https://www.ncbi.nlm.nih.gov/pmc/articles/PMC2704132/pdf/mayoclinproc_84_7_007.pdf).

<sup>38</sup> *Calculating Total Daily Dose of Opioids for Safer Dosage*, CTRS. FOR DISEASE CONTROL & PREVENTION, [https://www.cdc.gov/drugoverdose/pdf/calculating\\_total\\_daily\\_dose-a.pdf](https://www.cdc.gov/drugoverdose/pdf/calculating_total_daily_dose-a.pdf) (last visited May 13, 2018).

pain worsens, these medications continue to be useful unless side effects occur.” In 2010, Purdue distributed a letter to health care providers titled “Maximum Dose of OxyContin Tablets” that claimed: “when used appropriately, there is no established or fixed upper limit on the dosage of full, single entity, opioid agonists such as oxycodone.” The letter included an explicit superiority claim that “[l]ike all pure opioid agonists analgesics, with increasing doses there is increasing analgesia, unlike with mixed agonist/agonists or non-opioid analgesics, where there is a limit to the analgesic effect with increasing doses.”

10.23 Purdue also falsely claimed opioids are the first-line therapy for cancer pain treatment or for moderate-to-severe pain. No relevant authority supports claims that opioids are superior for treating cancer pain. In fact, the World Health Organization’s (“WHO”) “cancer pain ladder,” which has been at the forefront of medical treatment of cancer pain since it was first published in 1986, suggests a three-step approach to treating cancer pain: “If pain occurs, there should be prompt oral administration of drugs in the following order: nonopioids (aspirin and paracetamol); then, as necessary, mild opioids (codeine); then strong opioids such as morphine, until the patient is free of pain. To calm fears and anxiety, additional drugs—‘adjuvants’—should be used.”<sup>39</sup> Yet, third-party publications financed by Purdue falsely claimed that opioids are the best treatment for more severe forms of pain.

10.24 Purdue, through its third-party funding, misrepresented the WHO cancer pain ladder as suggesting different therapies corresponding to different degrees of pain, rather than a series of progressive steps for treatment of all cancer-related pain. These Purdue-funded third parties claimed opioids are “conventionally considered the first-line therapy for severe acute pain and

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<sup>39</sup> WHO’s Cancer Pain Ladder for Adults, WORLD HEALTH ORG., <http://www.who.int/cancer/palliative/painladder/en/> (last visited May 10, 2018).

moderate to severe persistent pain due to cancer, AIDS, or other advanced illnesses.” Examples of these claims include, “opioids are an essential option for treating moderate to severe pain associated with surgery or trauma, and for pain related to cancer” and “when the pain is severe, opioids should be considered.”<sup>40</sup>

10.25 According to the National Safety Council’s 2014 examination of the efficacy of types of pain medications, even in cases of acute pain, no scientific evidence supports a preference for opioids over NSAIDs and, in fact, “the evidence seems to indicate that NSAIDs are more effective for severe pain. The combination of acetaminophen and an NSAID may be the strongest option available for oral treatment of acute pain.”<sup>41</sup> Yet, Purdue, in a sponsored CME, claimed “[o]pioid analgesics are conventionally considered the first-line therapy for severe acute pain and moderate to severe persistent pain due to cancer, AIDS, and other advanced illnesses.”

#### **Purdue Misrepresented the Harm Caused by Opioids.**

10.26 The serious risks of opioids, including the risks of addiction, overdose, and death, are well-documented. Third-party publications funded by Purdue, however, assured readers that “most side effects [of opioids] go away after a few days.”<sup>42</sup> Purdue also minimized the more serious side effects of addiction and overdose by positioning less serious side effects such as constipation, nausea and vomiting, sleepiness, mental cloudiness, itching, dizziness, [and] difficulty urinating

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<sup>40</sup> *Treatment Options: A Guide for People Living with Pain*, AM. PAIN FOUND. 11 (2006, updated 2007), <https://web.archive.org/web/20111115011348/http://www.painfoundation.org/learn/publications/files/TreatmentOptions2006.pdf> (last visited May 13, 2018).

<sup>41</sup> Donald Teater, *Evidence for the Efficacy of Pain Medications*, NATIONAL SAFETY COUNCIL, <https://www.nsc.org/Portals/0/Documents/RxDrugOverdoseDocuments/Evidence-Efficacy-Pain-Medications.pdf> (last visited May 11, 2018).

<sup>42</sup> DEREK MCGINNIS, *EXIT WOUNDS* 110 (2009).

as the primary risks of opioids.<sup>43</sup> Through its third-party publications, Purdue presented the more serious risks of opioids as a secondary issue to these side effects, when they were acknowledged at all.

10.27 Purdue minimized the discussion of addiction and dependence and understated the severity of these risks when they were mentioned. Purdue also funded third-party marketing materials that dismissively addressed concerns about opioid addiction, implying that they were “myths and misunderstandings” and claimed the risk of addiction was “low in the general population.”<sup>44</sup> Moreover, Purdue proclaimed that “people who are not predisposed to addiction are unlikely to become addicted to opioid pain medications.”<sup>45</sup>

**Purdue Falsely Represented its Opioids’ Efficacy in Treating Chronic, Moderate, and Severe Pain.**

10.28 There is no scientific or clinical support for claims that opioids are the most effective treatment for chronic pain, or even that prolonged treatment with opioids is effective. Despite a 600% increase in opioid consumption in the past 20 years, several scientific reviews have “concluded that no evidence exists to support long-term use . . . of opioids to treat chronic pain.”<sup>46</sup> In fact, the CDC’s review of available research concluded that “opioids should not be considered first-line or routine therapy for chronic pain” and that “nonpharmacologic therapy and nonopioid pharmacologic therapy are preferred for chronic pain.”<sup>47</sup> And according to CDC Guidelines, “No

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<sup>43</sup> *Id.*; *Pain: A Guide for Physician Assistants and Patients*, PHYSICIAN ASSISTANT FOUND. 13, <http://pa-foundation.org/wp-content/uploads/Pain-Guide-for-PAs-and-Patients.pdf> (last visited May 10, 2018).

<sup>44</sup> *Id.* at 17.

<sup>45</sup> McGinnis, *supra* note 42, at 107.

<sup>46</sup> Teater, *supra* note 41.

<sup>47</sup> *CDC Guideline*, *supra* note 29, at 16, 19.

evidence shows a long-term benefit of opioids in pain and function versus no opioids for chronic pain with outcomes examined at least 1 year later (with most placebo-controlled randomized trials  $\leq 6$  weeks in duration).”<sup>48</sup>

10.29 According to the CDC Guidelines, when opioids are prescribed for chronic pain “they should be combined with nonpharmacologic and nonopioid pharmacologic therapy, as appropriate, to provide greater benefits to patients in improving pain and function.”<sup>49</sup> Contrary to Purdue’s representations, the CDC Guidance stressed 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.”<sup>50</sup>

10.30 Third-party publications funded by Purdue claimed: “[the] pain relieving properties of opioids are unsurpassed; they are today considered the ‘gold standard’ of pain medications, and so are often the main medications used in the treatment of chronic pain.”<sup>51</sup> Furthermore, Purdue, through an APF publication, claimed that opioids are “often necessary” for pain patients to “restore functioning and improve quality of life.”

10.31 Third-party publications funded by Purdue relied on flawed or incomplete data to make claims that its opioids were effective for long-term use. Purdue falsely claimed through the APF, yet again, in “A Policy Maker’s Guide,” that “[m]ultiple clinical studies have shown that long-acting opioids, in particular, are effective in improving: Daily function; Psychological health; and Overall health-related quality of life for people with chronic pain.”

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<sup>48</sup> *Id.* at 15.

<sup>49</sup> *Id.* at 17.

<sup>50</sup> *Id.* at 18.

<sup>51</sup> McGinnis, *supra* note 42, at 106.

10.32 Purdue also sponsored content in *The Atlantic* to advance unsubstantiated claims that “all physicians who treat chronic pain with opioids have a significant number of patients in our practices that are back at work as full-time employees or back at school as full-time students because their pain is tolerable and under control.”<sup>52</sup>

10.33 Moreover, Purdue created marketing materials entitled “pain vignettes” that provided case studies for five hypothetical patients with moderate to severe chronic pain from conditions such as back pain or arthritis. In each case, the script indicated that treatment with OxyContin would be appropriate. The vignettes implied that, with round-the-clock opioid treatment, the patients would be able to function more effectively.

**Purdue Made Billions of Dollars Through the Sale of Prescription Opioids in Texas.**

10.34 According to the 2010 Census, approximately 8% of the population resided in Texas.<sup>53</sup> Based on Texas’s estimated share of the U.S. population, Purdue has generated approximately \$2.48 billion in revenue from its branded prescription opioid products in Texas.<sup>54</sup> Moreover, Purdue’s opioid products constituted the filling of millions of prescriptions in Texas.

10.35 As part of its marketing efforts, Purdue employed sales representatives in Texas to visit health care providers. These representatives interacted with health care providers and distributed marketing materials that misrepresented the risk of addiction, the efficacy in treating chronic moderate and severe pain, the occurrence of pseudoaddiction, and the ease of preventing addiction. These aggressive marketing efforts directed at health care providers also carried the message that

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<sup>52</sup> Aronoff, *supra* note 31.

<sup>53</sup> See *Quick Facts: Texas*, U.S. CENSUS BUREAU, <https://www.census.gov/quickfacts/fact/table/TX/PST045216> (last visited May 11, 2018), and *Quick Facts: United States*, U.S. CENSUS BUREAU, <https://www.census.gov/quickfacts/fact/table/US/PST045217> (last visited May 11, 2018).

<sup>54</sup> See *OxyContin’s 12-Hour Problem*, *supra* note 20.

Purdue's abuse-deterrent drugs prevented addiction; that opioid dosages could be increased indefinitely; and that prescription opioids were superior to other pain treatments.

10.36 Purdue sales representatives kept notes regarding their visits with health care providers, referred to as "call notes." Purdue sales representatives made hundreds of thousands of calls on Texas health care providers. Misrepresentations recorded by representatives to health care providers include the following:

- Advising health care providers to treat opioid-naïve patients with 10 mg of OxyContin every twelve hours as opposed to treating the patient with a short-acting opioid;
- Indicating that the ceiling dose for pain treatment with prescription opioids was only limited by side effects;
- Inferring that the reformulated version of OxyContin would be less subject to abuse; and
- Claiming that those at risk for addiction from taking opioids could be readily identified by the health care provider selecting the right patient, relying on the health care provider's personal knowledge and trust of the patient, or identifying a personal or family history of substance abuse.<sup>55</sup>

10.37 Finally, Purdue also created an unbranded marketing campaign, called Partners Against Pain, to raise awareness about the importance of pain management.<sup>56</sup> On information and belief, thousands of Texans visited the unbranded website, Partnersagainstpain.com, which included links to unbranded publications providing information about how patients could communicate with

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<sup>55</sup> *Id.*

<sup>56</sup> *Patients & Caregivers: Understanding Pain*, PARTNERS AGAINST PAIN, <https://web.archive.org/web/20140213155742/http://www.partnersagainstpain.com/understanding-pain/management.aspx>.

health care providers, including approaches to discussing pain and asking for pain relief.<sup>57</sup> These linked publications minimized the risk of addiction to opioids.<sup>58</sup>

**Purdue Continued to Promote Opioids to Physicians Who Prescribed Opioids Inappropriately.**

10.38 Additionally, Purdue’s sales representatives continued promoting prescription opioids to suspect health care providers, despite their knowledge of inappropriate opioid prescribing practices utilized by those providers.<sup>59</sup> Purdue was required to train sales representatives to identify and report on “red flags” at provider offices, which included warning signs such as: an apparent pattern of an excessive number of patients for the practice type, long lines of patients waiting to be seen by a health care provider, waiting rooms filled to standing-room-only capacity, issuing prescriptions from a car, information from law enforcement about ongoing investigations, high rates of cash payments by patients, and reports of overdoses.<sup>60</sup> Purdue’s Legal Department was charged with monitoring these reports. In the event credible information of abuse or diversion involving a health care provider was found, Purdue was required to ensure that the provider was placed on the “Region Zero” list, which prohibited sales representatives from calling on the identified provider.<sup>61</sup> However, Purdue failed to properly monitor or make timely decisions about

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<sup>57</sup> *Patient Comfort Assessment Guide*, PARTNERS AGAINST PAIN, <https://web.archive.org/web/20130605121611/http://www.partnersagainstpain.com/printouts/Patient-Comfort-Assessment-Guide.pdf>; *Questions to Ask your Doctor*, PARTNERS AGAINST PAIN, <https://web.archive.org/web/20110621100122/http://partnersagainstpain.com/pain-management-resources/questions.aspx>.

<sup>58</sup> *Home Care of the Hospice Patient*, PARTNERS AGAINST PAIN 29, <https://web.archive.org/web/20100927163832/http://partnersagainstpain.com/patient-resources/Home%20Care%20of%20the%20Hospice%20Patient.pdf>.

<sup>59</sup> Harriet Ryan, Lisa Girion & Scott Glover, *More than 1 Million OxyContin Pills Ended up in the Hands of Criminals and Addicts. What the Drugmaker Knew*, L.A. TIMES (July 10, 2016), <http://www.latimes.com/projects/la-me-oxycontin-part2/>.

<sup>60</sup> *Id.*

<sup>61</sup> *Id.*

suspicious providers, and Purdue sales representatives continued detailing these providers.<sup>62</sup> Additionally, when assessing whether to place a provider on the “Region Zero” list, Purdue was required to review the provider’s prescribing history to determine whether that provider was an especially high-volume prescriber of opioid products.<sup>63</sup> On information and belief, Purdue failed to properly monitor and assess problem prescribers, and Purdue sales representatives continued to call on certain providers, often months after the Texas Medical Board disciplined them for improper opioid-prescribing practices.

## **XI. VIOLATIONS OF THE DTPA**

11.1 Plaintiff incorporates and adopts by reference the allegations contained in each and every preceding paragraph of this petition.

11.2 Plaintiff alleges violations by Defendants of DTPA § 17.46(a) and DTPA § 17.46(b) from June 2007 to the present.

11.3 Defendants as alleged and detailed above have, in the conduct of trade or commerce, engaged in false, misleading, or deceptive acts or practices in violation of DTPA § 17.46(a) and DTPA § 17.46(b) including and not limited to:

### **1. Misrepresenting the risk of addiction to prescription opioids.**

- (a) Falsely representing that prescription opioids pose a low risk of addiction that patients who had not previously experienced addiction would not become addicted to opioids;

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<sup>62</sup> *Id.*

<sup>63</sup> *Id.*

- (b) Falsely representing that many individuals who exhibit signs of addiction to opioids are actually experiencing pseudoaddiction and that doctors should treat this pseudoaddiction by increasing the patient's opioid dose;
- (c) Misrepresenting the signs of addiction and the ease in preventing addiction;
- (d) Misrepresenting that doctors and patients could increase opioid dosages indefinitely without risk and failed to disclose the increased risks to patients when taking prescription opioids at high doses;

**2. Misrepresenting the benefits of the use of prescription opioids.**

- (a) Misrepresenting that abuse-deterrent properties of some of their prescription opioids could curb addiction and abuse;
- (b) Misrepresenting that their prescription opioids were superior to NSAIDs by focusing on the side effects of NSAIDs at the same time minimizing the side effects and risk of addiction to prescription opioids;
- (c) Misrepresenting that their prescription opioids were superior to NSAIDs because opioids had no dose ceiling;
- (d) Misrepresenting the risk of taking high dosages of prescription opioids;
- (e) Falsely representing that OxyContin's abuse-deterrent formula reduces the risk of misuse, abuse, diversion, overdose, or addiction;

**3. Misrepresenting the efficacy of prescription opioids.**

- (a) Misrepresenting that prescription opioids are the best first line treatment for chronic pain;
- (b) Misrepresenting that long-term treatment with opioids is effective in the treatment of chronic pain;

- (c) Falsely representing that long-term treatment with opioids increases functionality;  
and
- (d) Falsely representing that prescription opioids were more effective than non-opioid prescription drugs in the treatment of chronic pain.

11.4 Defendants, through their actions in (1) misrepresenting the risk of addiction to prescription opioids, (2) misrepresenting the benefits of the use of prescriptive opioids, and (3) misrepresenting the efficacy of prescription opioids, violated the DTPA by:

- (a) Engaging in false, misleading, or deceptive acts or practices in violation of the DTPA, § 17.46(a);
- (b) Causing confusion or misunderstanding as to affiliation, connection, or association with, or certification by, another, in violation of DTPA, § 17.46(b)(3);
- (c) Representing that goods or services have sponsorship, approval, characteristics, ingredients, uses, benefits, or quantities which they do not have, or that a person has a sponsorship, approval, status, affiliation, or connection which he does not have, in violation of DTPA, § 17.46(b)(5);
- (d) Representing that goods or services are of a particular standard, quality, or grade, or that goods are of a particular style or model, if they are of another, in violation of the DTPA, § 17.46(b)(7); and
- (e) Failing to disclose information concerning goods or services which was known at the time of the transaction if such failure to disclose such information was intended to induce the consumer into a transaction which the consumer would not have entered had the information been disclosed, in violation of the DTPA, § 17.46(b)(24).

**XII. DISGORGEMENT**

12.1 All of the Defendants’ assets are subject to the equitable remedy of disgorgement, which is the forced relinquishment of all benefits that would be unjust for Defendants to retain, including all ill-gotten gains and benefits or profits that result from Defendants putting fraudulently converted property to a profitable use. Defendants should be ordered to disgorge all monies fraudulently taken from individuals and businesses together with all of the proceeds, profits, income, interest, and accessions thereto.

**XIII. TRIAL BY JURY**

13.1 Plaintiff herein requests a jury trial and tenders the jury fee to the Travis County District Clerk’s office, pursuant to Tex. R. Civ. P. 216 and the Tex. Gov’t Code § 51.604.

**XIV. CONDITIONS PRECEDENT**

14.1 All conditions precedent to Plaintiff’s claims for relief have been performed or have occurred.

**XV. REQUEST FOR DISCLOSURE**

15.1 Under Texas Rule of Civil Procedure 194, Plaintiff requests that Defendants disclose, within 50 days of the service of this request, the information or material described in Rule 194.2.

**XVI. PRAYER**

16.1 Plaintiff prays that Defendants be cited according to law to appear and answer herein.

16.2 Plaintiff further prays that after due notice and hearing a TEMPORARY INJUNCTION be issued; and upon final hearing a PERMANENT INJUNCTION be issued, restraining, and enjoining Defendants, Defendants’ officers, agents, servants, employees, attorneys—and any other

person in active concert or participation with any or all Defendants—from engaging in the following acts or practices:

- (a) Directly or indirectly disseminating information to persons not employed by Defendants about their opioid-containing prescription products excluding that required by regulatory agencies or information related solely to product pricing;
- (b) Directly or indirectly disseminating information to persons not employed by Defendants about the treatment of pain with opioid-containing prescriptions or the advantages to treating pain with opioid-containing products excluding that required by regulatory agencies or information related solely to product pricing;
- (c) Providing funds and or grants to third parties that directly or indirectly disseminate information to persons about opioid-containing products or the treatment of pain with opioid-containing products;
- (d) Directly or indirectly offering any discounts, coupons, rebates or other methods which have the effect of reducing or eliminating a patient’s co-payments or the cost of prescriptions for any opioid-containing product;
- (e) Providing financial support to any third-party that offers discounts, coupons, rebates, or other methods which have the effect of reducing or eliminating a patient’s co-payments or the cost of prescriptions for any opioid-containing product;
- (f) Representing, directly or indirectly, that prescription opioids have characteristics, approvals, uses, or benefits, or qualities which they do not have;

- (g) Making any written or oral statement about an opioid-containing prescription product, opioids generally, or the treatment of pain that is false, misleading and/or deceptive; and
- (h) Failing to state any facts relating to any opioid-containing prescription product, the omission of which would be material to a health care provider or consumer.

16.3 Plaintiff further prays that this Court award judgment for the Plaintiff as follows:

- (a) Ordering Defendants to pay civil penalties to the State of Texas for each violation of the DTPA up to a total of \$20,000 per each violation; and
- (b) Ordering Defendants to disgorge all ill-gotten gains.

16.4 Plaintiff further prays that upon final hearing, this Court order Defendants to pay Plaintiff's attorneys' fees and costs of court pursuant to Texas Government Code § 402.006(c).

16.5 Plaintiff further prays that this Court grant all other relief to which the Plaintiff, the State of Texas, is entitled.

Respectfully submitted,

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**ATTORNEYS FOR THE STATE OF TEXAS**

# CIVIL CASE INFORMATION SHEET

CAUSE NUMBER: \_\_\_\_\_ COURT: \_\_\_\_\_

**STYLED STATE OF TEXAS V. PURDUE PHARMA L.P.; PURDUE PHARMA INC.; THE PURDUE FREDERICK COMPANY, INC.; AND PURDUE  
TRANSDERMAL TECHNOLOGIES L.P.**

(e.g., John Smith v. All American Insurance Co; In re Mary Ann Jones; In the Matter of the Estate of George Jackson)

A civil case information sheet must be completed and submitted when an original petition or application is filed to initiate a new civil, family law, probate, or mental health case or when a post-judgment petition for modification or motion for enforcement is filed in a family law case. The information should be the best available at the time of filing.

<p><b>1. Contact information for person completing case information sheet:</b></p> <p>Name: <u>PATRICK SWEETEN</u>      Email: <u>patrick.sweeten@oag.texas.gov</u></p> <p>Address: <u>P. O. Box 12548</u>      Telephone: <u>512-463-4139</u></p> <p>City/State/Zip: <u>AUSTIN, TX 78701</u>      Fax: <u>512-936-0545</u></p> <p>Signature: <u>/s/ Patrick Sweeten</u>      State Bar No: <u>00798537</u></p>	<p><b>Names of parties in case:</b></p> <p>Plaintiff(s)/Petitioner(s): <u>STATE OF TEXAS</u></p> <p>_____</p> <p>Defendant(s)/Respondent(s): <u>PURDUE PHARMA L.P.; PURDUE PHARMA INC.; THE PURDUE FREDERICK COMPANY INC; AND PURDUE TRANSDERMAL TECHNOLOGIES L.P.</u></p> <p>_____</p> <p>_____</p>	<p><b>Person or entity completing sheet is:</b></p> <p><input type="checkbox"/> Attorney for Plaintiff/Petitioner <input type="checkbox"/> <i>Pro Se</i> Plaintiff/Petitioner <input type="checkbox"/> Title IV-D Agency <input type="checkbox"/> Other: _____</p> <p>Additional Parties in Child Support Case: Custodial Parent: _____ Non-Custodial Parent: _____ Presumed Father: _____</p>
[Attach additional page as necessary to list all parties]		

**2. Indicate case type, or identify the most important issue in the case (select only 1):**

Civil			Family Law	
Contract	Injury or Damage	Real Property	Marriage Relationship	Post-judgment Actions (non-Title IV-D)
<p><i>Debt/Contract</i></p> <p><input type="checkbox"/> Consumer/DTPA <input type="checkbox"/> Debt/Contract <input type="checkbox"/> Fraud/Misrepresentation <input type="checkbox"/> Other Debt/Contract: _____</p> <p><i>Foreclosure</i></p> <p><input type="checkbox"/> Home Equity—Expedited <input type="checkbox"/> Other Foreclosure</p> <p><input type="checkbox"/> Franchise <input type="checkbox"/> Insurance <input type="checkbox"/> Landlord/Tenant <input type="checkbox"/> Non-Competition <input type="checkbox"/> Partnership <input type="checkbox"/> Other Contract: _____</p>	<p><input type="checkbox"/> Assault/Battery <input type="checkbox"/> Construction <input type="checkbox"/> Defamation</p> <p><i>Malpractice</i></p> <p><input type="checkbox"/> Accounting <input type="checkbox"/> Legal <input type="checkbox"/> Medical <input type="checkbox"/> Other Professional Liability: _____</p> <p><input type="checkbox"/> Motor Vehicle Accident <input type="checkbox"/> Premises</p> <p><i>Product Liability</i></p> <p><input type="checkbox"/> Asbestos/Silica <input type="checkbox"/> Other Product Liability List Product: _____</p> <p><input type="checkbox"/> Other Injury or Damage: _____</p>	<p><input type="checkbox"/> Eminent Domain/Condemnation <input type="checkbox"/> Partition <input type="checkbox"/> Quiet Title <input type="checkbox"/> Trespass to Try Title <input type="checkbox"/> Other Property: _____</p> <p><b>Related to Criminal Matters</b></p> <p><input type="checkbox"/> Expunction <input type="checkbox"/> Judgment Nisi <input type="checkbox"/> Non-Disclosure <input type="checkbox"/> Seizure/Forfeiture <input type="checkbox"/> Writ of Habeas Corpus—Pre-indictment <input checked="" type="checkbox"/> Other: <u>State Enforcement</u></p>	<p><input type="checkbox"/> Annulment <input type="checkbox"/> Declare Marriage Void</p> <p><i>Divorce</i></p> <p><input type="checkbox"/> With Children <input type="checkbox"/> No Children</p> <p><b>Other Family Law</b></p> <p><input type="checkbox"/> Enforce Foreign Judgment <input type="checkbox"/> Habeas Corpus <input type="checkbox"/> Name Change <input type="checkbox"/> Protective Order <input type="checkbox"/> Removal of Disabilities of Minority <input type="checkbox"/> Other: _____</p>	<p><input type="checkbox"/> Enforcement <input type="checkbox"/> Modification—Custody <input type="checkbox"/> Modification—Other</p> <p style="text-align: center;"><b>Title IV-D</b></p> <p><input type="checkbox"/> Enforcement/Modification <input type="checkbox"/> Paternity <input type="checkbox"/> Reciprocal (UIFSA) <input type="checkbox"/> Support Order</p> <p><b>Parent-Child Relationship</b></p> <p><input type="checkbox"/> Adoption/Adoption with Termination <input type="checkbox"/> Child Protection <input type="checkbox"/> Child Support <input type="checkbox"/> Custody or Visitation <input type="checkbox"/> Gestational Parenting <input type="checkbox"/> Grandparent Access <input type="checkbox"/> Paternity/Parentage <input type="checkbox"/> Termination of Parental Rights <input type="checkbox"/> Other Parent-Child: _____</p>
<p><b>Employment</b></p> <p><input type="checkbox"/> Discrimination <input type="checkbox"/> Retaliation <input type="checkbox"/> Termination <input type="checkbox"/> Workers' Compensation <input type="checkbox"/> Other Employment: _____</p>	<p style="text-align: center;"><b>Other Civil</b></p> <p><input type="checkbox"/> Administrative Appeal <input type="checkbox"/> Antitrust/Unfair Competition <input type="checkbox"/> Code Violations <input type="checkbox"/> Foreign Judgment <input type="checkbox"/> Intellectual Property</p> <p><input type="checkbox"/> Lawyer Discipline <input type="checkbox"/> Perpetuate Testimony <input type="checkbox"/> Securities/Stock <input type="checkbox"/> Tortious Interference <input type="checkbox"/> Other: _____</p>			
<p style="text-align: center;"><b>Tax</b></p> <p><input type="checkbox"/> Tax Appraisal <input type="checkbox"/> Tax Delinquency <input type="checkbox"/> Other Tax</p>	<p style="text-align: center;"><b>Probate &amp; Mental Health</b></p> <p><i>Probate/Wills/Intestate Administration</i></p> <p><input type="checkbox"/> Dependent Administration <input type="checkbox"/> Independent Administration <input type="checkbox"/> Other Estate Proceedings</p> <p><input type="checkbox"/> Guardianship—Adult <input type="checkbox"/> Guardianship—Minor <input type="checkbox"/> Mental Health <input type="checkbox"/> Other: _____</p>			

**3. Indicate procedure or remedy, if applicable (may select more than 1):**

<input type="checkbox"/> Appeal from Municipal or Justice Court <input type="checkbox"/> Arbitration-related <input type="checkbox"/> Attachment <input type="checkbox"/> Bill of Review <input type="checkbox"/> Certiorari <input type="checkbox"/> Class Action	<input type="checkbox"/> Declaratory Judgment <input type="checkbox"/> Garnishment <input type="checkbox"/> Interpleader <input type="checkbox"/> License <input type="checkbox"/> Mandamus <input type="checkbox"/> Post-judgment	<input type="checkbox"/> Prejudgment Remedy <input type="checkbox"/> Protective Order <input type="checkbox"/> Receiver <input type="checkbox"/> Sequestration <input type="checkbox"/> Temporary Restraining Order/Injunction <input type="checkbox"/> Turnover
<b>4. Indicate damages sought (do not select if it is a family law case):</b>		
<input type="checkbox"/> Less than \$100,000, including damages of any kind, penalties, costs, expenses, pre-judgment interest, and attorney fees <input type="checkbox"/> Less than \$100,000 and non-monetary relief <input type="checkbox"/> Over \$100,000 but not more than \$200,000 <input type="checkbox"/> Over \$200,000 but not more than \$1,000,000 <input checked="" type="checkbox"/> Over \$1,000,000		

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