CAUSE NO. 07-04195

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GARY FITZSIMMONS
DISTRICT CLERK
DALLAS CO., TEXAS
DEPUTY

STATE OF TEXAS,	§	**IN THE DISTRICT COURT OF**
	§	
Plaintiff,	§	
	§	
vs. PURDUE PHARMA INC.;	§	
PURDUE PHARMA L.P.; and	§	
THE PURDUE FREDERICK	§	
COMPANY, INC. d/b/a THE PURDUE	§	
FREDERICK COMPANY,	§	**DALLAS COUNTY, T E X A S**
	§	
Defendants.	§	**68th JUDICIAL DISTRICT**

PLAINTIFF'S ORIGINAL PETITION

COMES NOW, THE STATE OF TEXAS, acting by and through Attorney General Greg Abbott ("State"), filing Plaintiff's Original Petition complaining of and against PURDUE PHARMA INC.; PURDUE PHARMA L.P.; THE PURDUE FREDERICK COMPANY, INC. d/b/a THE PURDUE FREDERICK COMPANY, ("Defendants" or "Purdue"), and would respectfully show the court the following:

STATEMENT OF THE CASE

1. This is a civil action brought under the Texas Deceptive Trade Practices - Consumer Protection Act, TEX. BUS. & COM. CODE ANN. §17.41 *et seq.* ("DTPA") complaining that Purdue Pharma's false, deceptive, or misleading marketing of the opioid painkiller OxyContin. Although OxyContin is a Schedule II narcotic with an abuse profile and addictive qualities similar to morphine, Purdue aggressively promoted OxyContin to doctors, nurses and consumers as a first-choice analgesic for treatment of a wide variety of pain symptoms. While it expanded the market for OxyContin, Purdue avoided and minimized the known risks of OxyContin abuse, addiction and diversion. Purdue failed to adequately warn doctors or

consumers of OxyContin's significant risks and failed to take reasonable steps to guard against OxyContin abuse and diversion, instead striving to "educate" doctors and consumers that concerns over abuse, addiction and diversion of OxyContin were misplaced. Purdue's aggressive promotion of OxyContin led to a dramatic increase in OxyContin prescriptions, which in turn furthered an increase in OxyContin abuse and diversion from legitimate users to illicit use of OxyContin. Purdue's conduct constitutes unfair and/or deceptive acts and practices in violation of §§17.46(a) and (b) of the DTPA.

AUTHORITY AND PARTIES

2. This action is brought by Attorney General Greg Abbott, through his Consumer Protection Division, in the name of the STATE OF TEXAS and in the public interest under the authority granted him by §17.47 of the Texas Deceptive Trade Practices - Consumer Protection Act, TEX. BUS. & COM. CODE ANN. §17.21 *et seq.*, upon the grounds that Purdue has engaged in false, misleading or deceptive acts or practices in the course of trade and commerce as defined in, and declared unlawful by §§17.46(a) and (b) of the DTPA.

3. Defendant Purdue Pharma L.P. is a limited partnership with its principal place of business at One Stamford Forum, Stamford, Connecticut. At all times relevant to this Petition, Purdue Pharma L.P. has been in the business of designing, testing, manufacturing, labeling, advertising, promoting, marketing, selling, and/or distributing OxyContin throughout the United States, including the State of Texas.

4. Defendant Purdue Pharma Inc. is a Delaware corporation with its principal place of business at One Stamford Forum, Stamford, Connecticut. At all times relevant to this Complaint, Purdue Pharma Inc. has been in the business of designing, testing, manufacturing,

labeling, advertising, promoting, marketing, selling, and/or distributing OxyContin throughout United States, including the [State]. Purdue Pharma Inc. is the general partner of Purdue Pharma, L.P., and at all relevant times has supervised and managed the operations and affairs of its subsidiary and affiliate, Purdue Pharma, L.P.

5. Defendant The Purdue Frederick Company, Inc., d/b/a The Purdue Frederick Company is a Delaware corporation with its principal place of business at One Stamford Forum, Stamford, Connecticut. At all times relevant to this Petition, The Purdue Frederick Company has been in the business of designing, testing, manufacturing, labeling, advertising, promoting, marketing, selling, and/or distributing OxyContin throughout United States, including the State of Texas.

6. Because the marketing conduct alleged in this Petition concerns all Defendants, in this complaint all defendants are collectively referred to as "Purdue."

VENUE

7. Venue of this action lies in Dallas County on the basis of §17.47(b) of the DTPA because the acts and practices that violate these statutes occurred in Dallas County, Texas.

PUBLIC INTEREST

8. Because Plaintiff STATE OF TEXAS has reason to believe that Purdue has engaged in, and will continue to engage in, the unlawful practice set forth below, Plaintiff STATE OF TEXAS has reason to believe that Purdue has caused and will cause immediate and irreparable injury, loss and damage to the STATE OF TEXAS, and its citizens, and will also cause adverse effects to business enterprises which conduct their trade and commerce in a lawful

manner in this State. Therefore, the Attorney General of the STATE OF TEXAS believes and is of the opinion that these proceedings are in the public interest.

ACTS OF AGENTS

9. Whenever in this petition it is alleged that Purdue did any act or thing, it is meant that Purdue performed or participated in such act or thing or that such act was performed by agents or employees of Purdue and in each instance, the agents or employees of Purdue were then authorized to and did in fact act on behalf of Purdue or otherwise acted under the guidance and direction of Purdue.

TRADE AND COMMERCE

10. Purdue has, at all times described below, engaged in conduct which constitutes "trade" and "commerce" as those terms are defined by §17.45(6) of the DTPA.

NOTICE BEFORE SUIT

11. Purdue was informed in general of the alleged unlawful conduct described below through Texas' participation in a multistate investigation of Purdue and as may be required by §17.47(a) of the DTPA.

FACTUAL ALLEGATIONS

Purdue Manufactures and Sells OxyContin, a Schedule II Narcotic Opioid Designed to Treat Serious, Long-Term Pain

12. OxyContin is an opioid analgesic – a narcotic substance that relieves a person's pain without causing the loss of consciousness. OxyContin is a controlled-release form of oxycodone hydrochloride. Oxycodone is a very powerful pain reliever similar to morphine, and is the active ingredient in OxyContin as well as oxycodone-combination drugs such as Percocet, Percodan and Tylex.

13. Purdue developed and manufactures OxyContin. OxyContin's controlled release of oxycodone purports to facilitate 12-hour dosing for OxyContin, which distinguished it from other oxycodone tablets typically administered in 4 to 6 hour doses. Due in part to its controlled-release feature, OxyContin contains more oxycodone than other oxycodone drugs.

14. OxyContin is a Schedule II narcotic, which means its manufacture and distribution is subject to the Drug Enforcement Agency's ("DEA") regulation and control. Classification of OxyContin as a Schedule II controlled substance means that the DEA has determined that OxyContin: I) has a high potential for abuse, ii) has been accepted for medical use in the United States subject to severe restrictions, and iii) abuse may lead to severe psychological or physical dependence.

15. As reflected by the DEA's oversight, OxyContin has an abuse profile, and addictive qualities, similar to morphine. Among other things, this means that: first, OxyContin users experience euphoria, making the drug prone to abuse (*i.e.*, non-medical use); second, OxyContin causes physical dependence in a short time, meaning that a user will experience withdrawal symptoms upon terminating use; and third, tolerance is common, meaning that, over time, dosage often must increase in order to provide the same level of pain relief.

16. In sum, opioids like OxyContin cause physical dependence and are prone to abuse and addiction. As a result, doctors have traditionally, and correctly, exercised caution in prescribing opioids, weighing their analgesic effect against the risks of dependence, addiction, abuse, and diversion from legitimate patients to illicit, non-medical use.

17. Although OxyContin posed the same risks as MS Contin and other opioids, Purdue, as part of its marketing strategy, sought to position OxyContin differently from other opioids by avoiding or minimizing the drug's known risks.

18. In December 1995, the FDA approved the use of OxyContin for the following "indications," that is, the circumstances for which the FDA has determined that a drug is safe and effective:

> Indications: "OxyContin Tablets are a controlled-release oral formulation of oxycodone hydrochloride indicated for the management of moderate-to-severe pain where use of an opioid analgesic is appropriate for more than a few days."

19. In 2001, the FDA changed the OxyContin indications. OxyContin is now indicated for the "management of moderate-to-severe pain *when a continuous around-the-clock analgesic is needed for an extended period of time.*"

20. Since 1995, the FDA also has restricted the appropriate marketing and use of OxyContin as reflected in the OxyContin label. Among other things, the FDA has determined that OxyContin, because it has not been shown to be safe and effective for these uses, should not be promoted:

- for use as a prn analgesic. "Prn" means as needed, or as required.
- for use as a preemptive analgesia (pre-operative), that is, not to be administered in advance of an operation for expected pain.
- for post-operative pain in patients not already on OxyContin.
- for post-operative pain unless the pain is moderate-to-severe and expected to persist for extended period.
- where contraindicated for patients with significant respiratory depression, acute or severe bronchial asthma or hypercarbia, or with paralytic ileus.

Purdue Promoted OxyContin through a Multifaceted Marketing Campaign

21. Purdue has marketed OxyContin to doctors, dentists, nurses, other healthcare professionals, and patients. Purdue's goals have been to increase the number of doctors prescribing OxyContin, increase the number of patients taking OxyContin, and increase the OxyContin dosages prescribed by doctors, all in order to increase OxyContin sales and generate profits for Purdue.

22. Purdue has, at various times:

a) employed hundreds of sales representatives paid to visit with doctors, nurses, pharmacists and other health care professionals to expand the prescription writing base and increase prescription writing for OxyContin;

b) prepared and distributed sales aids, visuals, hand outs, and "leave behind" promotional items to be used by sales representatives and distributed to healthcare professionals;

c) conducted seminars, trainings and purported educational programs for health care professionals to promote treatment of pain via increased opioid usage, specifically OxyContin;

d) placed OxyContin advertisements in medical journals and other publications directed at healthcare professionals;

e) maintained websites directed at patients, patient families, and healthcare professionals promoting pain treatment, specifically via prescribing OxyContin or other opioids.

23. Purdue's sales efforts are directed to: I) get doctors to prescribe and nurses to recommend OxyContin, ii) ensure that hospitals and managed care organizations place OxyContin on their drug formularies and treat it favorably vis-a-vis other painkillers, iii) encourage pharmacies to stock OxyContin, in all prescription strengths, and iv) encourage hospitals and long term care facilities to purchase and use OxyContin for their patients.

24. The bulk of sales representatives' efforts focus on visiting doctors, nurses and other medical staff. Purdue provides its sales representatives with precise information on doctors' prescribing histories for OxyContin and other opioid painkillers. Armed with this information, Purdue and its sales representatives identify "core" physicians and "A-1" sales targets, who are deemed to be actual or potential high-volume prescribers of OxyContin.

25. Purdue sales representatives visited these doctors and their staffs to encourage use of OxyContin. If a doctor prescribed opioids other than OxyContin, Purdue sales reps encouraged them to switch to OxyContin. If a doctor already prescribed OxyContin, Purdue sales representatives encouraged OxyContin for more patients, for broader uses, and in increased dosages or strengths.

26. Purdue linked sales representatives' compensation directly to increased OxyContin prescribing by those doctors and institutions in the representatives' territory, as discussed further below.

27. Purdue designed its seminars, trainings and "educational" programs for doctors, pharmacists and nurses to serve the same goals as Purdue's office sales visits: promote OxyContin as the opioid of choice, get healthcare professionals "comfortable" with prescribing high strength narcotic opioids, and ultimately increase OxyContin prescriptions.

28. Regardless of the promotion medium, Purdue and its sales representatives echoed several simple OxyContin sales messages, consistently reflected in Purdue's advertisements, marketing plans and instructions to sales representatives. With respect to encouraging doctors to prescribe OxyContin, Purdue sought to:

- "enhance the acceptance of opioids for non-cancer pain," and, with respect to OxyContin, avoid any stigma attached to use of opiates;
- expand OxyContin tablets use in non-malignant pain market by positioning it as "the one to start with and the one to stay with;"
- establish OxyContin as the first-line choice at Step 2 of the WHO pain ladder (mild to moderate pain);
- increase the use of OxyContin tablets for a wide variety of conditions, and for acute and sub-acute pain (*e.g.*, "post-op pain, trauma, fractures"); and
- encourage assessment of pain by physicians and communication of pain by patients, and attach an emotional aspect to non-cancer pain so physicians treat it more aggressively.

29. With respect to the characteristics of OxyContin itself, Purdue's marketing emphasized:

- that OxyContin is strong ("It Works");
- the duration of pain control -- that unlike other oxycodone medication, OxyContin need only be taken every 12 hours;

- the convenience of 12 hour dosing as compared to 4 or 6 hour analgesics (print ads showing six dosage cups vs. two and stating "the hard way vs. the easy way");
- that OxyContin acts quickly – that the onset of analgesia is within one hour in most patients; and
- that OxyContin was "appropriate for a wide range of patients."

30. Purdue promoted OxyContin to a wide variety of doctors, without regard for their training or experience prescribing opioids, encouraging OxyContin for an ever-increasing list of conditions, and patient types. While expanding the market in this way, Purdue failed to adequately account for known health and safety risks of OxyContin, especially the risks of OxyContin abuse, dependence, addiction and diversion.

Purdue's Marketing Strategy was to Steadily Expand OxyContin Usage from Cancer Pain Treatment to a Wide Array of Ailments

31. At the outset of the OxyContin launch, Purdue briefly marketed OxyContin principally for treatment of chronic pain in cancer patients. That quickly changed. Beginning in 1996, Purdue consistently expanded: a) the types of doctors and healthcare professionals to whom it promotes OxyContin; b) the classes of patients for whom it encourages OxyContin to be prescribed; and c) the array of diseases and types of pain for which it promotes OxyContin use.

32. One step in Purdue's plan to expand OxyContin use to all sorts of pain was its decision to focus its sales efforts on primary care physicians ("PCPs").

33. Purdue targeted PCPs as a fruitful avenue to increased OxyContin sales. Sales representatives visited thousands of primary care physicians and sought to convince them that OxyContin was an appropriate first-line painkiller for a wide variety of ailments. More than half

of doctor visits by Purdue sales reps were to PCPs. The aggressive marketing to PCPs paid off: Since 2002, PCPs have accounted for nearly half of all OxyContin prescriptions.

34. Purdue's promotional efforts also targeted additional types of physicians, eventually including surgeons, gerontologists, rheumatologists, orthopedics, arthritis specialists, obstetricians and gynecologists, emergency medicine physicians, and dentists. Purdue failed to take meaningful steps to educate these doctors on the risks of opioid use, abuse, addiction and diversion. Instead, Purdue repeated its simple sales messages: pain is undertreated, OxyContin provides easy dosing and prompt relief, and is the "one to start with and to stay with."

35. Purdue consistently expanded the pain ailments for which it aggressively promoted OxyContin, without a concomitant focus on limiting OxyContin to serious and prolonged pain.

36. As Purdue's promotional activities expanded the proposed uses for OxyContin – to include many diseases and many types of pain – Purdue's marketing strategy minimized OxyContin's risks. Instead of recommending caution in the use of a Schedule II narcotic with an abuse profile similar to morphine, Purdue in essence pitched OxyContin as simply a powerful pain reliever – for many types of pain and for many types sorts of patients – with few precautions to guard against its capacity for abuse, dependence, addiction and diversion.

37. Purdue also failed to closely follow appropriate step therapy and instead promoted OxyContin as the first-line pain reliever that could be used to treat all levels of pain – "the one to start with and stay with" and "the easy way."

38. Purdue's sales strategy to expand OxyContin's prescriber base and patient population was successful. Within years of its launch and through the present, OxyContin was and is prescribed by a wide range of doctors for a wide range of pain ailments.

While Expanding the Prescriber Base and Usage of OxyContin, Purdue Failed to Adequately Focus on OxyContin's Health and Safety Risks, Especially the Risks Related to Abuse and Diversion

39. From its product launch, Purdue knew that OxyContin was prone to abuse, dependence, addiction and diversion. But the linchpin of Purdue's marketing strategy was to distinguish OxyContin from other opioids and their well known risk of abuse, and to avoid the stigma attached to these other opioids, particularly morphine. Purdue's sales strategy focused on getting doctors "comfortable" with prescribing OxyContin, even though prescribing opioids warrants that doctors exercise caution, and OxyContin did not warrant different treatment.

40. In 2001, amidst significant media coverage of widespread OxyContin abuse, diversion and addiction, the FDA required Purdue to significantly alter its label to provide a so-called "black box" warning, including the following:

> Warning: OxyContin is an opioid agonist and a Schedule II controlled substance with an abuse liability similar to morphine.
>
> OxyContin Tablets are to be swallowed whole, and are not to be broken, chewed or crushed. Taking broken, chewed or crushed OxyContin Tablets leads to rapid release and absorption of a potentially fatal dose of oxycodone.

41. Even after the FDA required Purdue to bolster its OxyContin warning, Purdue continued to minimize the risks of abuse, addiction and diversion in its marketing. Instead,

Purdue repeated its message that pain is undertreated, that patients deserve opioid treatment, and that OxyContin is the answer. Any meaningful message on the risks of abuse, addiction and diversion would have undermined Purdue's sales objectives, and Purdue avoided it.

42. Purdue sought to portray "addiction" to opioids as exceedingly rare. By way of example, Purdue's videotape "From One Patient to Another," advised patients that "Less than 1% of patients taking opioids actually become addicted." A Purdue pamphlet entitled "Counseling Your Patients and Families Regarding the Use of Opioids," stated: "Many patients – and family members – will be surprised to discover that fewer than 1% of opioid-using patients become addicted." Purdue's focus on "addiction," narrowly defined, to the exclusion of broader concepts of psychological dependence, physical dependence, tolerance and abuse, made its representations misleading.

43. If doctors expressed concern over using OxyContin due to its capacity for abuse, dependence or addiction, Purdue trained its sales representatives to avoid and minimize those concerns.

44. Although Purdue, in response to public scrutiny of widespread OxyContin abuse, has claimed to implement programs designed to guard against diversion and abuse, it has continued to try to convince doctors that their concerns of addiction, dependence and abuse are misplaced.

Purdue Employed a Sales Approach and Incentive System that Exacerbated, Rather Than Guarded Against, the Risk of OxyContin Abuse, Addiction and Diversion

45. Purdue sales representatives were compensated in large measure for increasing the volume of OxyContin prescribed and sold. Purdue's sales goals were plain: to increase the number of doctors prescribing Oxycontin, to increase the number of prescriptions written by

each, and to increase dosages of OxyContin. Purdue's sales approach and incentive system failed to adequately balance Purdue's desire for increased OxyContin sales with safeguards against OxyContin abuse, addiction and diversion.

46. Both through its compensation structure and through its sales managers, Purdue cultivated a high pressure environment for its sales representatives. This pressure to increase sales was not properly balanced against public safety and failed to account for the known risks of OxyContin.

47. Purdue also instructed its sales representatives to focus their sales efforts on those doctors who already prescribed the greatest amount of OxyContin, urging them to write more prescriptions for more patients. Using detailed prescribing data on doctors, Purdue sales representatives strove to increase "new starts" and increase prescription volume by these key prescribers.

48. These aspects of Purdue's sales and incentive system all served to promote, not guard against, OxyContin abuse, diversion and addiction.

49. Purdue also failed to use its detailed prescribing information on doctors to guard against OxyContin abuse and diversion. Purdue, since OxyContin's launch, purchased detailed prescribing data from IMS Health ("IMS data"), showing the prescribing history and patterns of doctors, including the number of OxyContin prescriptions written, the dosages, as well as the same prescribing information with respect to competing opioids and other drugs. Purdue provides each sales representative this prescribing information for target doctors in their territory.

50. Purdue could have used the prescribing data to readily identify potential sources of abuse and diversion, such as "pill mills" that divert OxyContin to the illicit street market. Purdue then could have employed meaningful internal measures to guard against abuse and diversion risks. For instance, Purdue could have visited those doctors to review pain documentation practices or otherwise protect against potential abuse or diversion. Or, the company could have shared with law enforcement those prescribing patterns that evidenced a risk of abuse or diversion. For years, Purdue did not take those steps.

51. Purdue, notwithstanding its marketing claims focused on fighting abuse and diversion, declined to use the IMS prescribing data to protect against abuse and diversion risks. Purdue sales representatives instead targeted the highest prescribers and encouraged them to prescribe more OxyContin, in larger doses, to more patients. Purdue's marketing practices thus exacerbated the abuse and diversion risks.

52. Purdue's OxyContin marketing resulted in dramatic increases in OxyContin prescriptions.

VIOLATIONS OF THE TEXAS DECEPTIVE TRADE PRACTICES ACT

53. Purdue, as alleged above in paragraphs 1 through 52, has in the course of trade and commerce engaged in false, misleading and deceptive acts and practices declared unlawful in §17.46(a). Additionally, Purdue has violated §17.46(b) of the DTPA as follows:

A. Causing confusion or misunderstanding as to the safety of OxyContin by avoiding or minimizing the known risks, including the risks of abuse, dependence, addiction and diversion, in violation of §17.46(b)(2) of the DTPA;

B. Representing that OxyContin has benefits which it does not have, in violation of §17.46(b)(5) of the DTPA;

C. Representing that OxyContin is of a particular standard, quality, or grade, if it is of another, in violation of §17.46(b)(7) of the DTPA; and

D. Aggressively marketing OxyContin to a broad variety of doctors and patients, for an ever expanding array of ailments, sometimes contrary to its label and indications, while failing to adequately disclose and reasonably warn of and guard against the health and safety risks associated with OxyContin, including the risks associated with misuse, abuse, dependence, addiction and diversion, when such failure to disclose was intended to induce the consumer into a transaction into which the consumer would not have entered had the information been disclosed, in violation of §17.46(b)(24) of the DTPA.

INJURY TO CONSUMERS

54. By means of the foregoing unlawful acts and practices, Purdue has acquired money or other property from identifiable persons to whom such money or property should be restored, or who in the alternative are entitled to an award of damages.

PERMANENT INJUNCTION

55. The State alleges that by reason of the foregoing, Purdue should not continue to advertise, promote, or sell its drug OxyContin or any other drug in violation of the laws of Texas. The interests of the State of Texas require a permanent injunction to prohibit Purdue from advertising and selling its drugs in Texas, unless Purdue is in compliance with the DTPA.

56. Unless injunctive relief is granted, Purdue will continue to violate the laws of the State of Texas to irreparable injury of the State of Texas and to the general public.

PRAYER

57. WHEREFORE, Plaintiff prays that Purdue be cited according to law to appear and answer herein; that after due notice and upon final hearing a PERMANENT INJUNCTION be issued, restraining and enjoining Purdue, its successors, assigns, officers, agents, servants, employees, and any other person in active concert or participation with Purdue from engaging in the following acts or practices:

A. Making any false, misleading or deceptive representation regarding any of its pharmaceutical or biological products in violation of all applicable laws and regulations;

B. Failing to comply with all applicable laws and regulations relating to the marketing, sale, and promotion of its pharmaceutical and biological products;

C. Causing confusion or misunderstanding as to the safety of the drug OxyContin;

D. Representing that OxyContin has benefits which it does not have;

E. Representing that OxyContin is of a particular standard, quality, or grade, if it is of another; and

F. Failing to disclose that OxyContin posed increased health and safety risks, including the risks associated with misuse, abuse, dependence, addiction and diversion.

58. Plaintiff further prays that this court upon final hearing order Purdue to pay civil penalties in favor of the STATE OF TEXAS in the amount of $20,000.00 per violation of the DTPA.

59. Plaintiff further prays that upon final hearing that his Court order Purdue to restore all money or other property taken from persons by means of unlawful acts or practices, or, in the alternative, award judgment for damages to compensate for such losses.

60. Plaintiff further prays that upon final hearing that this Court order Purdue to pay to the STATE OF TEXAS attorney fees and costs of court pursuant to the TEX. GOVT. CODE §402.006(c).

61. Plaintiff further prays that upon final hearing that this Court grant all other relief to which the STATE OF TEXAS may show itself entitled.

Respectfully submitted,

Plaintiff State of Texas

GREG ABBOTT
Attorney General of Texas

KENT C. SULLIVAN
First Assistant Attorney General

JEFF L. ROSE
Deputy First Assistant Attorney General

PAUL D. CARMONA
Assistant Attorney General
Chief, Consumer Protection and Public Health Division

JOYCE WEIN ILIYA
Assistant Attorney General
Consumer Protection and Public Health Division

State Bar No. 00784319
1410 Main St., Suite 810
Dallas, Texas 75202
(214) 969-7639, ext. 111
Facsimile: (214) 969-7615