PART D
In The

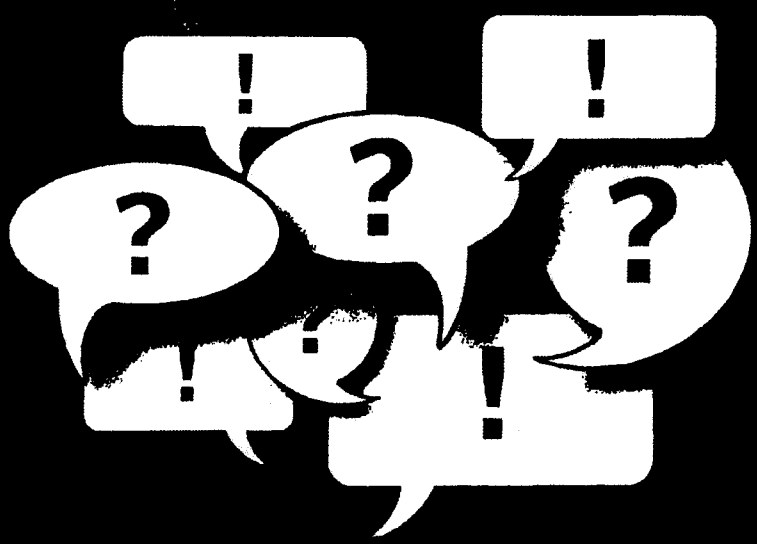
IN THE DISTRICT COURT OF CLEVELAND COUNTY
STATE OF OKLAHOMA

STATE OF OKLAHOMA, ex rel., MIKE HUNTER, ATTORNEY GENERAL OF OKLAHOMA,	§	
Plaintiff,	§	
vs.	§	Case No. CJ-2017-816 The Honorable Thad Balkman
(1) PURDUE PHARMA L.P.;	§	
(2) PURDUE PHARMA, INC.;	§	William C. Hetherington
(3) THE PURDUE FREDERICK COMPANY;	§	Special Discovery Master
(4) TEVA PHARMACEUTICALS USA, INC.;	§	
(5) CEPHALON, INC.;	§	
(6) JOHNSON & JOHNSON;	§	
(7) JANSSEN PHARMACEUTICALS, INC.;	§	*To be heard by the Honorable*
(8) ORTHO-McNEIL-JANSSEN PHARMACEUTICALS, INC., n/k/a JANSSEN PHARMACEUTICALS, INC.;	§	*Thad Balkman, District Judge*
(9) JANSSEN PHARMACEUTICA, INC., n/k/a JANSSEN PHARMACEUTICALS, INC.;	§	CONFIDENTIAL FILED UNDER SEAL PURSUANT TO PROTECTIVE ORDER DATED APRIL 16, 2018
(10) ALLERGAN, PLC, f/k/a ACTAVIS PLC, f/k/a ACTAVIS, INC., f/k/a WATSON PHARMACEUTICALS, INC.;	§	
(11) WATSON LABORATORIES, INC.;	§	
(12) ACTAVIS LLC; and	§	
(13) ACTAVIS PHARMA, INC., f/k/a WATSON PHARMA, INC.,	§	
Defendants.	§	

THE STATE'S RESPONSE IN OPPOSITION TO DEFENDANTS WATSON LABORATORIES, INC., ACTAVIS LLC, ACTAVIS PHARMA, INC. AND TEVA PHARMACEUTICALS USA, INC.'S MOTION FOR PARTIAL SUMMARY JUDGMENT AND BRIEF IN SUPPORT

EXHIBIT
28

MAKING PAIN TALK PAINLESS



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Talking with your doctor about pain can be confusing. You may hear words you know, and some you don't. This guide will give you definitions to the words doctors and nurses use when talking about pain. It is important to learn these words. You can take this guide with you and read it at home. Once you know these words you will feel more comfortable talking with your doctor. Knowing these words will make you a better partner in the management of your pain.

This guide is divided into 3 sections:

Section 1: Different kinds of pain
Section 2: Different kinds of pain medicine
Section 3: Side effects related to pain medicine

Section 1: Different kinds of pain

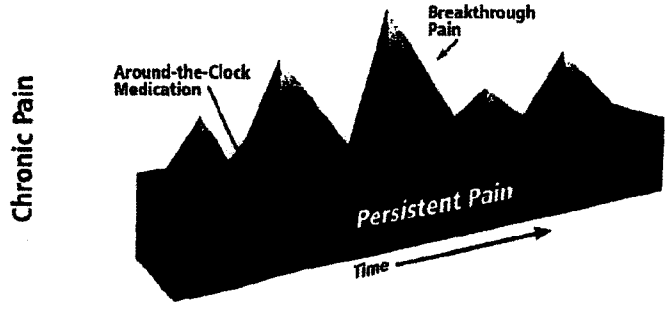
There are several kinds of pain. Different pains are caused by different things. It is important to know these differences. Your doctor will give you the medicine best suited for the pain you are having.

Acute pain: Pain that lasts for a short time, a few days to a few weeks. Acute pain may be caused by injury or surgery.

Chronic pain: Pain that lasts for more than 3 months. There are 2 kinds of chronic pain: breakthrough pain and persistent pain. You may suffer from one or both of these chronic pains.[1,2]

Persistent pain: This kind of pain lasts all day long. It does not spike like breakthrough pain. Your doctor might also call this pain "background pain" or "baseline pain."

Breakthrough pain: An intense flare or spike of pain that rises above your persistent pain (see below). Breakthrough pain occurs only with controlled persistent pain. There are specific medicines to control breakthrough pain.



Section 2: Different kinds of pain medicine

If you are in pain, your doctor will often give you medicine. You will be given medicine based on the kind of pain you are having. So, first, your doctor will try to figure out what kind of pain you are having. Your doctor will also try to find out what is causing your pain.

It is also important to know that different medicines are taken in different ways. The different ways to take medicine are called delivery systems. Examples of delivery systems are pills and shots, but there are other ways too.

Analgesic: Any medicine used to relieve pain.

Around-the-clock: Medicine that works for 8 hours or more. This will also be called "long-acting" or "sustained-release" medicine. Around-the-clock pain medicine is used for persistent pain.

Intravenous (IV): A delivery system whereby a needle is placed in a vein and secured. The medicine moves through a tube that lets the medicine enter right into your bloodstream.

Nonsteroidal anti-inflammatory drugs: Commonly called NSAIDs. These drugs treat mild pains and swelling. Most NSAIDs are over-the-counter pain relievers like Advil® (ibuprofen).

Opioids: These medicines are part of a class of strong painkillers. Opioids do not take the pain away, they interfere with and stop pain messages from being sent to the brain to change the feeling of pain. Opioids require a prescription from your doctor. Examples of opioids are morphine, fentanyl, oxycodone, and codeine.

Oral transmucosal: Another kind of delivery system. This kind of medicine is absorbed through the lining inside your mouth, between your cheek and gum.

Rapid-onset: This kind of medicine starts working in 15 minutes or less.

Transdermal: This is a delivery system for certain medicines. Medicine is absorbed into the body through a patch placed on the skin.

Section 3: Side effects related to pain medicine

When you take any kind of medicine there is a chance you will get side effects. Side effects are unwanted ways your body may respond to medicine. It is important to be aware that different medicines may have different side effects. Short-term side effects can happen within about the first 10 days of being on a medicine. Long-term side effects can happen after being on a medicine for more than 10 days.

If you feel or think anything out of the ordinary after taking a medicine you should tell your doctor or nurse right away. The number of side effects you have and how often you have them may be different for each medicine. Some side effects are easy to treat. Some side effects are more serious, even harmful, and you may need to stop taking the medicine because of them. It is important to discuss side effects with your doctor.

Continued on back cover.

Section 3: Side effects related to pain medicine (cont)

The following are common short-term side effects:

Constipation: Difficulty with bowel movements because of hardened stools (NOTE: May persist over time)

Decreased appetite: Not wanting to eat

Diarrhea: Loose stools

Dizziness: Feeling light-headed

Drowsiness: Feeling tired

Euphoria: An extreme feeling of well-being and happiness

Headache: Pain in the head

Nausea: Upset stomach

Rash: Spots or patches of itchy, irritated skin

Respiratory depression: Slow breathing, unable to take deep breaths

Vomiting: Emptying the contents of the stomach through the mouth

The following are possible long-term side effects or conditions:

Addiction: Characterized by 1 or more of the following: impaired control over drug use, compulsive use, continued use despite harm, and craving of a medicine. Addiction rarely occurs when you take medicine under your doctor's supervision.[3,4]

Physical dependence: When your body has come to depend on having the drug in your system. If you suddenly stopped you would feel sick. This is called withdrawal syndrome. If opioids are used for a long period of time, it is expected that you will become physically dependent on your medicine.

Pseudo-addiction: Medicine-seeking behavior caused by not taking enough pain medicine and can be mistaken for addiction. It is NOT addiction. If you feel you are not taking enough medicine to relieve your pain, talk with your doctor.

Pseudo-tolerance: Similar to tolerance, this is when your body needs more medicine to continue feeling pain relief. More medicine is needed because the original cause of pain has progressed, a new cause is present, or because of increased activity and not because your body has adjusted to the medicine.

Tolerance: When your body gets used to the medicine and its effects. A stronger amount of medicine is needed to maintain pain relief. Tolerance is NOT addiction.

You should always talk with your doctor or nurse if you have any questions. Now that you have read this guide you have a starting point in understanding your pain management and how to begin talking with your doctor about it.

References: 1. American Cancer Society. Breakthrough cancer pain: questions and answers. Available at: http://www.cancer.org/docroot/MIT/content/MIT_7_2x_Breakthrough_Cancer_Pain_Questions_and_Answers.asp?sitearea=MIT&viewmode=print&. Accessed November 7, 2005. 2. National Pharmaceutical Council. Pain: current understanding of assessment, management, and treatments. Available at: http://www.jcaho.org/news+room/ health+care+issues/pain_mono_npc.pdf. Accessed October 27, 2005. 3. Tolerance, physical dependence and addiction: definitions, clinical relevance and misconceptions. Available at: http://www.whorarcepain.wisc.edu. Accessed February 28, 2005. 4. American Academy of Pain Medicine, American Pain Society, and American Society of Addiction Medicine. Definitions related to the use of opioids for the treatment of pain (consensus document, approved 2001). Available at: www.painmed.org/productpub/statements/ pdfs/definition.pdf. Accessed August 4, 2005.

For more information please visit www.pain.com

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Section 3: Side effects related to pain medicine (cont)

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EXHIBIT
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CORPORATE CREATIONS®
Registered Agent • Director • Incorporation

Corporate Creations Network Inc.
11380 Prosperity Farms Road #221E, Palm Beach Gardens, FL 33410

July 5, 2017

EXHIBIT
Kolody
17
PENGAD 800-631-6989

Cephalon, Inc.
Jennifer Fuller-Ricciardi Sr. Legal Associate
Teva Pharmaceuticals USA, Inc.
425 Privet Road
HORSHAM PA 19044

SERVICE OF PROCESS NOTICE

The following is a courtesy summary of the enclosed document(s). **ALL information should be verified by you.**

Note: Any questions regarding the substance of the matter described below, including the status or to whom or where to respond, should be directed to the person set forth in line 12 below or to the court or government agency where the matter is being heard.

Item: 2017-194

1.	**Client Entity:**	Cephalon, Inc.
2.	**Title of Action:**	State of Oklahoma, ex rel, Mike Hunter Attorney General of Oklahoma vs. Purdue Pharma L.P.; et al.
3.	**Document(s) Served:**	Summons Original Petition Exhibits
4.	**Court/Agency:**	Cleveland County District Court, Oklahoma
5.	**State Served:**	Delaware
6.	**Case Number:**	CJ-2017-816
7.	**Case Type:**	Oklahoma Medicaid False Claims Act
8.	**Method of Service:**	Certified Mail
9.	**Date Received:**	Monday 7/3/2017
10.	**Date to Client:**	Wednesday 7/05/2017
11.	**# Days When Answer Due:**	20
	Answer Due Date:	7/23/2017
12.	**SOP Sender:** (Name, Address and Phone Number)	Mike Hunter Oklahoma City, OK (405) 521-3921
13.	**Shipped to Client By:**	FedEx Saver and Email with PDF Link
14.	**Tracking Number:**	779557913077
15.	**Handled By:**	081
16.	**Notes:**	None.

CAUTION: Client is solely responsible for verifying the accuracy of the estimated Answer Due Date. To avoid missing a crucial deadline, we recommend immediately confirming in writing with opposing counsel that the date of service in their records matches the Date Received.

NOTE: This notice and the information above is provided for general informational purposes only and should not be considered a legal opinion. The client and their legal counsel are solely responsible for reviewing the service of process and verifying the accuracy of all information. At Corporate Creations, we take pride in developing systems that effectively manage risk so our clients feel comfortable with the reliability of our service. We always deliver service of process so our clients avoid the risk of a default judgment. As registered agent, our role is to receive and forward service of process. To decrease risk for our clients, it is not our role to determine the merits of whether service of process is valid and effective. It is the role of legal counsel to assess whether service of process is invalid or defective. Registered agent services are provided by Corporate Creations Network Inc.

IN THE DISTRICT COURT OF CLEVELAND COUNTY
STATE OF OKLAHOMA

STATE OF OKLAHOMA, ex rel., MIKE HUNTER, ATTORNEY GENERAL OF OKLAHOMA,	§	
Plaintiff,	§	
vs.	§	
(1) PURDUE PHARMA L.P.; (2) PURDUE PHARMA, INC.; (3) THE PURDUE FREDERICK COMPANY; (4) TEVA PHARMACEUTICALS USA, INC.; (5) CEPHALON, INC.; (6) JOHNSON & JOHNSON; (7) JANSSEN PHARMACEUTICALS, INC.; (8) ORTHO-McNEIL-JANSSEN PHARMACEUTICALS, INC., n/k/a JANSSEN PHARMACEUTICALS, INC.; (9) JANSSEN PHARMACEUTICA, INC., n/k/a JANSSEN PHARMACEUTICALS, INC.; (10) ALLERGAN, PLC, f/k/a ACTAVIS PLC, f/k/a ACTAVIS, INC., f/k/a WATSON PHARMACEUTICALS, INC.; (11) WATSON LABORATORIES, INC.; (12) ACTAVIS LLC; and (13) ACTAVIS PHARMA, INC., f/k/a WATSON PHARMA, INC.,	§	Case No. CJ-2017-816 JURY TRIAL DEMANDED
Defendants.	§	

SUMMONS

TO: CEPHALON, INC.
c/o Corporate Creations Network, Inc., Registered Agent
3411 Silverside Road
Tatnall Building, Suite 104
Wilmington, DE 19810

TO THE ABOVE-NAMED DEFENDANT:

You have been sued by the above-named Plaintiffs, and you are directed to file a written answer to the attached Petition in the Court at the above address within twenty (20) days after service of this summons upon you, exclusive of the day of service. Within the same time, a copy of your answer must be delivered or mailed to the attorneys for the Plaintiffs.

Unless you answer the Petition within the time stated, judgment will be rendered against you with costs of this action. Issued this 30 day of June, 2017.

MARILYN WILLIAMS, COURT CLERK
S / Carol Frazier
By: _____

(SEAL)

ATTORNEYS FOR PLAINTIFF:

Mike Hunter, OBA No. 4503
ATTORNEY GENERAL FOR
THE STATE OF OKLAHOMA
Abby Dillsaver, OBA No. 20675
GENERAL COUNSEL TO
THE ATTORNEY GENERAL
Ethan A. Shaner, OBA No. 30916
DEPUTY GENERAL COUNSEL
313 N.E. 21st Street
Oklahoma City, OK 73105
Telephone: (405) 521-3921
Facsimile: (405) 521-6246

Michael Burrage, OBA No. 1350
Reggie Whitten, OBA No. 9576
WHITTEN BURRAGE
512 N. Broadway Avenue, Suite 300
Oklahoma City, OK 73102
Telephone: (405) 516-7800
Facsimile: (405) 516-7859
Emails: mburrage@whittenburragelaw.com
rwhitten@whittenburragelaw.com

Bradley E. Beckworth, OBA No. 19982
Jeffrey J. Angelovich, OBA No. 19981
NIX, PATTERSON & ROACH, LLP
512 N. Broadway Avenue, Suite 200
Oklahoma City, OK 73102
Telephone: (405) 516-7800
Facsimile: (405) 516-7859
Emails: bbeckworth@nixlaw.com
jangelovich@npraustin.com

Glenn Coffee, OBA No. 14563
GLENN COFFEE & ASSOCIATES, PLLC
915 N. Robinson Ave.
Oklahoma City, OK 73102
Telephone: (405) 601-1616
Email: gcoffee@glenncoffee.com

This summons was served on _____.
(date of service)

_____
Signature of person serving summons

YOU MAY SEEK THE ADVICE OF AN ATTORNEY ON ANY MATTER CONNECTED WITH THIS SUIT OR YOUR ANSWER. SUCH ATTORNEY SHOULD BE CONSULTED IMMEDIATELY SO THAT AN ANSWER MAY BE FILED WITHIN THE TIME LIMIT STATED IN THE SUMMONS.

RETURN OF SERVICE BY PROCESS SERVER

I certify that I received the foregoing Summons on the _____ day of _____, 2017, and that I delivered a copy of said summons with a copy of the Petition attached to each of the following named Defendants personally at the address and on the date set forth opposite each name, to wit:

DEFENDANT	ADDRESS WHERE SERVED	DATE OF SERVICE
_____	_____	_____
_____	_____	_____
_____	_____	_____

Usual Place of Residence

I certify that I received the foregoing Summons on the _____ day of _____, 2017, and that on _____, I served _____ by leaving a copy of said Summons with a copy of the Petition attached at _____, which is his/her usual place of residence with _____, a member of his/her family fifteen (15) years of age or older.

_____

IN THE DISTRICT COURT OF CLEVELAND COUNTY
STATE OF OKLAHOMA

STATE OF OKLAHOMA, ex rel., MIKE HUNTER, ATTORNEY GENERAL OF OKLAHOMA,	§	STATE OF OKLAHOMA } S.S. CLEVELAND COUNTY }
Plaintiff,	§	FILED
vs.	§	JUN 30 2017
(1) PURDUE PHARMA L.P.; (2) PURDUE PHARMA, INC.; (3) THE PURDUE FREDERICK COMPANY; (4) TEVA PHARMACEUTICALS USA, INC.; (5) CEPHALON, INC.; (6) JOHNSON & JOHNSON; (7) JANSSEN PHARMACEUTICALS, INC.; (8) ORTHO-McNEIL-JANSSEN PHARMACEUTICALS, INC., n/k/a JANSSEN PHARMACEUTICALS, INC.; (9) JANSSEN PHARMACEUTICA, INC., n/k/a JANSSEN PHARMACEUTICALS, INC.; (10) ALLERGAN, PLC, f/k/a ACTAVIS PLC, f/k/a ACTAVIS, INC., f/k/a WATSON PHARMACEUTICALS, INC.; (11) WATSON LABORATORIES, INC.; (12) ACTAVIS LLC; and (13) ACTAVIS PHARMA, INC., f/k/a WATSON PHARMA, INC.,	§	In the office of the Court Clerk MARILYN WILLIAMS
Defendants.	§	Case No. CJ-2017-816 JURY TRIAL DEMANDED

ORIGINAL PETITION

TABLE OF CONTENTS

"The most depraved criminals are often the dispensers of these habit-forming drugs."
--Editorial Comment, *American Medicine,* 1915[1]

I. INTRODUCTION

1. Opioids are highly addictive, habit-forming drugs. They always have been. That is why, for centuries, medical professionals employed opium-based drugs with caution and only prescribed them in limited circumstances to patients with cancer, terminal illnesses, or acute short-term pain.

2. Defendants manufacture and sell opioids and, therefore, the limited uses for which doctors prescribed them were undermining Defendants' bottom line. Defendants wanted to increase their opioid sales. And increase them they did. For example, from 1996 to 2000, OxyContin sales rose from $48 million to more than $1 billion. By 2009, OxyContin retail sales reached $3 billion.

3. One way to sell more opioids was to expand the market beyond a niche for cancer patients, the terminally ill, and acute short-term pain and persuade medical professionals to prescribe more opioids to a broader range of patients with chronic non-cancer related pain. To convince medical professionals to prescribe more opioids to a broader range of patients, Defendants elected to falsely downplay the risk of opioid addiction and overstate the efficacy of opioids for more wide-ranging conditions, including chronic non-cancer pain.

4. Over a period of several years, Defendants executed massive and unprecedented marketing campaigns through which they misrepresented the risks of addiction from their opioids and touted unsubstantiated benefits. To encourage physicians to prescribe more opioids, Defendants event went so far as to tell prescribers that classic signs of addiction should actually

[1] 21 (O.S.), 10 (N.D.) (November 1915): 799-800 (discussing spread of narcotic drug addiction).

be treated with ***more*** opioid use because they were signs of "pseudoaddiction" which meant the patient was supposedly experiencing undertreated pain.

5. The damage Defendants' false and deceptive marketing campaigns caused to the State of Oklahoma is catastrophic. Oklahoma is one of the leading states in prescription painkiller sales per capita, with 128 painkiller prescriptions dispensed per 100 people in 2012. Drug overdose deaths in Oklahoma increased eightfold from 1999 to 2012, surpassing car crash deaths in 2009. According to 2016 statistics, Oklahoma ranks number one in the nation in milligrams of opioids distributed per adult resident, with approximately 877 milligrams of opioids distributed per adult resident.

6. A 2016 government study estimated the national economic impact of prescription opioid overdoses, abuse and dependence to be $78.5 billion annually, with one-fourth of the amount funded by public sources including government funded insurance and government expenditures on treatment of substance abuse. As a result of Defendants' egregious conduct, the State of Oklahoma paid, and continues to pay, millions of dollars for health care costs that stem from prescription opioid dependency. These costs include unnecessary and excessive opioid prescriptions, substance abuse treatment services, ambulatory services, inpatient hospital services and emergency department services, among others. Defendants' conduct also caused the State of Oklahoma to incur substantial social and economic costs including criminal justice costs, and lost work productivity costs, among others.

7. Plaintiff, the State of Oklahoma, by and through its Attorney General (hereinafter "Oklahoma" or "the State"), seeks to recover for the damages caused by Defendants' wrongdoing and impose all applicable penalties under Oklahoma law. As such, the State, upon

personal knowledge as to its own acts and beliefs, and upon information and belief as to all other matters, alleges as follows:

II. JURISDICTION AND VENUE

8. The State is asserting the claims set forth in Section V below, one of which is the Oklahoma Medicaid False Claims Act ("OMFCA"), Okla. Stat. tit. 63, §§5053.1-7. Under §5053.7 of the OMFCA, "[t]he district courts shall have jurisdiction over any action brought under the laws of the state for the recovery of funds paid by a state or local government if the action arises from the same transaction or occurrence as an action brought under the [OMFCA]."

9. Further, this Court has jurisdiction over Defendants because Defendants conduct business in Cleveland County and throughout Oklahoma, and have deliberately engaged in significant acts and omissions within Oklahoma that have injured the State and its citizens. Defendants purposefully directed their activities at Oklahoma and its citizens, and the claims arise out of those activities.

10. Venue is proper in this Court under §5053.7 because at least one of the Defendants transacts business and committed acts proscribed by the OMFCA in this judicial district.

11. Venue is also proper in this Court under Okla. Stat. tit. 12, §137.

III. PARTIES

A. Plaintiff

12. The State of Oklahoma is a sovereign state of the United States. This action is brought for and on behalf of the sovereign State, by and through Mike Hunter, the Attorney General and chief law officer for the State and all its departments and agencies.

B. Defendants

i. The Purdue Defendants

13. Defendant Purdue Pharma L.P. is a limited partnership organized under the laws of the State of Delaware with its principal place of business in Connecticut. Defendant Purdue Pharma Inc. is a New York corporation with its principal place of business in Connecticut. Defendant Purdue Frederick Company is a Delaware corporation with its principal place of business in Connecticut. At all relevant times, Purdue Pharma L.P., Purdue Pharma Inc., and the Purdue Frederick Company (collectively "Purdue") acted in concert with one another and acted as agents and/or principals of one another in relation to the conduct described herein.

14. Defendant Purdue manufactures several opioids, including OxyContin, MS Contin, Dilaudid/Dilaudid HP, Butrans, Hysingla ER, and Targiniq ER and promotes, markets, and sells its opioids in the State of Oklahoma.

ii. The Actavis Defendants

15. Defendant Allergan Plc is a public limited company incorporated in Ireland with its principal place of business in Dublin, Ireland. Actavis Plc acquired Allergan Plc in March 2015, and the combined company changed its name to Allergan Plc in March 2015. Before that, Defendant Watson Pharmaceuticals, Inc. acquired Actavis, Inc. in October 2012, and the combined company changed its name to Actavis, Inc. as of January 2013 and then Actavis Plc in October 2013. Defendant Watson Laboratories, Inc. is a Nevada corporation with its principal place of business in Corona, California, and is a wholly-owned subsidiary of Allergan Plc (f/k/a Actavis, Inc., f/k/a Watson Pharmaceuticals, Inc). Defendant Actavis Pharma, Inc. (f/k/a Actavis, Inc.) is a Delaware corporation with its principal place of business in New Jersey and was formerly known as Watson Pharma, Inc. Defendant Actavis LLC is a Delaware limited

liability company with its principal place of business in Parsippany, New Jersey. At all relevant times, Allergan Plc, Actavis Plc, Actavis, Inc., Actavis LLC, Actavis Pharma, Inc., Watson Pharmaceuticals, Inc., Watson Pharma, Inc., and Watson Laboratories, Inc. (collectively, "Actavis") acted in concert with one another and acted as agents and/or principals of one another in relation to the conduct described herein.

16. Defendant Actavis manufactures several branded opioids, including Kadian and Norco, and several generic opioids, and promotes, markets, and sells its opioids in the State of Oklahoma.

iii. The Cephalon Defendants

17. Defendant Cephalon, Inc. is a Delaware corporation with its principal place of business in Pennsylvania. Defendant Teva Pharmaceuticals USA, Inc. ("Teva USA") is a Delaware corporation with its principal place of business in Pennsylvania, and acquired Cephalon in October 2011. Defendants Cephalon and Teva USA are collectively referred to herein as "Cephalon." After Teva USA acquired Cephalon in October 2011, Teva USA and Cephalon acted in concert with one another and acted as agents and/or principals of one another in relation to the conduct described herein.

18. Defendant Cephalon manufactures several opioids, including Actiq and Fentora and promotes, markets, and sells its opioids in the State of Oklahoma.

iv. The Janssen Defendants

19. Defendant Janssen Pharmaceuticals, Inc. is a Pennsylvania corporation with its principal place of business in New Jersey, and is a wholly owned subsidiary of Defendant Johnson & Johnson (J&J), a New Jersey corporation with its principal place of business in New Jersey. Defendant Ortho-McNeil-Janssen Pharmaceuticals, Inc., now known as Janssen

Pharmaceuticals, Inc., is a Pennsylvania corporation with its principal place of business in New Jersey. Defendant Janssen Pharmaceutica Inc., now known as Janssen Pharmaceuticals, Inc., is a Pennsylvania corporation with its principal place of business in New Jersey. At all relevant times, Janssen Pharmaceuticals, Inc., Johnson & Johnson, Ortho-McNeil-Janssen Pharmaceuticals, Inc, Janssen Pharmaceuticals, Inc., Janssen Pharmaceutica Inc. (collectively, "Janssen") acted in concert with one another and acted as agents and/or principals of one another in relation to the conduct described herein.

20. Defendant Janssen manufactures, or manufactured in the past, several opioids, including Duragesic, Nucynta, and Nucynta ER and promotes, markets, and sells its opioids in the State of Oklahoma.

IV. FACTUAL ALLEGATIONS

A. Defendants' Conduct Created A Devastating Opioid Epidemic in Oklahoma

i. Defendants' Deceptive and Misleading Prescription Opioid Marketing Campaign Has Caused a Devastating Public Health Crisis in Oklahoma

21. Defendants make billions of dollars in profits through their deceptive and misleading opioid marketing campaign. The U.S. opioid market generates at least $10 billion a year in profits to opioid manufacturers like Defendants. For example, Purdue's sales of OxyContin alone have generated estimated sales of more than $35 billion since its release in 1996. While Defendants' unprecedented prescription opioid disinformation campaign yields drug manufacturers like Defendants billions of dollars in annual profits, Oklahoma is left bearing the enormous costs of the resulting public health crisis wreaking havoc in its communities.

22. According to the Center for Disease Control and Prevention (the "CDC"), an increase in the availability and accessibility of opioids has contributed to the prescription drug abuse epidemic in the nation. As sales of prescription opioids have quadrupled since 1999, so

have overdose deaths involving prescription opioids. From 1999 to 2015, more than 183,000 people died in the U.S. from overdoses related to prescription opioids. In 2014, almost 2 million Americans abused or were dependent on prescription opioids. According to the CDC, as many as 1 in 4 people prescribed opioids long term for non-cancer pain in primary care settings struggles with opioid addiction.

23. Oklahoma has been hit particularly hard by Defendants' deceptive marketing of opioids. Oklahoma is one of the leading states in prescription painkiller sales per capita, with 128 painkiller prescriptions dispensed per 100 people in 2012. Drug overdose deaths in Oklahoma increased eightfold from 1999 to 2012, surpassing car crash deaths in 2009. In 2012, Oklahoma had the fifth-highest unintentional poisoning death rate and prescription opioids contributed to the majority of these deaths.

24. In 2014, Oklahoma's unintentional poisoning rate was 107% higher than the national rate.

25. In 2015, 823 fatal drug overdoses occurred in Oklahoma, an almost 140% increase over 2001, with opioids contributing to the largest number of these deaths. As of 2015, there were more prescription drug overdose deaths each year in Oklahoma than overdose deaths from alcohol and all illegal drugs combined.

26. According to 2016 statistics, Oklahoma ranks number one in the nation in milligrams of opioids distributed per adult resident with approximately 877 milligrams of opioids distributed per adult resident.

27. A National Survey on Drug Use and Health revealed Oklahoma leads the nation in non-medical use of painkillers, with nearly 5% of the population aged 12 and older abusing or misusing painkillers.

28. The accessibility and availability of prescription opioids also is fueling illicit opioid addiction. According to the CDC, past misuse of prescription opioids is the strongest risk factor for a person starting and using heroin. Between 2000 and 2014, the number of overdose deaths from heroin nationwide quintupled.

29. As the State passes stricter legislation to combat opioid over-prescription, Oklahomans addicted to prescription opioids are turning to illicit opioids such as heroin as a cheaper and more accessible alternative. From 2007 to 2012, the number of heroin deaths in Oklahoma increased tenfold.

30. Defendants' conduct is affecting even Oklahoma's youngest and most vulnerable citizens. Oklahoma hospitals are reporting an increasing number of newborns testing positive for drugs or alcohol at birth. The national rate of babies born with neonatal abstinence syndrome ("NAS"), a group of conditions newborns experience when withdrawing from exposure to drugs like opioids, increased fivefold from 2000 to 2012. In 2014, the number of newborns testing positive for prescription medications doubled the number reported in 2013. Babies born with NAS require lengthy hospital stays and other medical treatment and thus, dramatically increase health care costs for the State of Oklahoma and its citizens.

ii. Defendants' Deceptive and Misleading Marketing Campaign Has Caused an Immense Financial Burden on Oklahoma, Its Businesses, Consumers, Communities and Citizens

31. Defendants' deceptive marketing campaign and the resulting opioid abuse and addiction epidemic caused, and continues to cause, the State of Oklahoma, its businesses, communities and citizens to bear enormous social and economic costs including increased health care, criminal justice, and lost work productivity expenses, among others.

32. As Oklahomans aged 35-54 have the highest death rate of any age group for

prescription opioid-related overdoses, Defendants' conduct caused Oklahoma businesses, communities, workers and families to incur the substantial costs and losses of poor work performance, injuries, absenteeism, unemployment and lack of economic productivity.

33. The Governor's and Attorney General's Task Force on Mental Health, Substance Abuse and Domestic Violence's report on the economic impact of substance abuse on the State of Oklahoma revealed substance abuse related issues cost the State billions of dollars annually.

34. Defendants' deceptive and misleading marketing campaign caused Oklahoma to pay millions of dollars for unnecessary or excessive opioid prescriptions.

35. From 2007 to present, the Purdue Defendants caused to be submitted over 95,000 prescriptions for reimbursement to the Oklahoma Health Care Authority, on behalf of the Oklahoma Medicaid system, for the Purdue Defendants' opioids. The Oklahoma Health Care Authority has paid approximately $49,965,906.05 for these drugs. Exhibit 1.

36. From 2009 to present, the Actavis Defendants caused to be submitted, over 1,300 prescriptions for reimbursement to the Oklahoma Health Care Authority, on behalf of the Oklahoma Medicaid system, for the Actavis Defendants' opioids. The Oklahoma Health Care Authority has paid approximately $1,097,382.32 for these drugs. Exhibit 2.

37. From 2007 to present, the Cephalon Defendants have caused to be submitted approximately 245 prescriptions for reimbursement to the Oklahoma Health Care Authority, on behalf of the Oklahoma Medicaid system, for the Cephalon Defendants' opioids. The Oklahoma Health Care Authority has paid approximately $647,410.96 for these drugs. Exhibit 3.

38. From 2007 to present, the Janssen Defendants have caused to be submitted over 2,600 prescriptions for reimbursement to the Oklahoma Health Care Authority, on behalf of the Oklahoma Medicaid system, for the Janssen Defendants' opioids. The Oklahoma Health Care

Authority has paid approximately $1,209,446.77 for these drugs. Exhibit 4.

39. The above amounts include only amounts the Oklahoma Medicaid program paid for Defendants' branded opioids prescriptions. They do not include amounts the Oklahoma Medicaid program paid for any generic opioids prescriptions that were manufactured, promoted, marketed and sold in Oklahoma by any Defendants.

40. Defendants' conduct caused Oklahoma private insurers, businesses and consumers to pay millions of dollars for unnecessary or excessive opioid prescriptions.

41. Defendants' decades long false and deceptive marketing campaign caused Oklahoma and its consumers to bear other substantial health care costs related to prescription opioid abuse and addiction.

42. Defendants' conduct caused the State of Oklahoma to incur substantial costs and losses for prescription opioid dependency related health care costs including substance abuse treatment services, ambulatory services, inpatient hospital services and emergency department services, among others.

43. Defendants' conduct caused Oklahoma businesses and consumers to incur substantial costs and losses for prescription opioid dependency related health care costs including substance abuse treatment services, ambulatory services, inpatient hospital services, and emergency department services, among others.

44. Oklahomans that abuse or misuse opioids are more likely to utilize medical services, such as emergency departments, physician outpatient visits, and inpatient hospital stays. According to the CDC, every day, over 1,000 people are treated in emergency departments for misusing prescription opioids. In 2014 alone, the government recorded 1.27 million emergency

room visits or hospital inpatient stays for opioid-related issues, a 64 percent increase for inpatient care and a 99 percent jump for emergency room treatment compared from 2005.

45. The public health crisis caused by Defendants' deceptive marketing campaign also is overwhelming Oklahoma's criminal justice system. The opioid epidemic costs Oklahoma millions of dollars a year on criminal justice related costs. Oklahoma spends 50 percent of its annual criminal justice system budget on substance abuse related costs. And a 2016 CDC study reported the prescription opioid epidemic caused $7.7 billion in criminal justice related costs borne directly by states and local government.

46. Defendants' deceptive marketing campaign also caused Oklahoma to expend substantial resources on education and prevention programs to combat an escalating opioid abuse epidemic. The State's public education efforts include a statewide comprehensive media campaign to reduce prescription drug abuse in Oklahoma, the development and delivery of comprehensive presentations on prescription drug abuse, and funding to high-needs counties to implement community-based prescription drug abuse prevention, among other programs.

47. The State of Oklahoma worked to provide information to the public on appropriate disposal and storage of prescription opioids. The State also initiated programs and expended significant resources to educate prescribers and dispensers of prescription opioids including working to develop an online pain management curriculum and creating and distributing opioid prescribing and dispensing guidelines. The State also worked to educate providers on the Oklahoma Prescription Monitoring Program (PMP) which requires dispensers of Schedule II, III, IV and V controlled substances to submit prescription dispensing information to the Oklahoma Bureau of Narcotics and Dangerous Drugs Control within 24 hours of dispensing a scheduled narcotic and allows prescribers to check the prescription history of their

patients. The State also developed and distributed education materials and educated providers and dispensers on proper storage and disposal of prescription opioids.

48. Oklahoma also spent significant resources and funds to enhance its PMP and coordinate the sharing of data among state agencies. In 2015, the Oklahoma Legislature passed a bill requiring prescribers to check the PMP the first time they prescribe opiate painkillers and two other classes of drugs and to check every 180 days thereafter. The State also is working to establish hospital emergency department discharge databases, and implement public health surveillance of neonatal abstinence syndrome.

49. The State of Oklahoma would not have needed to spend substantial public resources and funding on opioid use and abuse education, prevention and intervention programs but for Defendants' false and deceptive prescription opioid marketing campaign.

50. Despite Oklahoma's efforts to combat the opioid abuse and addiction crisis caused by Defendants' conduct, opioid dependency remains an escalating public health crisis.

B. Defendants Falsely and Deceptively Marketed Their Opioids in Oklahoma

51. Defendants caused catastrophic damage to the State of Oklahoma by dramatically altering the perception of opioids by doctors and patients alike. Prior to Defendants' deceptive marketing campaign, the medical community and consumers primarily relied on opioids for limited purposes, such as surgery recovery, cancer treatment, and end-of-life palliative care. This was largely due to the risk of addiction and abuse posed by these powerful drugs. Defendants sought to change that perception in two key ways. First, Defendants misrepresented the risks of addiction and abuse from opioids. Defendants falsely represented that the risks of addiction were overstated and that scientific studies supported a low risk of addiction associated with their drugs. Second, Defendants touted unsubstantiated benefits of opioid treatment,

including its effectiveness in treating chronic non-cancer related pain. Defendants repeated these misrepresentations to physicians and consumers throughout the country, including directly to physicians and consumers in Oklahoma. At times, Defendants specifically targeted vulnerable patient populations. Each Defendant employed massive and unprecedented marketing campaigns premised on these two key misrepresentations.

i. Defendants Spent Millions of Dollars to Falsely Market Their Opioids

52. Defendants utilized several mediums to distribute the false representations regarding their opioids. Defendants targeted this deceptive marketing to both prescribers and consumers of opioids to change their perceptions of these drugs and develop brand loyalty.

53. Through their marketing campaign, Defendants falsely represented and/or omitted the risks of addiction and falsely touted the benefits of their opioids. For example:

- Defendant Purdue distributed a series of advertisements known as "pain vignettes" which included purported case studies of patients with chronic pain conditions and recommended OxyContin for each. One vignette, for example, described a "54-year old writer with osteoarthritis of the hands" and implied that OxyContin would help him work more effectively.

- Defendant Purdue distributed a promotional video stating, among other things: "There's no question that our best, strongest pain medicines are the opioids...In fact, the rate of addiction amongst pain patients who are treated by doctors is much less than 1%. They don't wear out, they go on working. They do not have serious medical side effects...These drugs which I repeat are our best, strongest pain medications should be used much more than they are for patients in pain."

- According to an interview by a former Purdue sales manager from 2003, Defendant Purdue trained its sales representatives for OxyContin "to say things like it is 'virtually' non-addicting...That's what we were instructed to do. It's not right, but that's what they told us to say." This same manager claimed he was trained that OxyContin was "non-habit forming."

- Defendant Purdue misrepresented OxyContin in medical journal advertisements as, among other things, having been studied for all kinds of arthritis, promoting for use with the elderly without provide accompanying risk information, and omitting information about abuse and addiction potential.

- Defendant Purdue represented OxyContin was less addictive and safer than other brands of oxycodone.

- Defendant Actavis distributed written product advertisements that minimized and/or omitted the serious risks associated with Kadian and also misrepresented its benefits by making unsupported representations, such as it would, among other things, "Allow patients to live with less pain and get adequate rest with less medication" and implying it would relieve stress caused by pain and help patients enjoy their lives.

- Defendant Actavis's predecessor caused a patient education brochure to be distributed in 2007 for Kadian that claimed addiction is "less likely if you have never had an addiction problem."

- Defendant Actavis trained its sales representatives with documents claiming that "most chronic benign pain patients do have markedly improved ability to function when maintained on chronic opioid therapy"; long-acting opioids were less likely to produce addiction than short-acting opioids; and certain behaviors, generally associated with addiction, actually constituted "pseudoaddiction."

- Defendant Janssen made unsubstantiated representations that Nucynta was appropriate for broader pain conditions than indicated and downplayed its risks.

- Defendant Cephalon, through its sales force and other marketing, misrepresented Actiq and Fentora as being appropriate for non-cancer pain and non-opioid-tolerant individuals, despite their labels' contrary warnings.

54. Defendants employed large forces of sales representatives who spoke directly to doctors and repeated their misrepresentations, falsely representing the risk of addiction was low and touting unsubstantiated benefits of long term opioid treatment, including that such long-term treatment would improve function in patients. Defendants conducted these aggressive marketing campaigns directly to Oklahoma physicians and consumers.

55. The scale of Defendants' marketing campaigns was massive. For example, Defendant Purdue, from 1996-2001, hosted dozens of national pain-management and speaker-training conferences for physicians, pharmacists, and nurses to be trained as part of Purdue's national speaker bureau. These speakers then promoted Defendant Purdue's opioids and further spread its misrepresentations. During this same time frame, Purdue more than doubled its

number of sales representatives from 318 to 671. Defendant Purdue utilized a bonus system for its sales representatives designed to encourage maximum OxyContin prescriptions. In 2001 alone, Defendant Purdue reportedly paid $40 million in sales bonuses. Defendant Purdue targeted much of its marketing at primary care physicians, rather than pain specialists. Further, Defendant Purdue also relied on several types of branded items to promote its products including hats, toys, coffee mugs, and even a pen that had a conversion chart attached to it allowing a physician to calculate dosages to convert a patient from other opioid pain relievers to OxyContin. In other words, Defendant Purdue treated the marketing of a Schedule II controlled substance as if it were peddling paper products.

56. Overall, Defendants grossly misrepresented to Oklahoma physicians and consumers the risk of addiction, including falsely stating that the risk of addiction was less than 1%. Defendants made such misrepresentations by touting supposed "studies" like the "Porter & Jick Study"—which Defendants grossly misrepresented as being a comprehensive study. In fact, this "Study" comprised a 101-word paragraph in a medical journal from 1980, which focused exclusively on hospitalized patients who were given narcotics in a hospital setting. It did not establish or support the misrepresentation for which Defendants used it (*i.e.* that addiction is rare from opioid treatment of pain). Defendants also misrepresented that the risk of addiction from opioids is particularly low if prescribed by a doctor and/or if the patient has no prior addiction history.

57. Defendants spent millions of dollars on these direct marketing campaigns to ensure the success of their deceptive messaging.

ii. Defendants Falsely Marketed Their Opioids in Oklahoma Through Other Clandestine Channels

58. Direct marketing under their own brand was not the end of Defendants' scheme.

Defendants could not work this scheme without providing some "scientific" support for their statements. Defendants did this by operating through "Key Opinion Leaders" or "KOLs" and third-party groups to further spread their misrepresentations about opioids.

1. *Defendants Used Members of the Medical Community to Falsely Market Their Opioids*

59. KOLs are doctors who act as consultants or advisors to Defendants and through whom Defendants tout their misrepresentations regarding the risk of addiction and benefits of opioids. Defendants paid KOLs to give speeches, talks, and speak at continuing medical education seminars (CMEs) about opioids, advocating that they could be used effectively to treat things like chronic pain and downplaying the risks of addiction and abuse. By operating through KOLs, Defendants added perceived legitimacy and/or impartiality to their misrepresentations regarding opioids.

60. Defendants operated through many of the same KOLs including Dr. Russell Portenoy and Dr. Lynn Webster.

61. Dr. Portenoy is the former Chairman of the Department of Pain Medicine and Palliative Care at Beth Israel Medical Center in New York. Multiple Defendants utilized Dr. Portenoy as a KOL, providing him with funding and consultant fees, to help spread their misrepresentations regarding their opioids and opioid use in general. Dr. Portenoy spread these same misrepresentations through speeches, CMEs, and media appearances, including one of Defendants' favorite misrepresentations that less than 1% of opioid users become addicted. For example, in 2010 Dr. Portenoy appeared on *Good Morning America* and is quoted as stating that "[a]ddiction, when treating pain, is distinctly uncommon." Dr. Portenoy has since acknowledged that at least certain of his statements and misrepresentations were false and unsupported.

62. Dr. Webster is the former Chief Medical Director of Lifetree Clinical Research, a pain clinic in Utah. Like Dr. Portenoy, multiple Defendants utilized Dr. Webster as a KOL, providing him with funding and consultant fees in exchange for spreading their misrepresentations regarding opioids and opioid use in general through CMEs and speeches. Dr. Webster also spoke about the concept of "pseudoaddiction" which Defendants used to convince prescribers that classic signs of addiction should actually be treated with ***more*** opioid use because they were signs of "pseudoaddiction" which meant the patient was supposedly experiencing undertreated pain. Like Dr. Portenoy, Dr. Webster has since acknowledged several of the misrepresentations he previously made regarding opioids and opioid use.

2. Defendants Funded Seemingly Third-Party Groups to Spread Their False Marketing Even Further and Give Their Statements False Credibility

63. In addition to KOLs, Defendants relied on seemingly unaffiliated and impartial organizations to promote opioid use. Defendants utilized and funded these organizations to spread their misrepresentations by downplaying the risks of addiction of opioids and the benefits of use for conditions like chronic pain. Defendants funded, directed, and controlled several such organizations, and certain of Defendants' KOLs also served in various roles for these organizations, including as board members and officers.

64. For example, the American Pain Foundation (the "APF") was one of the more prominent "pain advocacy" organizations Defendants utilized to spread their misrepresentations. While APF purported to be an independent organization, it obtained much of its funding from pharmaceutical companies such as Defendants. In 2010, the APF reportedly obtained almost 90% of its $5 million funding from drug and medical device companies including certain Defendants such as Purdue. Defendants, through the APF, created treatment guides and other materials for patients and others that downplayed the addiction risks of opioids and exaggerated

their benefits. Defendants, through the APF, also specifically promoted opioid use among veterans. APF made these materials available nationwide, including in Oklahoma. These guides were funded by Defendants to spread their misrepresentations further and add perceived legitimacy and impartiality. For example, one guide described the supposedly low risk of addiction from opioids, claimed signs of requiring larger doses were not indications of addiction but signs that larger doses were needed, and that most of the side effects of opioids go away quickly. As another example, in 2007, Defendants Purdue and Cephalon sponsored an APF treatment guide that omitted and understated the risks of addiction from long-term opioid treatment. While the APF held itself out as an independent and impartial organization, it was controlled and influenced by Defendants. The APF eventually shut its doors in 2012 after details of its relationship with the pharmaceutical industry, including certain Defendants, came to light.

65. Another supposedly unaffiliated and impartial group Defendants utilized was the American Academy of Pain Medicine ("AAPM"). The AAPM claimed addiction risk of opioid treatment was low when used to treat people in pain. For example, in 2009, the AAPM in conjunction with another pain advocacy group issued treatment guidelines promoting the use of opioids for chronic non-cancer pain. These guidelines were authored and issued under the AAPM name but were funded by Defendants and several of Defendants' KOLs participated in drafting the guidelines themselves.

66. The list of groups Defendants funded and utilized to spread their misrepresentations is long. Indeed, Defendants have been tied to at least the following groups that distributed pro-opioid messages for Defendants with the same misrepresentations regarding the risk of addiction and benefits: the American Pain Society; American Geriatrics Society, American Chronic Pain Association, American Society of Pain Education, National Pain

Foundation, and Pain & Policy Studies Group. Defendants used groups like those listed above to spread their misrepresentations about the risk of addiction of opioids and their benefits.

C. Defendants' Representations Were False and Misleading

67. Through the misrepresentations and omissions described above, Defendants convinced doctors and consumers that, despite the instructions on their drug labels and the longstanding practice of prescribing opioids only in limited circumstances, there is a low risk of addiction with long-term opioid use. Additionally, Defendants convinced doctors and consumers, through their misrepresentations and omissions, that opioids are effective treatment for chronic non-cancer pain and signs of addiction could actually be signs of "pseudoaddiction" requiring heavier doses of opioids. Defendants convinced Oklahoma doctors and consumers of these same misrepresentations.

68. Defendants' representations were false, deceptive, and unsupported. Numerous studies demonstrate the addiction and abuse risk posed by opioids, including when used to treat chronic pain. Even some of Defendants' own KOLs have admitted several of their representations regarding opioid use, risks, and benefits were false and unsupported, including Drs. Portenoy and Webster. For example, Dr. Webster, once a wide proponent of the concept of "pseudoaddiction" for Defendants, has since stated "It obviously became too much of an excuse to give patients more medication...It led us down a path that caused harm. It is already something we are debunking as a concept."

69. In fact, according to the 2016 *CDC Guideline for Prescribing Opioids for Chronic Pain*, "[e]xtensive evidence shows the possible harms of opioids," including "opioid use disorder" and "overdose." Also, "the clinical evidence review...did find that continuing opioid therapy for 3 months substantially increases risk for opioid use disorder." Further, "[n]o

evidence shows a long-term benefit of opioids in pain and function versus no opioids for chronic pain with outcomes examined at least 1 year later." Moreover, "[e]xtensive evidence suggests some benefits of nonpharmacologic and nonopioid pharmacologic treatments compared with long-term opioid therapy, with less harm."

70. Defendants knew their misrepresentations were false and unsupported. Among other things, Defendants' marketing efforts often contradicted their own labels, which acknowledged the risk of abuse and addiction.

71. The nationwide opioid epidemic gripping this country and ravaging the State of Oklahoma also confirms Defendants' representations about the low risk of addiction and abuse their drugs posed were false. Thousands of Oklahomans have lost their lives to this epidemic and many more Oklahomans' lives, families and communities are destroyed by opioid addiction.

D. Defendants Concealed the Truth About their Campaign

72. The nature of Defendants' marketing scheme required Defendants to conceal the truth for it to be effective. Thus, Defendants operated from behind the scenes, spreading their deceptive misrepresentations through KOLs and third-party groups to conceal their own involvement. Defendants also concealed the falsity of their misrepresentations regarding addiction risk and the benefits of long-term opioid treatment. As such, while the opioid epidemic spread, Defendants' role and responsibility remained concealed. The State could not have acquired such knowledge through the exercise of reasonable diligence.

V. CAUSES OF ACTION

A. Oklahoma Medicaid False Claims Act, 63 Okl. St. §§ 5053.1-7

73. The allegations set forth above are incorporated by reference herein.

74. The State brings these claims on behalf of itself against Defendants under Section 5053.1 of the Oklahoma Medicaid False Claims Act.

i. Count 1

75. Each Defendant knowingly caused to be presented false or fraudulent claims for payment by Oklahoma Medicaid by marketing their drugs in a manner aimed at downplaying the risks of opioids (specifically the risks of addiction and abuse), overstating their efficacy, and, thus, wrongly increasing the number of prescriptions made to Oklahoma Medicaid patients.

76. Each Defendant knew that healthcare providers to whom it marketed its drugs had treated and would continue to treat Oklahoma Medicaid patients.

77. Each Defendant knew it was downplaying the addiction and abuse risks of opioids.

78. Each Defendant knew it was overstating the efficacy of opioids.

79. Each Defendant knew these misrepresentations were material and false, or made these misrepresentations with deliberate ignorance of the truth or falsity of the information or in reckless disregard of the truth or falsity of the information.

80. Each Defendant knew its false statements were material to healthcare providers' decision to prescribe opioids to Oklahoma Medicaid patients. Indeed, Defendants intended such statements to be material to encourage additional opioid prescriptions.

81. Each Defendant knew its marketing scheme would cause claims to be submitted for payment by Oklahoma Medicaid, which claims would not have been submitted but for Defendants' false marketing.

82. Because of the false or fraudulent claims Defendants knowingly caused to be presented, the State sustained substantial actual damages.

ii. Count 2

83. Each Defendant knowingly made or used, or caused to be made or used, false statements material to a false or fraudulent claim submitted for payment by Oklahoma Medicaid because Defendants (and their agents) made and used false statements regarding the risks, efficacy, and medical necessity of opioids in marketing their drugs to healthcare providers who treat and prescribe medicines to Oklahoma Medicaid patients.

84. Each Defendant knew that healthcare providers to whom they marketed their drugs had treated and would continue to treat Oklahoma Medicaid patients.

85. Each Defendant knew it was downplaying the addiction and abuse risks of opioids.

86. Each Defendant knew it was overstating the efficacy of opioids.

87. Each Defendant knew these misrepresentations were material and false, or made these misrepresentations with deliberate ignorance of the truth or falsity of the information or in reckless disregard of the truth or falsity of the information.

88. Each Defendant knew its false statements were material to healthcare providers' decision to prescribe opioids to Oklahoma Medicaid patients. Indeed, Defendants intended such statements to be material to encourage additional opioid prescriptions.

89. But for Defendants' false statements, the false claims at issue would not have been submitted for payment by Oklahoma Medicaid.

90. Because of the false or fraudulent claims Defendants knowingly caused to be presented, the State sustained substantial actual damages.

91. Under the Oklahoma Medicaid False Claims Act, the State seeks all actual damages and penalties as permitted under the Oklahoma Medicaid False Claims Act; and all

other appropriate relief to which the State is entitled under the Oklahoma Medicaid False Claims Act, including costs of bringing this action.

B. Oklahoma Medicaid Program Integrity Act, 56 Okl. St. §§ 1001-1008

92. The allegations set forth above are incorporated by reference herein.

93. The State of Oklahoma brings these claims on behalf of itself against Defendants under Sections 1001-1008 of the Oklahoma Medicaid Program Integrity Act.

94. Each Defendant willfully and knowingly caused to be made, by commission or omission, false claims for payment to Oklahoma Medicaid by marketing its drugs in a manner that minimized or misrepresented their risks of addiction and abuse, overstated their efficacy, and, thereby, wrongly increased the number of prescriptions made to Oklahoma Medicaid patients.

95. Each Defendant knew that healthcare providers to whom it marketed its drugs had treated and would continue to treat Oklahoma Medicaid patients.

96. Each Defendant knew it was minimizing and misrepresenting the addiction and abuse risks of opioids and overstating the efficacy of opioids.

97. Each Defendant knew its false statements would encourage healthcare providers to prescribe opioids to Oklahoma Medicaid patients. Indeed, each Defendant intended such statements to encourage additional opioid prescriptions.

98. Each Defendant knew its deceptive marketing scheme would cause false claims to be submitted for payment to Oklahoma Medicaid and would cause the Oklahoma Medicaid program to approve and pay false claims.

99. The false claims would not have been submitted and would not have been paid by the Oklahoma Medicaid program but for Defendants' improper false marketing.

100. Because the Oklahoma Medicaid program approved and paid false claims submitted because of Defendants' improper conduct, the State of Oklahoma sustained substantial actual damages and Defendants are liable to the State.

101. Under the Oklahoma Medicaid Program Integrity Act, the State seeks full restitution of all funds or payments Defendants' received in violation of the Oklahoma Medicaid Program Integrity Act, all penalties as permitted under the Oklahoma Medicaid Program Integrity Act; and all other appropriate relief to which the State is entitled under the Oklahoma Medicaid Program Integrity Act, including costs of bringing this action, litigation, and attorney's fees.

C. Oklahoma Consumer Protection Action, 15 Okl. St. §§ 751-65

102. The allegations set forth above are incorporated by reference herein.

103. The State, on behalf of itself and the residents of the State of Oklahoma, brings these claims against Defendants under Sections 756.1 and 761.1 of the Oklahoma Consumer Protection Act.

104. In carrying out their marketing campaigns described herein—including through advertising and sales calls—each Defendant violated the Oklahoma Consumer Protection Act.

105. Defendants engaged in "deceptive trade practices" as defined by the Oklahoma Consumer Protection Act because, as described herein, Defendants made misrepresentations and omissions in marketing their opioids that deceived or could reasonably be expected to deceive or mislead consumers.

106. Further, Defendants engaged in "unfair trade practices" as defined by the Oklahoma Consumer Protection Act because, as explained herein, Defendants' intentional practices of marketing their respective opioids so as to downplay their risks, overstate their

efficacy, and misrepresent their medical necessity, including for off-label uses, constitute practices which offend established public policy and which are immoral, unethical, oppressive, unscrupulous or substantially injurious to consumers.

i. Count 1

107. Defendants knowingly made false or misleading representations as to the characteristics, ingredients, uses, and benefits of their respective opioids by downplaying the risks of addiction and abuse, overstating the efficacy, and misrepresenting the medical necessity of their opioids.

108. Specifically, Defendants engaged in the following conduct:

- Defendants knowingly misrepresented the state of the science and material facts regarding the addictiveness of their respective opioids;
- Defendants knowingly omitted material information related to the addictiveness of their respective opioids;
- Defendants knowingly misrepresented the efficacy of their respective opioids by marketing their opioids as improving function for patients for which there was no evidence to support these claims; and
- Defendants knowingly misrepresented the benefits and efficacy of their respective opioids by vastly overstating their ability to safely and effectively treat or manage pain on a long-term and/or short-term basis and omitting or downplaying the severe risk of addiction.

109. Defendants' misrepresentations caused actual damages to the State and residents of the State.

ii. Count 2

110. Defendants knowingly made false or misleading representations as to the source, sponsorship, approval, or certification of their respective opioids by downplaying the risks of addiction and abuse, overstating the efficacy, and misrepresenting the medical necessity of their opioids and propping up these false and misleading representations with additional false statements regarding certain academic reports and studies related to opioids.

111. Defendants also knowingly made false representations as to the sponsorship, approval, status, affiliation or connection of certain persons in the medical and academic communities with respect to their opioids.

112. Specifically, Defendants engaged in the following conduct:

- Defendants misrepresented and/or omitted the results and conclusions of academic reports and studies related to the addictiveness, effectiveness, and medical necessity of their opioids;
- Defendants made false representations and/or omissions as to the sponsorship, approval, and/or certification by the medical professionals who performed or authored these academic reports and studies, which Defendants misused in their marketing efforts; and
- Defendants made false representations and/or omissions as to the sponsorship, approval, and/or certification by the journals that published these academic reports and studies, which Defendants misused in their marketing efforts.

113. Defendants misleadingly used these academic reports and studies to induce consumers, to prescribe, order, and/or purchase Defendants' opioids.

114. Defendants' misrepresentations caused actual damages to the State and residents

of the State.

115. Under the Oklahoma Consumer Protection Act, the State seeks: a declaratory judgment that Defendants' acts or practices violate the Oklahoma Consumer Protection Act; an injunction against Defendants from violating the Oklahoma Consumer Protection Act; actual damages and penalties as provided under the Oklahoma Consumer Protection Act; reasonable expenses and investigation fees, including attorney's fees; and all other appropriate relief to which the State is entitled under the Oklahoma Consumer Protection Act.

D. Public Nuisance, 50 Okl. St. § 2

116. The allegations set forth above are incorporated by reference herein.

117. The State, on behalf of itself, brings this claim against Defendants to abate the public nuisance they created.

118. Defendants' misrepresentations and omissions regarding opioids, as set forth above, have created an opioid epidemic in Oklahoma that constitutes a public nuisance. Defendants have created a condition that affects entire communities, neighborhoods, and considerable numbers of persons.

119. Defendants' misrepresentations and omissions regarding opioids constitute unlawful acts and/or omissions of duties, that annoy, injure, or endanger the comfort, repose, health, and/or safety of others. The annoyance, injury and danger to the comfort, repose, health, and safety of Oklahoma citizens includes, but is not limited to:

- Drug overdose deaths in Oklahoma increased eightfold from 1999 to 2012, surpassing car crash deaths in 2009;
- In 2012, Oklahoma had the fifth-highest unintentional poisoning death rate and prescription opioids contributed to the majority of those deaths;

- In 2014, Oklahoma's unintentional poisoning rate was 107% higher than the national rate;
- Oklahoma leads the nation in non-medical use of painkillers, with nearly 5% of the population aged 12 and older abusing or misusing painkillers;
- Prescription opioid addiction often leads to illicit opioid use and addiction;
- According to the CDC, past misuse of prescription opioids is the strongest risk factor for heroin initiation and use;
- From 2007 to 2012, the number of heroin deaths in Oklahoma increased tenfold;
- Oklahoma hospitals are reporting an increasing number of newborns testing positive for prescription medications; and
- Defendants' deceptive marketing campaign and the resulting opioid abuse and addiction epidemic caused the State of Oklahoma, its businesses, communities and citizens to bear enormous social and economic costs including increased health care, criminal justice, and lost work productivity expenses, among others.

120. The State seeks to abate the public nuisance Defendants created and all necessary relief to abate such public nuisance.

E. Fraud (Actual and Constructive) and Deceit

121. The allegations set forth above are incorporated by reference herein.

122. Defendants made false representations to healthcare providers working for the State, and/or omitted material facts, regarding the risks, efficacy, and medical necessity of their opioids, which assertions Defendants knew were false, made recklessly without knowledge of the truth, and/or had no reasonable ground for believing such assertions. Namely, Defendants knowingly and/or recklessly:

- downplayed the substantial risks of addiction and other side-effects of their opioids, including affirmatively stating in sales calls and other marketing outlets that their drugs were not as addictive as they truly are, stating that classic signs of addiction were actually an indication of "pseudoaddiction" requiring more opioid treatment, and omitting the high risk of addiction actually present;
- overstated the efficacy of their opioids, including making false statements regarding the effectiveness of the drugs for treating chronic non-cancer pain and their ability to improve function; and
- misrepresented the medical usefulness and necessity of their opioids, including affirmatively marketing their drugs for off label uses without solicitation and not in response to questions from healthcare providers.

123. Defendants' misrepresentations and omissions had a tendency to deceive others, to violate public confidence, and/or injure public interests. Defendants, having chosen to speak and make representations to healthcare providers working for the State regarding their opioids, were under a duty to disclose the whole truth, and not disclose partial and misleading truths.

124. Defendants intended healthcare providers working for the State to rely upon Defendants' false assertions regarding the risks, efficacy, and medical necessity of their opioids, to increase the number of opioid prescriptions made by healthcare providers. Indeed, Defendants made such false representations and omissions, at times, contrary to what their own drug labels stated.

125. Healthcare providers working for the State did in fact rely on Defendants' false representations, as seen by the increasing number of opioid prescription claims that have been submitted to and paid by Oklahoma Medicaid.

126. Oklahoma Medicaid would not have incurred the costs associated with paying for unnecessary opioid prescription claims *but for* Defendants' false representations and omissions regarding the risks, efficacy, and medical necessity of Defendants' opioids.

127. These unnecessary payments made by Oklahoma Medicaid constitute damages suffered by the State.

128. The State seeks to recover all damages caused by Defendants' fraudulent representations and omissions.

129. Defendants acted with knowledge and willful intent, with reckless disregard for the rights of others, and/or intentionally and with malice towards others. As such, the State seeks to recover punitive damages against Defendants.

F. Unjust Enrichment

130. Due to Defendants' conduct as described herein, Defendants were unjustly enriched at the expense of the State.

131. For years, Defendants have peddled their opioids on the basis of false claims regarding the drugs' addictiveness and effectiveness and, in doing so, have siphoned millions of dollars from the State's coffers into their corporate bank accounts. While many Oklahomans' lives are ravaged by opioid abuse and addiction, Defendants have lined their pockets with State monies paid for opioid prescriptions that, but for Defendants' deceptive marketing scheme described herein, would never have been prescribed.

132. The State is entitled to recover Defendants' ill-gotten gains.

133. The Court should impose a constructive trust under the doctrine of unjust enrichment.

VI. JURY DEMAND

134. Plaintiff requests a trial by jury on all issues so triable.

VII. PRAYER

WHEREFORE, Plaintiff prays for relief and judgment as follows:

A. Declaration that Defendants have violated the Oklahoma Medicaid False Claims Act;

B. All actual damages and penalties as permitted under the Oklahoma Medicaid False Claims Act, including actual damages resulting from costs of opioid prescriptions paid by the State, addiction treatment costs, increased health care costs, criminal justice costs, and lost work productivity expenses, among others;

C. Declaration that Defendants have violated the Oklahoma Medicaid Program Integrity Act;

D. Full restitution for all funds or payments Defendants received in violation of the Oklahoma Medicaid Program Integrity Act.

E. All penalties as permitted under the Oklahoma Medicaid Program Integrity Act;

F. All other appropriate relief to which the State is entitled under the Oklahoma Medicaid Program Integrity Act, including costs of bringing this action, litigation, and attorney's fees.

G. Declaration that Defendants' acts or practices violated the Oklahoma Consumer Protection Act;

H. An injunction against Defendants from violating the Oklahoma Consumer Protection Act;

I. Actual damages and penalties as provided under the Oklahoma Consumer Protection Act;

J. Reasonable expenses and investigation fees, including attorney's fees;

K. Abatement of the public nuisance Defendants have created and all costs necessary to abate such nuisance;

L. All actual damages caused by Defendants' fraud;

M. Punitive damages;

N. Disgorgement of Defendants' ill-gotten gains; and

O. All other relief to which the State is entitled.

Dated: June 30, 2017

Mike Hunter, OBA No. 4503
ATTORNEY GENERAL FOR
THE STATE OF OKLAHOMA
Abby Dillsaver, OBA No. 20675
GENERAL COUNSEL TO
THE ATTORNEY GENERAL
Ethan A. Shaner, OBA No. 30916
DEPUTY GENERAL COUNSEL
313 N.E. 21st Street
Oklahoma City, OK 73105
Telephone: (405) 521-3921
Facsimile: (405) 521-6246
Emails: abby.dillsaver@oag.ok.gov
ethan.shaner@oag.ok.gov

Michael Burrage, OBA No. 1350
Reggie Whitten, OBA No. 9576
WHITTEN BURRAGE
512 N. Broadway Avenue, Suite 300
Oklahoma City, OK 73102
Telephone: (405) 516-7800
Facsimile: (405) 516-7859
Emails: mburrage@whittenburragelaw.com
rwhitten@whittenburragelaw.com

Bradley E. Beckworth, OBA No. 19982
Jeffrey J. Angelovich, OBA No. 19981
NIX, PATTERSON & ROACH, LLP
512 N. Broadway Avenue, Suite 200
Oklahoma City, OK 73102
Telephone: (405) 516-7800
Facsimile: (405) 516-7859
Emails: bbeckworth@nixlaw.com
jangelovich@npraustin.com

Glenn Coffee, OBA No. 14563
GLENN COFFEE & ASSOCIATES, PLLC
915 N. Robinson Ave.
Oklahoma City, OK 73102
Telephone: (405) 601-1616
Email: gcoffee@glenncoffee.com
ATTORNEYS FOR PLAINTIFF

EXHIBIT 1

Dispensed between 1/1/2007-*6/21/2017

Drug	Corporation Name	Claims	Units	Paid	Year Dispensed
DILAUDID	PURDUE PHARMA L.P.	1	20.00	$6.98	2008
DILAUDID	PURDUE PHARMA L.P.	88	9,689.00	$9,539.65	2009
DILAUDID	PURDUE PHARMA L.P.	38	4,139.00	$4,150.73	2010
DILAUDID	PURDUE PHARMA L.P.	29	3,890.00	$5,213.38	2011
DILAUDID	PURDUE PHARMA L.P.	38	6,423.00	$9,198.54	2012
DILAUDID	PURDUE PHARMA L.P.	18	2,790.00	$5,374.94	2013
DILAUDID	PURDUE PHARMA L.P.	9	2,160.00	$3,909.64	2014
DILAUDID	PURDUE PHARMA L.P.	10	1,200.00	$5,375.76	2015
DILAUDID	PURDUE PHARMA L.P.	21	2,169.00	$11,298.40	2016
DILAUDID	PURDUE PHARMA L.P.	5	452.00	$2,790.07	*2017
	Total	257	32,932.00	$56,858.09	
DILAUDID-HP	PURDUE PHARMA L.P.	2	1,750.00	$6,885.46	2010
	Total	2	1,750.00	$6,885.46	
HYSINGLA ER	PURDUE PHARMA L.P.	997	29,414.00	$356,877.76	2015
HYSINGLA ER	PURDUE PHARMA L.P.	2,356	69,647.00	$966,022.94	2016
HYSINGLA ER	PURDUE PHARMA L.P.	1,231	36,337.00	$533,789.25	*2017
	Total	4,584	135,398.00	$1,856,689.95	
MS CONTIN	PURDUE PHARMA L.P.	32	6,270.00	$36,419.46	2007
MS CONTIN	PURDUE PHARMA L.P.	12	2,850.00	$18,743.15	2008
MS CONTIN	PURDUE PHARMA L.P.	14	3,789.00	$17,877.09	2009
MS CONTIN	PURDUE PHARMA L.P.	11	3,920.00	$19,189.55	2010
MS CONTIN	PURDUE PHARMA L.P.	8	2,880.00	$15,742.91	2011
MS CONTIN	PURDUE PHARMA L.P.	12	4,320.00	$27,391.18	2012
MS CONTIN	PURDUE PHARMA L.P.	13	4,380.00	$32,055.79	2013
MS CONTIN	PURDUE PHARMA L.P.	11	3,960.00	$34,693.35	2014
MS CONTIN	PURDUE PHARMA L.P.	11	3,960.00	$41,005.82	2015
MS CONTIN	PURDUE PHARMA L.P.	12	4,320.00	$51,794.68	2016
MS CONTIN	PURDUE PHARMA L.P.	6	2,160.00	$26,001.21	*2017
	Total	142	42,809.00	$320,914.19	
OXYCONTIN	PURDUE PHARMA L.P.	2,318	158,805.00	$1,120,199.33	2007
OXYCONTIN	PURDUE PHARMA L.P.	10,477	705,740.00	$4,596,342.80	2008
OXYCONTIN	PURDUE PHARMA L.P.	10,765	706,359.00	$5,177,861.24	2009
OXYCONTIN	PURDUE PHARMA L.P.	9,802	640,201.00	$5,006,801.66	2010
OXYCONTIN	PURDUE PHARMA L.P.	9,105	601,224.00	$5,141,554.59	2011
OXYCONTIN	PURDUE PHARMA L.P.	7,693	509,720.00	$4,597,836.96	2012
OXYCONTIN	PURDUE PHARMA L.P.	7,064	465,271.00	$4,375,287.75	2013
OXYCONTIN	PURDUE PHARMA L.P.	6,581	431,599.00	$4,227,237.38	2014
OXYCONTIN	PURDUE PHARMA L.P.	9,415	568,839.00	$4,925,986.10	2015
OXYCONTIN	PURDUE PHARMA L.P.	11,459	671,199.00	$5,714,468.93	2016
OXYCONTIN	PURDUE PHARMA L.P.	5,835	339,569.00	$2,840,981.62	*2017
	Total	90,514	5,798,526.00	$47,724,558.36	
	Grand Total	95,499	6,011,415.00	$49,965,906.05	

EXHIBIT 2

Dispensed between 1/1/2007-*6/21/2017

Drug	Corporation Name	Claims	Units	Paid	Year Dispensed
KADIAN	ALLERGAN	38	2,252.00	$21,405.15	2009
KADIAN	ALLERGAN	575	36,020.00	$346,964.49	2010
KADIAN	ALLERGAN	548	36,966.00	$435,243.93	2011
KADIAN	ALLERGAN	87	6,645.00	$151,659.78	2012
KADIAN	ALLERGAN	42	2,321.00	$65,492.22	2013
KADIAN	ALLERGAN	39	2,206.00	$76,616.75	2014
	Total	1,329	86,410.00	$1,097,382.32	

EXHIBIT 3

Dispensed between 1/1/2007-*6/21/2017

Drug	Corporation Name	Claims	Units	Paid	Year Dispensed
ACTIQ	TEVA PHARMACEUTICALS USA, INC	43	3,284.00	$140,867.05	2007
ACTIQ	TEVA PHARMACEUTICALS USA, INC	1	90.00	$8,219.15	2008
	Total	44	3,374.00	$149,086.20	
FENTORA	TEVA PHARMACEUTICALS USA, INC	37	2,502.00	$53,680.69	2007
FENTORA	TEVA PHARMACEUTICALS USA, INC	34	2,326.00	$67,275.06	2008
FENTORA	TEVA PHARMACEUTICALS USA, INC	18	1,208.00	$27,816.65	2009
FENTORA	TEVA PHARMACEUTICALS USA, INC	16	1,189.00	$37,192.09	2010
FENTORA	TEVA PHARMACEUTICALS USA, INC	20	1,548.00	$56,303.06	2011
FENTORA	TEVA PHARMACEUTICALS USA, INC	18	1,524.00	$58,336.26	2012
FENTORA	TEVA PHARMACEUTICALS USA, INC	16	1,064.00	$56,888.71	2013
FENTORA	TEVA PHARMACEUTICALS USA, INC	30	2,100.00	$114,187.82	2014
FENTORA	TEVA PHARMACEUTICALS USA, INC	11	616.00	$26,500.44	2015
FENTORA	TEVA PHARMACEUTICALS USA, INC	1	28.00	$143.98	2016
	Total	201	14,105.00	$498,324.76	
	Grand Total	245	17,479.00	$647,410.96	

EXHIBIT 4

Dispensed between 1/1/2007-*6/21/2017

Drug	Corporation Name	Claims	Units	Paid	Year Dispensed
DURAGESIC	JOHNSON AND JOHNSON	69	676.00	$15,968.37	2007
DURAGESIC	JOHNSON AND JOHNSON	14	225.00	$10,576.58	2008
DURAGESIC	JOHNSON AND JOHNSON	49	510.00	$24,707.78	2009
DURAGESIC	JOHNSON AND JOHNSON	102	1,175.00	$59,897.43	2010
DURAGESIC	JOHNSON AND JOHNSON	90	970.00	$58,471.95	2011
DURAGESIC	JOHNSON AND JOHNSON	88	970.00	$62,026.38	2012
DURAGESIC	JOHNSON AND JOHNSON	65	790.00	$66,059.83	2013
DURAGESIC	JOHNSON AND JOHNSON	45	550.00	$52,983.08	2014
DURAGESIC	JOHNSON AND JOHNSON	30	300.00	$34,665.48	2015
DURAGESIC	JOHNSON AND JOHNSON	29	290.00	$32,474.21	2016
DURAGESIC	JOHNSON AND JOHNSON	6	55.00	$3,818.15	*2017
	Total	587	6,511.00	$421,649.24	
NUCYNTA	JOHNSON AND JOHNSON	50	4,206.00	$9,302.61	2009
NUCYNTA	JOHNSON AND JOHNSON	128	10,800.00	$26,809.76	2010
NUCYNTA	JOHNSON AND JOHNSON	264	20,962.00	$58,164.90	2011
NUCYNTA	JOHNSON AND JOHNSON	298	24,771.00	$73,199.01	2012
NUCYNTA	JOHNSON AND JOHNSON	190	18,942.00	$62,966.90	2013
NUCYNTA	JOHNSON AND JOHNSON	188	16,658.00	$62,041.85	2014
NUCYNTA	JOHNSON AND JOHNSON	147	11,815.00	$56,978.22	2015
NUCYNTA	JOHNSON AND JOHNSON	132	10,739.00	$64,369.17	2016
NUCYNTA	JOHNSON AND JOHNSON	68	5,925.00	$33,969.29	*2017
	Total	1,465	124,818.00	$447,801.71	
NUCYNTA ER	JOHNSON AND JOHNSON	13	690.00	$3,553.99	2011
NUCYNTA ER	JOHNSON AND JOHNSON	73	4,157.00	$24,382.72	2012
NUCYNTA ER	JOHNSON AND JOHNSON	75	4,335.00	$29,836.63	2013
NUCYNTA ER	JOHNSON AND JOHNSON	93	5,514.00	$38,349.16	2014
NUCYNTA ER	JOHNSON AND JOHNSON	139	8,172.00	$90,105.80	2015
NUCYNTA ER	JOHNSON AND JOHNSON	113	6,519.00	$96,200.34	2016
NUCYNTA ER	JOHNSON AND JOHNSON	80	4,580.00	$57,567.18	*2017
	Total	586	33,967.00	$339,995.82	
	Grand Total	2,638	165,296.00	$1,209,446.77	

EXHIBIT

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U.S. Department of Justice

United States Attorney

Eastern District of Pennsylvania

615 Chestnut Street
Suite 1250
Philadelphia, Pennsylvania 19106-4476
(215) 861-8200

For Immediate Release

September 29, 2008

PHARMACEUTICAL COMPANY CEPHALON TO PAY $425 MILLION FOR OFF-LABEL DRUG MARKETING

PHILADELPHIA - United States Attorney General Michael B. Mukasey and Acting United States Attorney Laurie Magid today announced the filing of a criminal information[1] against, and a civil settlement with, the pharmaceutical company Cephalon, headquartered in West Chester, PA, for the off-label marketing of three of its drugs. Joining Magid in today's announcement were FDA Special Agent-in-Charge Kim Rice, Special Agent-in-Charge of the Office of Inspector General for the Department of Health and Human Services Philadelphia Patrick Doyle, Special Agent-in-Charge of United States Postal Service Office of Inspector General Elizabeth Farcht.

The information alleges that from approximately January 2001 through at least 2006, Cephalon promoted the drugs Actiq, Gabitril, and Provigil for uses other than what the federal Food and Drug Administration approved. The company is charged with one count of Distribution of Misbranded Drugs: Inadequate Directions for Use, a misdemeanor offense.

Under the provisions of the Food, Drug and Cosmetic Act, a company must specify the intended uses of a product in its new drug application to the FDA. Before approving a drug, the FDA must determine that the drug is safe and effective for the use proposed by the company. Once approved, the drug may not be marketed or promoted for so-called "off label" uses - meaning any use not specified in an application and approved by FDA.

The FDA approved Actiq, a fentanyl product manufactured as a lollipop, for use only in opioid-tolerant cancer patients (meaning those patients for whom morphine-based painkillers are no longer effective). The drug is a strong and highly addictive narcotic, with significant potential for abuse. From 2001 through at least 2006, Cephalon was allegedly promoting the drug for non-cancer patients to use for such maladies as migraines, sickle-cell pain crises, injuries, and in anticipation of changing wound dressings or radiation therapy. Cephalon also promoted Actiq for use in patients who were not yet opioid-tolerant, and for whom it could have life-threatening

[1]An Indictment or Information is an accusation. A defendant is presumed innocent unless and until proven guilty.

results.

The FDA approved Gabitril for use as an anti-epilepsy drug in the treatment of partial seizures. From 2001 to 2005, Cephalon allegedly promoted Gabitril as a remedy for anxiety, insomnia, and pain. In 2005, following reports of seizures in patients taking Gabitril who did not have epilepsy, the FDA required Cephalon to send a warning letter to doctors advising them of the connection between off-label Gabitril use and risk of seizures. The company then ceased promotion of the drug.

The FDA first approved Provigil to treat excessive daytime sleepiness associated with narcolepsy, then expanded the label to include treatment of excessive sleepiness associated with sleep apnea, and shift work sleep disorder. From 2001 through 2006, Cephalon allegedly promoted Provigil as a non-stimulant drug for the treatment of sleepiness, tiredness, decreased activity, lack of energy, and fatigue. In 2002, the FDA sent Cephalon a letter instructing the company not to continue to promote Provigil off-label. The company ignored the FDA's letter.

Defendant Cephalon undertook its off-label promotional practices using a variety of techniques. It trained its sales force to disregard the restrictions of the FDA-approved label, and to promote the drugs for off-label uses. For example, the Actiq label stated that the drug was for "opioid tolerant cancer patients with breakthrough cancer pain, to be prescribed by oncologist or pain specialists familiar with opioids." Using the mantra "pain is pain," Cephalon instructed the Actiq sales representatives to focus on physicians other than oncologists, including general practitioners, and to promote the drug for many uses other than breakthrough cancer pain. In the case of Gabitril, which had been approved for use for epilepsy, Cephalon told the sales force to visit not just neurologists, but also psychiatrists, and to promote the drug for anxiety and other psychiatric indications. Cephalon also structured its sales quota and bonuses in such a way that sales representatives could reach their sales goals only if they promoted and sold the drugs for off-label uses.

"These are potentially harmful drugs that were being peddled as if they were, in the case of Actiq, actual lollipops instead of a potent pain medication intended for a specific class of patients," said Magid. "This company subverted the very process put in place to protect the public from harm, and put patients' health at risk for nothing more than boosting its bottom line. People have an absolute right to their doctors' best medical judgement. They need to know the recommendations a doctor makes are not influenced by sales tactics designed to convince the doctor that the drug being prescribed is safe for uses beyond what the FDA has approved."

Defendant Cephalon employed sales representatives and retained medical professionals to speak to doctors about off-label uses of Actiq, Gabitril, and Provigil. The company funded continuing medical education programs, through millions of dollars in grants, to promote off-label uses of its drugs, in violation of the FDA's requirements.

In a plea agreement with the United States, Cephalon agrees to pay $50 million to resolve this information, of which $40 million will be applied to a criminal fine, and $10 million will be applied as substitute assets to satisfy the forfeiture obligation.

In a separate civil settlement among Cephalon, the United States and various states, executed contemporaneously with this guilty plea agreement, Cephalon will pay $375 million, plus interest, to resolve False Claims Act claims by the United States Medicaid and Medicare Trust Funds and other federal programs and agencies, including Tricare, the Federal Employees Health Benefit program, the Postal Worker's Compensation Program, the Federal Employees Compensation Act Program, the Energy Employees Occupational Illness Compensation Program, Department of Veterans Affairs, Defense Logistics Agency, Bureau of Prisons, and the Public Health Service Entities. The state Medicaid programs and the District of Columbia will share $116 million of the civil settlement.

"This settlement is further evidence of the Department's willingness to prosecute cases involving violations of the FDCA and to recover taxpayer dollars used to pay for drugs sold as a result of illegal marketing campaigns," said Assistant Attorney General Gregory Katsas.

"Today's settlement demonstrates the government's continued scrutiny of sales and marketing practices by pharmaceutical companies that put profits ahead of the public health," said Special Agent-in-Charge Kim Rice of FDA's Office of Criminal Investigations. "The FDA will continue to seek this kind of criminal resolution and stiff sanctions when pharmaceutical companies undermine the drug approval process by promoting drugs for uses for which they have not been proven to be safe and effective."

"This case should serve as still another warning to all those who break the law in order to improve their profits," said Patrick Doyle, head of the Philadelphia Regional Office of the Department of Health and Human Services Office of Inspector General (OIG). "OIG, working with our law enforcement partners, will pursue and bring to justice those who would steal from vulnerable beneficiaries and the taxpayers."

The civil settlement also resolves four qui tam ("whistle blower") actions filed in the Eastern District of Pennsylvania: United States of America ex rel. Lucia Paccione v. Cephalon, Inc., Civil Action No. 03-6268; United States of America and the States of California, Delaware, Florida, Hawaii, Illinois, Louisiana, Massachusetts, Nevada, New Hampshire, New Mexico, Texas, Tennessee and Virginia and the District of Columbia ex rel. Joseph Piacentile v. Cephalon, Inc., Civil Action No. 03-6277; United States of America; the States of California, Delaware, Florida, Hawaii, Illinois, Massachusetts, Nevada, New Mexico, Tennessee, Texas, Virginia, the District of Columbia, and New York; ex rel. Bruce Boise v. Cephalon, Inc., Civil Action No. 04-4401 and United States of America ex rel. Michael Makalusky v. Cephalon, Inc.,

Civil Action No. 05-1904. Three of those cases were filed by former Cephalon sales representatives who were disturbed by the company's off-label marketing practices. The relators will receive $46,469,978 from the federal share of the settlement amount.

United States Postal Service Office of Inspector General Special Agent- in-Charge Elizabeth A. Farcht stated, "These types of investigations are an important part of the Postal Service Office of Inspector General's mission to prevent and detect fraud, waste, and misconduct in the Postal Service, and to promote the integrity and efficiency of postal programs. This includes federal programs that the postal service participates in or contributes to such as the federal workers' compensation program, under which these drugs were paid for by the postal service. Drugs promoted off-label can lead to potential safety issues and unnecessary, inflated program costs for the Postal Service and others."

As part of the resolution of these allegations, the HHS Office of Inspector General and Cephalon have entered into a five-year Corporate Integrity Agreement. The Agreement requires that Cephalon send doctors a letter advising of this resolution, and give them a means to report questionable conduct of sales representatives; that it post payments to doctors on its web site; and that its Board and top management regularly certify that the company has an effective compliance program and is in compliance with all applicable requirements.

The case was investigated by the Food and Drug Administration's Office of Criminal Investigation, the Department of Health and Human Services' Office of the Inspector General, the Postal Service Office of the Inspector General, and the Office of Personnel Management Office of Inspector General. The case was prepared by Assistant United States Attorney Marilyn May and Assistant United States Attorney Cathy Votaw, together with Jeffrey Steger of the Department of Justice Office of Consumer Litigation.

Assistance was provided by Laura Pawlowski from the FDA Office of Chief Counsel, as well as representatives of the National Association of Medicaid Fraud Control Units, headed by Charles William Gambrell, Jr., Director South Carolina Medicaid Fraud Control Unit, and the Connecticut Attorney General's Office. The Corporate Integrity Agreement was negotiated by Mary Riordan and Maame Gyamfi in the Office of General Counsel, Office of Inspector General, Department of Health and Human Services. The Department of Justice acknowledges Cephalon's cooperation with the investigation and resolution of this case.

UNITED STATES ATTORNEY'S OFFICE
EASTERN DISTRICT, PENNSYLVANIA
Suite 1250, 615 Chestnut Street
Philadelphia, PA 19106

Contact: PATTY HARTMAN
Media Contact
215-861-8525

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