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		PART C
IN THE DISTRICT COURT OF	CLEVELAND COUNTY	FILED
		MAY <b>2</b> 4 2019
STATE OF OKLAHOMA, ex rel.,		-
MIKE HUNTER,	For Judge Balkman's	In the office of the
ATTORNEY GENERAL OF OKLAHOMA, Plaintiff,	Consideration Court	Clerk MARILYN WILLIAMS
VS.	]	
(1) PURDUE PHARMA L.P.;		
(2) PURDUE PHARMA, INC.;		
(3) THE PURDUE FREDERICK COMPANY,		
(4) TEVA PHARMACEUTICALS USA, INC.;		
(5) CEPHALON, INC.;	1	
(6) JOHNSON & JOHNSON;		· · ·
(7) JANSSEN PHARMACEUTICALS, INC,		
(8) ORTHO-MCNEIL-JANSSEN	Case No. CJ-2017-816	
PHARMACEUTICALS, INC., n/k/a	Honorable Thad Balkman	
JANSSEN PHARMACEUTICALS;		
(9) JANSSEN PHARMACEUTICA, INC.,		
n/k/a JANSSEN PHARMACEUTICALS, INC.;	William C. Hetherington	
(10) ALLERGAN, PLC, f/k/a ACTAVIS PLC,	Special Discovery Master	
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.	ļ	

DEFENDANTS TEVA PHARMACEUTICALS USA, INC., CEPHALON, INC., WATSON LABORATORIES, INC., ACTAVIS LLC, AND ACTAVIS PHARMA, INC., f/k/a\_WATSON PHARMA, INC.'S TRIAL BRIEF "The most depraved criminals are often the dispensers of these habit-forming drugs." --Editorial Comment, American Medicine, 1915<sup>1</sup>

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# 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

<sup>&</sup>lt;sup>1</sup> 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.

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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. <u>PARTIES</u>

#### A. Plaintiff

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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

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#### 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

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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., Johnson & Johnson, Ortho-McNeil-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.

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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. <u>Defendants' Deceptive and Misleading Prescription Opioid Marketing Campaign</u> <u>Has Caused a Devastating Public Health Crisis in Oklahoma</u>

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.

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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.

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

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.

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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.

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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.

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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.

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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.

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- 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-opioidtolerant 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 speakertraining 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. <u>Defendants Falsely Marketed Their Opioids in Oklahoma Through Other</u> <u>Clandestine Channels</u>

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.

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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

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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

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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. <u>CAUSES OF ACTION</u>

# 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. <u>Count 1</u>

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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

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. <u>Count 2</u>

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. <u>Count 1</u>

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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. <u>Count 2</u>

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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

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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.

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## 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

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# EXHIBIT 1

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

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					Year
Drug	Corporation Name	Claims	Units .	Pald	Dispensed
DILAUDID	PURDUE PHARMA L.P.	1	20.00	\$6.98	200
DILAUDID	PURDUE PHARMA L.P.	88		\$9,539.65	200
DILAUDID	PURDUE PHARMA L.P.	38		\$4,150.73	
DILAUDID	PURDUE PHARMA L.P.	29		Ş5,213.38	201
DILAUDID	PURDUE PHARMA L.P.	38		\$9,198.54	
DILAUDID	PURDUE PHARMA L.P.	18		\$5,374.94	201
DILAUDID	PURDUE PHARMA L.P.	9		\$3,909.64	201
DILAUDID	PURDUE PHARMA L.P.	10		\$5,375.76	201
DILAUDID	PURDUE PHARMA L.P.	21	2,169.00	\$11,298.40	201
DILAUDID	PURDUE PHARMA L.P.	5	452.00	\$2,790.07	*201
	Total	257	32,932.00	\$56,858.09	•
DILAUDID-HP	PURDUE PHARMA L.P.	2	1,750.00	\$6,885.46	201(
•	Tótal	· 2	1,750.00	\$6,885.46	
HYSINGLA ER	PURDUE PHARMA L.P.	997	29,414.00	\$356,877.76	201
HYSINGLA ER	PURDUE PHARMA L.P.	2,356	69,647.00	\$966,022.94	2010
HYSINGLA ER PUR	PURDUE PHARMA L.P.	1,231	36,337.00	\$533,789.25	*201
	Total	4,584	135,398.00	\$1,85 <del>6</del> ,689.95	
VIS CONTIN	PURDUE PHARMA LP.	32	6,270.00	\$36,419.46	2007
MS CONTIN	PURDUE PHARMA L.P.	12	2,850.00	\$18,743.15	2008
VIS CONTIN	PURDUE PHARMA L.P.	14	3,789.00	\$17,877.09	200
<b>MS CONTIN</b>	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
<b>MS CONTIN</b>	PURDUE PHARMA L.P.	13	4,380.00	\$32,055.79	201
AS CONTIN	PURDUE PHARMA L.P.	11	3,960.00	\$34,693.35	2014
AS CONTIN	PURDUE PHARMA LP.	11	3,960.00	\$41,005.82	2015
AS CONTIN	PURDUE PHARMA LP.	12	4,320.00	\$51,794.68	2016
AS CONTIN	PURDUE PHARMA L.P.	6	2,160.00	\$26,001.21	*2017
	Total	142	42,809.00	\$320,914.19	
XYCONTIN	PURDUE PHARMA LP.	2,318	158,805.00	\$1,120,199.33	2007
XYCONTIN	PURDUE PHARMA L.P.	10,477	705,740.00	\$4,596,342.80	2008
XYCONTIN	PURDUE PHARMA L.P.	10,765	706,359.00	\$5,177,861.24	2009
XYCONTIN	PURDUE PHARMA L.P.	9,802	640,201.00	\$5,006,801.66	2010
XYCONTIN	PURDUE PHARMA L.P.	9,105	601,224.00	\$5,141,554.59	2011
XYCONTIN	PURDUE PHARMA L.P.	7,693	509,720.00	\$4,597,836.96	2012
XYCONTIN	PURDUE PHARMA L.P.	7,064	465,271.00	\$4,375,287.75	2013
XYCONTIN	PURDUE PHARMA LP.	6,581	431,599.00	\$4,227,237.38	2014
XYCONTIN	PURDUE PHARMA L.P.	9,415	568,839.00	\$4,925,986.10	2015
XYCONTIN	PURDUE PHARMA L.P.	11,459	671,199.00	\$5,714,468.93	2016
DXYCONTIN PURDUE PHARMA L.P. Total Grand Total		5,835	339,569.00	\$2,840,981.62	*2017
		90,514	5,798,525.00	\$47,724,558.36	
		95,499	6,011,415.00	\$49,965,906.05	

# **EXHIBIT 2**

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

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					Year
Drug	Corporation Name	Claims	Units	Paid	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**

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

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					Year
Drug	Corporation Name	Claims	Units	Paid	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
	Tótal	- 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	<b>\$114,187.82</b>	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**

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Dispensed between 1	1/1/2007-*6/21/2017
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					Year
Drug	Corporation Name	Claims	- Sharping	Paid	Dispensed
DURAGESIC	JOHNSON AND JOHNSON	69			2007
DURAGESIC	JOHNSON AND JOHNSON	14			
DURAGESIC	JOHNSON AND JOHNSON	49	1		
DURAGESIC	JOHNSON AND JOHNSON	102			2010
DURAGESIC	JOHNSON AND JOHNSON	90		· · · · · · · · · · · · · · · · · · ·	
DURAGESIC	JOHNSON AND JOHNSON	88			2012
DURAGESIC	JOHNSON AND JOHNSON	65		1	2013
DURAGESIC	JOHNSON AND JOHNSON	45		\$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		\$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		2014
NUCYNTA	JOHNSON AND JOHNSON	147	11,815.00	\$56,978.22	2015
NUCYNTA	JOHNSON AND JOHNSON	132	10,739.00		2016
NUCYNTA	JOHNSON AND JOHNSON	68	5,925.00	\$33,969.29	*2017
	Total	1,465	124,818.00		
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
VUCYNTA 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
UCYNTA ER	JOHNSON AND JOHNSON	113	6,519.00	\$96,200.34	2016
IUCYNTA 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	

JUL 0 3 2017

## EXHIBIT E

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#### **Prior Authorization Archives**

#### **Therapeutic Categories:**

#### Cardiovascular

- Antihypertensives
- Fibric Acid Derivatives
- <u>Plavix</u>
- <u>Revatio</u>
- <u>Statins</u>
- <u>Zetia</u>

#### Respiratory

- <u>Antihistamines</u>
- <u>Brovana</u>
- <u>HFA Rescue Inhalers</u>
- Long-Acting Bronchial Dilators
- <u>Nasal Allergy</u>
- <u>Singulair</u>
- <u>Synagis</u>
- <u>Xolair</u>
- <u>Xopenex</u>

#### **Central Nervous System/Behavioral Health**

- ADHD and Narcolepsy
- Antidepressants
- Anxiolytic/Hypnotic
- Bladder Control Drugs
- <u>Narcotic Analgesics</u>
- Smoking Cessation

#### **Skeletal System**

- <u>Amrix and Fexmid</u>
- <u>Bisphosonates</u>
- <u>Forteo</u>
- <u>NSAIDs (Non-Steroidal Anti-Inflammatory Drugs)</u>
- <u>Skeletal Muscle Relaxants</u>
- <u>Soma</u>

#### Enodocrine

- <u>Diabetic Medications</u>
- Erythropoietin Stimulating Agents
- <u>Growth Hormone</u>

#### Topical

- <u>Antifungal</u>
- Elidel / Protopic
- <u>Lidoderm Patch</u>
- <u>Pediculicides</u>
- <u>Topical Antibiotic Medications</u>

#### Ocular

- <u>Ocular Allergy</u>
- Ophthalmic Anti-Infective/Steroid
- <u>Ophthalmic Glaucoma</u>

#### **Gastro Intestinal**

- <u>Amitiza</u>
- <u>Anti-Ulcer</u>

#### Antihypertensives

PA Criteria: Tier 1 products are covered with no authorization necessary.

Tier 2 authorization requires:

- · documented inadequate response to two Tier 1 medications, or
- · adverse drug reaction to all the Tier 1 medications, or
- previous stabilization on the Tier 2 medication, or
- a unique indication for which the Tier 1 antihypertensives are not indicated

Tier 3 authorization requires:

- documented inadequate response to two Tier 1 medications and documented inadequate response to all available Tier 2 medications, or
- · adverse drug reaction to all the Tier 1 or all Tier 2 medications, or
- previous stabilization on the Tier 3 medication, or
- a unique indication for which the lower tiered antihypertensives are not indicated
- Prior Authorization form

ACE/HCTZ		
Tier 1	Tier 2	Tier 3
<ul> <li>quinapril/HCTZ (Accuretic)</li> <li>captopril/HCTZ (Capozide)</li> <li>benazepril/HCTZ (Lotensin HCT)</li> <li>fosinopril/HCTZ (Monopril HCT)</li> <li>lisinopril/HCTZ (Prinzide, Zestoretic)</li> <li>moexipril/HCTZ (Uniretic)</li> <li>enalapril/HCTZ (Vasoretic)</li> </ul>		
	ACE Inhibit	ors
Tier 1	Tier 2	Tier 3
• quinapril (Accupril) • ramipril (Altace)		<ul> <li>perindopril erbumine (Aceon)</li> </ul>

<ul> <li>captopril (Capoten)</li> <li>benazepril (Lotensin)</li> <li>trandolapril (Mavik)</li> <li>fosinopril (Monopril)</li> <li>lisinopril (Prinivil, Zestril)</li> <li>moexipril (Univasc)</li> <li>enalapril (Vasotec)</li> <li>enalaprilat (Vasotec IV)</li> </ul>		
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CCB (Calcium Channel Blockers)			
Tier 1		Tier 2	
<ul> <li>nifedipine ER</li> <li>nifedipine (Adalat, Procardia)</li> <li>nifedipine CC (Adalat CC)</li> <li>amlodipine/atorvastatin (Caduet)</li> <li>verapamil (Calan, Isoptin, Verelan)</li> <li>verapamil SR (Calan SR, Isoptin SR, Verelan PM)</li> <li>nicardipine (Cardene)</li> <li>diltiazem (Cardizem)</li> <li>diltiazem CD (Cardizem CD)</li> <li>diltiazem SR (Cardizem SR)</li> <li>diltiazem ER (Cartia XT, Diltia XT)</li> <li>diltiazem XR (Dilacor XR)</li> <li>isradipine (Dynacirc, Dynacirc CR)</li> <li>nifedipine XL (Nifedical XL, Procardia XL)</li> <li>nimodipine (Nimotop)</li> <li>amlodipine (Plendil)</li> <li>diltiazem (Tiazac, Taztia XT)</li> </ul>		<ul> <li>nicardipine</li> <li>diltiazem (C</li> <li>verapamil (C</li> <li>nisoldipine</li> </ul>	Cardizem LA) Covera HS)
	ACE	/ССВ	
Tier 1	Tier 2		Tier 3
• Tier 1 ACE + Tier 1 CCB	<ul> <li>benazepril/a</li> </ul>	lodipine (Lexxel) amlodipine (Lotrel) /verapamil (Tarka)	

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#### ARBs (Angiotensin Receptor Blockers) Medication

PA Criteria:

Tier 1 products are covered with no authorization necessary.

Tier 2 authorization requires inadequate response to two Tier 1 medications or

- · adverse drug reaction to all Tier 1 class of medications or
- previous stabilization on the Tier 2 medications, or
- a unique indication for which the Tier 1 antihypertensives are not indicated

Tier 3 authorization requires documented inadequate response to two Tier 1 medications and documented inadequate response to all available tier 2 medications, or

- · adverse drug reaction to all Tier 1 or Tier 2 classes of medications, or
- previous stablilization on the Tier 3 medication, or
- a unique indication for which the lower tiered antihypertensives are not indicated.
- <u>Prior Authorization form</u>

\* Clinical exception applies to members who have diabetes.

Tier 1	Tier 2	Tier 3
<ul> <li>quinapril (Accupril)</li> <li>captopril (Capoten)</li> <li>benazepril (Lotensin)</li> <li>trandolapril (Mavik)</li> <li>fosinopril (Monopril)</li> <li>lisinopril (Prinivil, Zestril)</li> <li>moexipril (Univasc)</li> <li>enalapril (Vasotec, Vasotec IV)</li> </ul>	<ul> <li>irbesartan/HCTZ (Avalide)</li> <li>irbesartan (Avapro)</li> <li>valsartan (Diovan)</li> <li>valsartan/HCTZ (Diovan HCT)</li> <li>amlodopine/valsartan (Exforge)</li> <li>amlodopine/valsartan/HCTZ (Exforge HCT)</li> <li>telmisartan (Micardis)</li> <li>telmisartan/HCTZ (Micardis HCT)</li> </ul>	<ul> <li>candesartan (Atacand)</li> <li>candesartan/HCTZ (Atacand HCT)</li> <li>amlodipine/olmesartan (Azor)</li> <li>olmesartan (Benicar)</li> <li>olmesartan/HCTZ (Benicar HCT)</li> <li>losartan (Cozaar)</li> <li>losartan/HCTZ (Hyzaar)</li> <li>eprosartan (Teveten)</li> <li>eprosartan/HCTZ (Teveten HCT)</li> </ul>

Tier 3 authorization requires:

- FDA approved indication
- Recent trial, within the previous 6 months and at least 4 weeks in duration, of an ACE Inhibitor (or an ARB if previous trial of an ACEI) and a diuretic, used concomitantly at recommended doses, that did not yield adequate blood pressure control.

Tier 1	Tier 2	Tier 3
<ul> <li>Tier 1 ACE Inhibitor + Diuretic</li> </ul>	• ARB + Diuretic	• aliskiren (Tekturna)

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HMG-CoA	Reductase	inhibitors	(Statins)
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#### PA Criteria:

The following are criteria for approval of a Tier-2 Product:

- Previous failure to achieve desired LDL reduction with a preferred statin defined by at least 6-8 weeks of continuous therapy at standard to high dose.
- · Previous stabilization on non-preferred medication.
- Documented increased risk for drug interactions. Specifically: concurrent immunosuppressant therapy, HIV antiretroviral therapy, and therapy with other potent inhibitors of CYP450 system.
- Documented adverse effect or contraindication to the preferred products

Tier 1	Tier 2
<ul> <li>lovastatin (generic)</li> <li>fluvastatin (Lescol &amp; Lescol XL)</li> <li>atorvastatin (Lipitor)</li> <li>pravastatin (Pravachol)</li> <li>simvastatin (Zocor)</li> </ul>	<ul> <li>lovastatin/niacin (Advicor)</li> <li>lovastatin (Altoprev &amp; Mevacor)</li> <li>rosuvastatin (Crestor)</li> <li>pravastatin (Pravigard)</li> <li>ezetimibe/simvastatin (Vytorin)</li> </ul>

## \*Use of the brand name products when generic is available is subject to the brand name override process.

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#### Fibric Acid Derivatives

PA criteria:

- The approval criteria for a tier 2 medication is as follows:
- Laboratory documented failure with a tier one medication after 6 months trial with a tier one medications.
- Documented adverse effect, drug interaction, or contraindication to tier 1 products.

Tier 1	Tier 2
<ul> <li>clofibrate (Atromid - S)</li> <li>fenofibrate (Fenoglide)</li> <li>micronized fenofibrates (Lofibra)</li> <li>gemfibrozil (Lopid)</li> <li>micronized fenofibrates (Tricor)</li> <li>fenofibrates (Trilipix)</li> </ul>	<ul> <li>micronized fenofibrates (Antara)</li> <li>micronized fenofibrates (Lipofen)</li> <li>fenofibrates (Triglide)</li> </ul>

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Zetia

PA criteria:

#### Diagnosis

- Hypercholesterolemia, primary
- Hypercholesterolemia, homozygous familial
- Sitosterolemia, homozygous

Laboratory documentation that member has not met (LDL) cholesterol goals after therapeutic lifestyle changes and statin therapy for at least 6 months.

Not a candidate for statin therapy due to:

- Documented active liver disease.
- Documented unexplained, persistent elevations of serum transaminases.
- Documented statin related myopathy.
- <u>Prior Authorization form</u>

Plavix

#### PA criteria:

- · Plavix requires prior authorization for all members.
- Plavix therapy will be approved for members meeting approved diagnostic criteria that have failed aspirin therapy (due to either side effects or event recurrence),
- Or have a documented aspirin allergy, or use Plavix concomitantly with aspirin. The approved diagnoses are as follows:
  - Recent Stroke
  - Recent myocardial infarction
  - Established peripheral artery disease
  - Acute coronary syndrome (unstable angina/non-Q-wave MI)
  - Percutaneous coronary intervention with stent placement (aspirin trial not required)
  - Transient ischemic attacks
- All diagnoses get approval for duration of 1 year.
- Prior Authorization form

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#### Revatio

PA Criteria:

- Diagnosis and medical supervision by a pulmonary specialist and/or cardiologist
- Pulmonary Arterial Hypertension (early stage, NYHA Class II)

Gender:

• Prior authorization required only for male **SoonerCare** members.

Quantity Limitations:

• 90 tablets per 30 days

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#### Antihistamines

PA Criteria:

Tier 1 products are covered with no authorization necessary for members under age 21.

• For members 21 years and older, Tier 1 products are available with prior authorization.

Tier 2 authorization requires a documented 14 day trial of all Tier 1 products within the last 30 days.

Tier 3 authorization requires a 14 day trial with all Tier 2 products within the last 60 days (unless no ageappropriate Tier 2 product exists).

- Xyzal not covered for members under age 6.
- For all antihistamine authorizations, the diagnosis must be for a chronic allergic condition.
- <u>Prior Authorization form</u>

Tier 1	Tier 2	Tier 3
<ul> <li>OTC cetirizine (Zyrtec)</li> <li>OTC loratadine (Claritin)</li> </ul>	• fexofenadine (Allegra)	<ul> <li>desloratadine (Clarinex)</li> <li>fexofenadine (syrup, ODT)</li> <li>levocetirizine (Xyzal)</li> </ul>

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Singulair

PA criteria:

#### For members with a diagnosis of asthma the following criteria will apply:

Children age 11 and under:

- Diagnosis of asthma, or
- A claim for inhaled corticosteroid, or
- Use of 3 or more rescue medications
- All claims should be within the member's previous year's history.

Children age 12 and older and adults:

- Diagnosis of mild or moderate persistent asthma, and/or exercise induced asthma, and
- Trial of inhaled corticosteroid AND corticosteroid/LAB, A therapy within the previous 6 months, with inadequate control of asthma.

Claims submitted for Singulair will trigger an automatic check for asthma diagnoses and prior fills of inhaled corticosteroids / asthma rescue medications in the member's claims history. If the appropriate criteria are detected, these claims will be paid with no prior authorization required.

#### For members with a diagnosis of allergic rhinitis the following criteria will apply:

For members 2 years of age or older:

- Trials of an antihistamine and nasal corticosteroid, each 14 days in duration, that have failed to relieve allergic rhinitis symptoms.
- Agents may be used concomitantly or consecutively within the past 30 days.

For members less than two years of age:

- Trial of an oral antihistamine, 14 days in duration, which has failed to relieve allergic rhinitis symptoms, (Trial must have occurred within the past 30 days.)
- <u>Prior Authorization form</u>
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# HFA Rescue Inhalers • Tier-1 products are available without prior authorization. • Tier-2 authorization requires: 1) Approved or clinically accepted indication, and 2) Specific reason member cannot use all available tier-1 products Tier 1 • ProAir HFA (albuterol HFA) • Proventil HFA (albuterol HFA) • Ventolin HFA (albuterol HFA) • Ventolin HFA (albuterol HFA) • Ventolin HFA (albuterol HFA) \*Xopenex authorization requests should document why the member is unable to use racemic albuterol. If prescribed for asthma, member should also be utilizing inhaled corticosteroid therapy for long-term control. Dose of levalbuterol requested cannot be less than the racemic equivalent documented on the prior authorization request.

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#### Nasal Allergy

PA criteria:

Nasal allergy medications will be included in product-based prior authorization effective 4/28/08. Tier 1 products will be covered with no prior authorization necessary.

Tier 2 Authorization Requires

- Documented adverse effect or contraindication to the Tier 1 products , or
- Documented trials with all available Tier 1 corticosteroids with no beneficial response with the drug having been titrated to the recommended dose. Each trial must be at least 3 weeks in duration.
- <u>Prior Authorization form</u>

Tier 1	Tier 2
Corticosteroids • beclomethasone (Beconase AQ) • fluticasone (Flonase) • triamcinolone (Nasacort) • flunisolide (Nasalide/Nasarel)	<ul> <li>mometasone (Nasonex)</li> <li>ciclesonide (Omnaris)</li> <li>budesonide (Rhinocort AQ)</li> </ul>

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• fluticasone (Veramyst)

#### Other

- azelastine (Astelin)
- azelastine (Astepro)
- ipratropium bromide (Atrovent)
- olopatadine HCL (Patanase)

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#### Xolair

#### PA Criteria:

- Member must be between 12-75 years of age.
- Member must have a diagnosis of severe persistent asthma (as per NAEPP guidelines).
- Member must have a positive skin test to at least one perennial aeroallergen. Specific positive perennial allergens must be listed on the petition.
- Member must have a pretreatment serum IgE level between 30-700 IU/ml.
- Member weight must be between 30-150kg.
- Member must have been on high dose ICS (as per NAEPP Guidelines) for a minimum of 3 months.
- Medication must be prescribed by either a pulmonary or an allergy/asthma specialist.
- Member must have been in the ER or hospitalized, due to an asthma exacerbation, twice in the past 6 months. Date of visits must be listed on petition, or
- Have been determined to be dependent on systemic steroids to prevent serious exacerbations.

For Xolair requests, please submit these forms together:

- <u>Xolair Statement of Medical Necessity</u>
- <u>Universal Petition for Medication Authorization</u>

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#### Xopenex

PA criteria:

Xopenex

- PA required for use of this product in excess of 90 days of therapy in a 360 day period.
- A quantity limit of 288 units every 30 days will apply to Xopenex solution.
- Please state need of this product over albuterol.

Criteria for approval:

- In the prior authorization request, the prescriber should explain why the member is unable to use long acting bronchodilators and/or inhaled corticosteroid (ICS) therapy for long-term control as recommended in the NAEPP guidelines.
- <u>Prior Authorization form</u>

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#### Advair and Symbicort

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PA Criteria:

1) Diagnosis of COPD, or

2) Diagnosis of Asthma:

- Member must be 4 years of age or older, and
- Member must have used an inhaled corticosteroid (Aerobid, Alvesco, Asmanex, Azmacort, Flovent, Pulmicort, or QVAR) for at least one month immediately prior to request for authorization, and
- Member's asthma considered uncontrolled by the prescriber
  - Requires rescue inhaler more than 2 days per week for reasons other than prevention of exercise induced bronchospasms, and/or requires oral systemic corticosteroids, or
- · Clinical situation warranting initiation with combination therapy due to severity of asthma
- <u>Prior Authorization form</u>

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Brovana

#### PA Criteria:

- Members must be over 18 years of age and have one of the following diagnoses: COPD, chronic bronchitis, or emphysema.
- Member must have previous trial with Advair, Serevent, or Foradil in the past 45 days. A clinical exception will be given for those members who are unable to effectively use hand-actuated devices or who have become unstable on nebulized short-acting agonist therapy.
- Quantity limit of 120ml for a 30 day supply.
- <u>Prior Authorization form</u>

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**Synagis** PA Criteria: • Members must be included in one of the following age groups at the beginning of RSV season: Infants and children less than 24 months old with Chronic Lung Disease (CLD) (formerly bronchopulmonary dysplasia) who have required medical treatment (O2, bronchodilator, corticosteroid, or diuretic therapy) for CLD in the 6 months prior to RSV season. Infants up to 24 months old with moderate to severe pulmonary hypertension, cyanotic heart disease, or those on medications to control congestive heart failure. Infants less than 12 months of age, born at 28 weeks gestation or earlier. Infants less than 6 months old, born at 29-31 weeks gestation. Infants less than 12 months of age, born before 35 weeks gestation, with congenital abnormalities of the airway. Infants less than 12 months of age, born before 35 weeks gestation, with severe neuromuscular disease. Infants, up to 3 months old at the start of the season, born at 32-34 weeks gestation, who have one of the following risk factors: Child care attendance Siblings younger than 5 years of age Synagis form back to top

Anxiolytic		
<ul> <li>PA Criteria:</li> <li>No PA required for First 90 days of therapy. (I authorization.)</li> <li>Clarification of dosing schedule and diagnosis receiving duplicate therapy (e.g. an anxiolytic</li> <li>Additional information regarding recent attem recurrent PA petitions for high dose anxiolytic</li> <li>Prior Authorization form</li> </ul>	and hypnotic medications). 1pts at dose reductions should be included on	
<ul> <li>lorazepam (Ativan)</li> <li>chlordiazepoxide (Librium)</li> <li>oxazepam (Serax)</li> <li>clorazepate dipotassium (Tranxene)</li> <li>diazepam (Valium)</li> <li>alprazolam (Xanax)</li> </ul>		
Prior Authorization required. • alprazolam rapdis (Niravam) • alprazolam XR (Xanax XR)		
Inso	mnia	
<ul> <li>Fier 1 products are available without prior authorization for members age 18 or older.</li> <li>Prior authorization is required for all products formembers under age 18.</li> <li>Tier 2 authorization requires: <ul> <li>Minimum of 30 day trial with at least two Tier 1 products (one of which must be zolpidem) and clinical documentation of attempts to correct any primary cause for insomnia.</li> <li>FDA approved diagnosis.</li> <li>No concurrent anxiolytic benzodiazepine therapy greater than TID dosing and no concurrent ADHD medications.</li> <li>Prior Authorization form</li> </ul> </li> </ul>		
Tier 1	Tier 2	
<ul> <li>zolpidem tartrate (Ambien)</li> <li>flurazepam (Dalmane)</li> <li>triazolam (Halcion)</li> <li>estazolam (ProSom)</li> <li>temazepam (Restoril) 15mg &amp; 30mg</li> <li>zaleplon (Sonata)</li> </ul>	<ul> <li>zolpidem tartrate (Ambien CR)</li> <li>eszopiclone (Lunesta)</li> <li>temazepam (Restoril) 7.5 &amp; 22.5mg</li> <li>ramelteon (Rozerem)</li> </ul>	

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#### ADHD and Narcolepsy PA Criteria: Dose not to exceed 1.5 times the FDA approved maximum. No concurrent use of multiple products from this category, ie, Strattera + Stimulant, Methylphenidate + Amphetamine • Prior authorization is required for all stimulants for adults age 21 and older. Tier 2 authorization requires: Documented trial of a longer-acting Tier 1 medication within the last 30 days with inadequate results, and Diagnosis of ADHD or Narcolepsy Tier 3 authorization requires: • Documented trial of one Tier 1 medication long-acting product and one Tier 2 medication or two trials with either a Tier 1 or a Tier 2 medication with inadequate results (both trials within the last 60 days), and Diagnosis of ADHD or Narcolepsy. • Prior Authorization form Tier 1 Tier 2 Tier 3 amphetamine salt combo amphetamine salt combo methylphenidate patch (Adderall XR) (Adderall) (Daytrana) methylphenidate • methylphenidate ER dextroamphetamine ER (Concerta) (Metadate CD, Metadate (Dexedrine, Dextrostat) dexmethylphenidate • methamphetamine ER) (Focalin, Focalin XR) • methylphenidate (Ritalin (Desoxyn) methylphenidate IR armodafinil (Nuvigil) LA) (Ritalin, Methylin) modafinil (Provigil) atomoxetine (Strattera) methylphenidate SR (Ritalin SR) lisdexamfetamine (Vyvanse)

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#### Antidepressants

#### SSRIs (Selective Serotonin Reuptake Inhibitors)

#### PA Criteria:

The following are criteria for approval of a Tier 2 Product:

- Documented adverse effect, drug interaction, or contraindication to the Tier 1 products.
- Failure with a Tier 1 medication defined as no beneficial or minimally beneficial response after at least 4 weeks of continuous use within the last 6 months.
- Unique indication not covered by a Tier 1 product.
- Previously stabilized on Tier 2 product.
- Petition for a tier 2 medication may be submitted for consideration when a unique member specific situation exists or prescription by a psychiatrist.

Tier 3 Authorization Criteria

- Recent trials of a Tier 1 and a Tier 2 medication (within the last 6 months) with inadequate response after a minimum of 4 weeks of continuous therapy at recommended doses, or
- Unique FDA-approved indication for which Tier 1 and Tier 2 medications are not indicated, or
- Documented prior stabilization on the Tier 3 medication within the last 100 days. A past history of success on the Tier 3 medication will also be considered with adequate documentation.

Tier 1	Tier 2	Tier 3	
<ul> <li>citalopram (Celexa)</li> <li>fluoxetine (Prozac, Sarafem)</li> <li>fluvoxamine (Luvox)</li> <li>paroxetine (Paxil, Paxil CR)</li> <li>sertraline (Zoloft)</li> </ul>	<ul> <li>escitalopram (Lexapro tabs &amp; liquid)</li> <li>fluvoxamine (Luvox CR)</li> <li>fluoxetine 40mg caps</li> <li>fluoxetine (Prozac weekly)</li> <li>paroxetine (Pexeva)</li> </ul>		
	Dual Acting Antidepressants		
Tier 1	Tier 2	Tier 3	
<ul> <li>Any Tier 1 SSRI or</li> <li>trazodone (Desyrel)</li> <li>venlafaxine (Effexor)</li> <li>mirtazapine (Remeron, Remeron SolTab)</li> <li>bupropion (Wellbutrin, Wellbutrin SR, Wellbutrin XL)</li> </ul>	• venlafaxine extended release tablets	<ul> <li>bupropion (Aplenzin)</li> <li>duloxetine (Cymbalta)</li> <li>venlafaxine (Effexor XR capsules)</li> <li>desvenlafaxine (Pristiq)</li> <li>nefazodone (Serzone)</li> </ul>	
Monoamine Oxidase Inhibitors			
Tier 1	Tier 2	Tier 3	
		<ul> <li>selegiline transderm (Emsam)</li> <li>phenelzine (Nardil)</li> <li>tranylcypromine(Parnate)</li> <li>selegiline (Zelapar)</li> </ul>	

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#### **Bladder** Control Drugs

The following are criteria for approval of a Tier 2 product:

• Tier-1 drug failure (i.e. inadequate clinical response or adverse effect), or

- Contraindication to the tier 1 drugs, or
- Stabilization on the tier 2 drug, or
- A unique indication which the tier 1 drugs lack.
- Patients who are currently stabilized on a Tier 2 medication will be allowed to continue their current treatment without prior authorization.

Tier 1	Tier 2
<ul> <li>tolterodine (Detrol)</li> <li>tolterodine extended release (Detrol LA)</li> <li>oxybutynin (Ditropan)</li> <li>darifenacin (Enablex)</li> <li>fesoterodine fumarate tablets (Toviaz)</li> <li>flavoxate (Urispas)</li> <li>solifenacin (VESIcare)</li> </ul>	<ul> <li>oxybutinin extended release (Ditropan XL)</li> <li>oxybutynin (Oxytrol)</li> <li>trospium (Sanctura, Sanctura XR)</li> </ul>

\*hyoscyamine can be used as adjuvant therapy only. By itself, it will not count as a tier 1 trial.

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#### Narcotic Analgesics

PA Criteria:

Tier 1 medications are available without prior authorization.

Tier 2 authorization requires:

- documented 30 day trial/titration period with at least two Tier 1 medications within the last 90 days, or
- clinically appropriate pain therapy requiring time-released medication

Tier 3 authorization requires:

- documented 30 day trial with at least two long-acting Tier 2 medications within the last 90 days, or
- documented allergy or contraindication to all Tier 2 medications

Other criteria for this category:

- Members with an oncology-related diagnosis are exempt from the step therapy process, although quantity and dosage limits still apply. Actiq and Fentora are approved only for oncology-related diagnoses
- Only one long-acting and one short-acting agent can be used concurrently
- <u>Prior Authorization form</u>

Tier 1	Tier 2	Tier 3	Oncology Only
Immediate Release	Long Acting		
• codeine	• morphine ER		-

<ul> <li>propoxyphene/APAP (Darvocet)</li> <li>propoxyphene(Darvon)</li> <li>hydromorphone (Dilaudid)</li> <li>methadone (Dolophine)</li> <li>ASA/butalbital/caffeine/codeine (Fiorinal with Codeine)</li> <li>hydrocodone/APAP (Lortab)</li> <li>morphine Immediate Release (MSIR)</li> <li>oxymorphone (Opana)</li> <li>oxymorphone/APAP (Percocet)</li> <li>oxymorphone/ASA (Percodan)</li> <li>tramadol/APAP (Ultracet)</li> </ul>	<ul> <li>fentanyl patches (Duragesic)</li> <li>oxymorphone (Opana ER)</li> </ul>	<ul> <li>morphine sulfate (Avinza)</li> <li>morphine sulfate (Kadian)</li> <li>oxycodone (OxyContin)</li> <li>tramadol ER (Ultram ER, Ryzolt)</li> </ul>	
		Short Acting	
	• hydrocodone (Xodol)		<ul> <li>fentanyl (Actiq)</li> <li>fentanyl (Fentora)</li> </ul>

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#### Darvocet A500/Balacet 325

PA criteria:

- Concurrent use of acetaminophen-containing products.
- Documented renal insufficiency or hepatic impairment or documented need to restrict acetaminophen use.
- Prior Authorization form

A quantity limit of #180/30 on each of the products also applies.

#### Ultram ER

PA criteria:

- FDA approved diagnosis for the use of Ultram ER.
- Diagnosis indicating that the member has a condition that requires extended pain treatment with an around-the-clock dosing schedule,
- The reason immediate release tramadol is inappropriate, and
- The physician's signature

A quantity limit of #30/30 days also applies.

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#### **Smoking Cessation**

PA criteria:

• 90 day benefit without PA; does not count towards prescription limit.

- After 90 days will require a PA with proof of behavior modification program enrollment for continued therapy. For example see <u>Smoking Cessation Program</u> or call the Oklahoma Tobacco Helpline at (800) QUIT-NOW.
- Coverage includes Chantix, Zyban and nicotine replacement products with a valid prescription.
- After the patient has had 180 days of treatment in a 365 day period, the patient must wait another 180 days before smoking cessation treatment will be covered again.
- Prior Authorization form

NSAIDs		
<ul> <li>PA Criteria:</li> <li>Two consecutive trials with Tier 1 products within the last 120 days that did not yield adequate results.</li> <li>Clinical exceptions for NSAIDs in Tier 2 are demonstrated by the following conditions: <ul> <li>History of upper GI bleeding, or</li> <li>History of NSAID-induced ulcer, or</li> <li>Active peptic ulcer disease, or</li> <li>Concurrent chronic use of oral corticosteroids, or</li> <li>Chronic NSAID therapy in elderly or debilitated patients, or</li> <li>Indomethacin for management of gout.</li> <li>These clinical conditions are demonstrated by documentation sent by the prescribing physician and pharmacist.</li> </ul> </li> </ul>		
Tier 1	Tier 2	
<ul> <li>naproxen sodium (Anaprox)</li> <li>flurbiprofen (Ansaid)</li> <li>diclofenac potassium (Cataflam)</li> <li>sulindac (Clinoril)</li> <li>oxaprozin (Daypro)</li> <li>etodolac (Lodine)</li> <li>etodolac ER (Lodine XL)</li> <li>meclofenamate (Meclomen)</li> <li>meloxicam (Mobic)</li> <li>ibuprofen (Motrin)</li> <li>fenoprofen (Nalfon)</li> <li>naproxen (Naprosyn)</li> <li>naproxen EC (Naprosyn EC)</li> <li>ketoprofen ER (Oruvail)</li> <li>mefanamic acid (Ponstel)</li> <li>nabumetone (Relafen)</li> <li>tolmetin (Tolectin)</li> <li>diclofenac sodium (Voltaren XR)</li> <li>diclofenac sodium (Voltaren Gel)</li> </ul>	<ul> <li>diclofenac sodium/misoprostol (Arthrotec)</li> <li>celecoxib (Celebrex)</li> <li>piroxicam (Feldene)</li> <li>diclofenac epolamine (Flector)</li> <li>indomethacin (Indocin)</li> <li>naproxen sodium (Naprelan)</li> <li>Diclofenac Potassium (Zipsor)</li> </ul>	

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#### Skeletal Muscle Relaxants

#### PA Criteria:

• Tier 1 products are covered with no authorization necessary.

Tier 2 authorization requires:

• Documented trial of two Tier 1 medications within the last 90 days with no beneficial response after a minimum of 2 weeks of continuous therapy during which time the medication has been titrated to the recommended dose.

Tier 1	Tier 2	Special PA
<ul> <li>cyclobenzaprine (Flexeril)</li> <li>baclofen (Lioresal)</li> <li>orphenadrine (Norflex)</li> <li>chlorzoxazone (Parafon Forte, Paraflex)</li> <li>methocarbamol (Robaxin)</li> <li>tizanidine (Zanaflex)</li> </ul>	• metaxolone (Skelaxin)	<ul> <li>carisoprodol 350mg w/aspirin</li> <li>carisoprodol 350mg, ASA, codeine</li> <li>cyclobenzaprine ER (Amrix) Caps</li> <li>cyclobenzaprine 7.5mg (Fexmid) Tabs</li> <li>carisoprodol (Soma) 250mg</li> <li>tizanidine (Zanaflex) Caps</li> </ul>
Soma		

#### PA Criteria:

- A cumulative 90 therapy day window per 365 days will be in place for these products, further approval will be based on the following:
- An additional approval for 1 month will be granted to allow titration or change to a Tier1 muscle relaxant. Further authorizations will not be granted.
- Clinical exceptions may be made for members with the following diagnosis and approvals will be granted for the duration of one year:
  - Multiple Sclerosis
  - Cerebral Palsy
  - Muscular Dystrophy
  - Paralysis
- A quantity limit of 120 per 30 days will also apply for the carisoprodol and carisoprodol combination products.

**Soma 250** Approval for coverage is based on the following criteria:

- Documentation regarding member's inability to use other skeletal muscle relaxants including carisoprodol 350 mg, and specific reason member cannot be drowsy for even a short time period. Member must not have other sedating medications in current claims history.
- A diagnosis of acute musculoskeletal pain, in which case, the approval will be for 14 days per 365 day period. Conditions requiring chronic use will not be approved.

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Osteoporosis		
Tier 1	er 1 Tier 2	
<ul> <li>alendronate (Fosamax)</li> <li>calcium + vitamin D</li> </ul>	<ul> <li>alendronate +D (Fosamax +D)</li> <li>lbandronate (Boniva)</li> <li>risedronate (Actonel)</li> </ul>	<ul> <li>zoledronic acid (Reclast)</li> <li>teriparatide (Forteo)</li> </ul>
Bisphosphonate		
PA Criteria:		
*Calcitonin and raloxifene are not	included as Tier-1 trials.	
<sup>†</sup> Must be used at recommended doses in conjunction with Tier-1 bisphosphonate for trial to be accepted unless member has a recent laboratory result showing adequate Vitamin D or member is unable to tolerate calcium. OTC Calcium and Vitamin D are only covered for members with osteoporosis. See a list of covered <u>calcium products</u> .		
<ul> <li>Criteria for Moving to Higher Tiers:</li> <li>1. Treatment failure with all lower tiered products, or</li> <li>2. Contraindication to all lower tiered products, or</li> <li>3. Allergic reaction to all lowered tiered products, or</li> <li>4. Specific indication not covered by a lower tiered product.</li> <li>5. No concomitant use of bisphosphonate therapy will be approved. No additional bisphosphonate may be approved for 365 days following zoledronic acid infusion.</li> <li>6. Clinical Exceptions:</li> </ul>		
<ul> <li>Risedronate (Actonel) may be approved for members with high risk for gastric side effects.</li> <li>Zoledronic acid (Reclast)may be approved for members with a diagnosis of Paget's disease or for osteoporosis if secondary diagnosis meets criteria below: <ul> <li>Severe esophageal disease (e.g., ulcerations, strictures)</li> <li>Inability to take anything by mouth</li> <li>Inability to sit or stand for prolonged periods</li> <li>Inability to take an oral bisphosphonate for other special medical circumstances that justify the method of administration</li> </ul> </li> </ul>		
<ul> <li>Forteo Criteria:</li> <li>Teriparatide (Forteo) may be used after a minimum 12 month trial with a bisphosphonate plus adequate calcium and vitamin D (unless contraindicated, intolerant, or allergic) and a BMD (T-score at or below -2.5) test within the last month.</li> <li><u>Prior Authorization form</u></li> </ul>		

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#### Amrix and Fexmid

#### PA criteria:

- Approval requires FDA approved indication and clinical documentation of inability to take other generically available forms of cyclobenzaprine hydrochloride.
- A quantity limit of 30 capsules for 30 days placed on Amrix.
- A quantity limited of 90 tablets for 30 days placed on Fexmid.

#### Zanaflex

PA Criteria:

- Trizanidine tablets must be tried prior to consideration of the capsules. The capsules maybe considered for
- approval if there is supporting information as to why the member cannot take the tablets

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#### **Erythropoietin Stimulating Agents**

\*SoonerCare members with Medicare DO NOT need a Prior Authorization\*

PA Criteria:

FDA approved indication for specific products.

- Treatment of Anemia of Chronic Renal Failure Patients
- Treatment of Anemia of Zidovudine-treated HIV-infected Patients
- Treatment of Anemia of Cancer Patients on Chemotherapy
  - Myelosuppressive Chemotherapy-induced Anemia (Hb 8-10 g/dl) Non-Curative
- Reduction of Allogeneic Blood Transfusion in Surgery Patients

Most recent Hb levels (and date obtained) should be included on petition. Each approval will be for 8 weeks in duration. Authorization can be granted for up to 8 weeks following the final dose of myelosuppressive chemotherapy in a chemotherapy regimen. Authorization for surgery patients will be for a maximum of 4 weeks.

Continuation Criteria:

- Continue dose if Hb is  $\leq 12.0 \text{ g/dL}$ .
- If Hb is increasing and approaching 12 g/dL then reduce dose by at least 25%
- If more than 1 g/dL increase (but Hb not greater than upper limits listed below) has occurred in a 2 week period reduce dose by 25 to 50%.

Discontinuation Criteria

- ESRD Discontinue treatment if Hb is at or above 13.0 g/dL.
- All others Discontinue treatment if Hb is at or above 12 g/dL
- If a minimum increase of 1 g/dL has not been achieved after initial 8 weeks of therapy.

**Reinitiation Criteria:** 

• If Hb decreases to  $\leq$ 10 g/dL then therapy may be reinitiated at 25 to 50% of the prior dose.

Once the initial request has been submitted and approved, continuation of therapy may occur with submission of the continuation form.

- Aranesp
- Epogen
- Procrit

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Growth Hormone	
A Criteria:	
<ul> <li>Classic Human Growth Hormone hGH Deficiency or,</li> <li>Short Stature (including Prader-Willi Syndrome) or,</li> <li>Short Stature associated with chronic renal insufficiency or,</li> <li>Small for Gestational Age (SGA) or,</li> <li>Turner's Syndrome or 45 X, 46 XY mosiacism in males or,</li> <li>Hypoglycemia associated with hGH insufficiency or,</li> <li>AIDS wasting (Serostim only)</li> <li>SHOX (short stature homeobox-containing gene) deficiency</li> <li><u>Prior Authorization form</u></li> </ul>	
<ul> <li>Genotropin</li> <li>Humatrope</li> <li>Increlex</li> <li>Iplex</li> <li>Norditropin</li> <li>Norditropin Nordiflex</li> <li>Nutropin</li> <li>Nutropin AQ</li> <li>Protropin</li> <li>Saizen</li> <li>Serostim</li> <li>Tev-Tropin</li> </ul>	

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#### **Diabetic Medications**

PA criteria: Byetta

- Patients must have Type 2 diabetes and currently taking metformin, sulfonylurea, thiazolidinedione, or a combination and have not achieved adequate glycemic control (HbA1C ≥ 6.5)
- Members that have been on a sulfonylurea, metformin or thiazolidinedione for 90 of the past 180 days will NOT require prior authorization
- · Clinical exception will be allowed if Byetta is prescribed by an endocrinologist

#### PA criteria: Symlin

Patients with type 1 and 2 diabetes using insulin must:

• Be using basal-bolus insulin regimen (basal insulin plus rapid acting with meals), and

- Have failed to achieve adequate glycemic control on a basal-bolus regimen or are gaining excessive weight on basal-bolus regimen, and
- Receiving ongoing care under the guidance of a health care professional.

Patients meeting the following criteria should **NOT** be considered for Symlin therapy

- poor compliance with insulin regimen
- poor compliance with self-blood glucose monitoring
- HbA1c>9%
- · recurrent severe hypoglycemia requiring assistance in past 6 months
- presence of hypoglycemia unawareness
- diagnosis of gastroparesis
- require use of drugs that stimulate GI motility
- pediatric patients (<15 years old)

#### PA criteria: Fortamet Glumetza

Approval will be based on clinical documentation of inability to take other forms of generic metformin ER - after slow titration of 500mg ER at 2 week intervals up to 2000mg daily.

#### Elidel / Protopic

#### PA criteria:

- **Clinical Diagnosis:** short term and intermittent treatment for mild to moderate atopic dermatitis (eczema).
- The first 90 days of a 12 month period will be covered without a prior authorization.
- After the initial period, authorization will be granted with documentation of one trial of a topical corticosteroid of six weeks duration within the past 90 days.
- Therapy will be approved only once each 90 day period to ensure appropriate short-term and intermittent utilization as advised by the FDA.
- Quantities will be limited to 30 grams for use on the face, neck, and groin, and 100 grams for all other areas.
- Authorizations will be restricted to those patients who are not immunocompromised.
- Exception for age restrictions granted only if prescription is written by a dermatologist.
- Age restrictions:
  - Elidel 1%  $\geq$ 2 years of age
  - Protopic 0.03% for ≥2 years of age
  - Protopic 0.1% for  $\geq$ 15 years of age (Approved for adult-use only)

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#### **Lamisil Granules**

#### PA criteria:

- Member unable to swallow tablets, and
- FDA-approved indication of tinea capitis, and
- No improvement after at least 3 weeks of therapy with griseofulvin, or
- Intolerance of hypersensitivity to griseofulvin or penicillin
- Prior Authorization form

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Antifungal Step Therapy		
<ul> <li>Criteria for Tier 2 Product:</li> <li>Approval of a Tier 2 product will be granted following trials of at least two Tier 1 topical antifungal products within the last 30 days.</li> <li>For treatment of Onychomycosis, a trial of oral antifungals (6 weeks for fingernails and 12 weeks for toenails) will be required in order for approval of Penlac.</li> </ul>		
Tier 1 Tier 2		
<ul> <li>ciclopirox</li> <li>clotrimazole</li> <li>clotrimazole/betamethasone</li> <li>econazole</li> <li>ketoconazole</li> <li>nystatin</li> <li>nystatin/triamcinolone</li> <li>hydrocortisone/lodoquinol</li> <li>Most other available generic antifungal products</li> </ul>	<ul> <li>benzoic acid/salicylic acid (Bensal HP)</li> <li>sertaconazole nitrate (Ertaczo)</li> <li>sulconazole (Exelderm)</li> <li>ketoconazole foam 2% (Extina)</li> <li>terbinafine (Lamisil Spray)</li> <li>Ciclopirox solution, shampoo &amp; gel (Loprox)</li> <li>clotrimazole (Lotrimin Lotion 1%)</li> <li>butenafine (Mentax)</li> <li>naftifine (Naftin)</li> <li>oxiconazole (Oxistat)</li> <li>miconazole/zinc oxide/white petrolatum (Vusion)</li> <li>ketoconazole gel (Xolegel)</li> <li>ketoconazole gel +1% pyrithione zinc shampoo (Xolegel DUO)</li> </ul>	

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# Lidoderm Patch PA criteria: • FDA approved diagnosis (Postherpetic Neuraigia) • Provide documented treatment attempts at recommended dosing or contraindication to at least one agent from two of the following drug classes:

- Tricyclic antidepressants
- Anticonvulsants
- Topical or Oral Analgesics
- Quantity limit of no more than 3 patches per day with a maximum of 90 patches in a month.
- <u>Prior Authorization form</u>

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#### **Topical Antibiotic Medications**

Tier 1 products are available without prior authorization.

Tier 2 authorization requires:

• Documented five-day trial of a Tier 1 product within the last 30 days.

- Clinical exception for adverse effects with all Tier 1 products, or unique indication not covered by Tier-1 products.
- Prior authorization will be for 10 days.

Tier 1	Tier 2
<ul> <li>Cortisporin Cream 0.5%</li> <li>Cortisporin Ointment 1%</li> <li>Gentamicin Cream 0.1%</li> <li>Gentamicin Ointment 0.1%</li> <li>Gentamicin Powder</li> <li>Mupirocin Ointment 2%</li> </ul>	<ul> <li>Altabax Ointment 1%</li> <li>Bactroban Cream 2%</li> <li>Bactroban Nasal Ointment 2%</li> <li>Centany Kit 2%</li> </ul>

Pediculicides
PA Criteria:
Covered OTC products
Malathion lotion (Ovide): No prior authorization necessary
<ul> <li>Member must be at least 6 years old</li> <li>Quantity limit of 60ml for 7 day supply; may be repeated once if needed for current infestation after 7 days from original fill date</li> </ul>
PA Criteria:
Lindane lotion & shampoo
<ul> <li>Available only after first-line treatment with an OTC product has failed</li> <li>Member must be at least 13 years old or weigh at least 110 pounds</li> <li>Quantity limit of 60ml for 7 day supply</li> <li>One 7 day supply per 30 days maximum</li> </ul>
Crotamiton lotion & cream (Eurax)
<ul> <li>Available only after treatment with OTC product has failed</li> <li>quantity limit of 60 grams or milliliters for 30 day supply</li> </ul>

<u>Covered OTC products</u>

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#### **Ocular Allergy**

Criteria for Tier 2 Product:

- FDA approved diagnosis.
- A trial of at least one Tier 1 product of a similar type for a minimum of two weeks in the last 30 days.
- Documentation of clinical need for Tier 2 product over Tier 1 should be noted on the petition.
- Clinical exceptions granted for products with allergic reaction or contraindication.

Tier 1	Tier 2
<ul> <li>ketotifen fumarate (Alaway, Zaditor OTC)</li> <li>epinastine (Elestat)</li> <li>cromolyn sodium (Opticrom)</li> <li>azelastine (Optivar)</li> <li>olopatadine (Patanol)</li> </ul>	<ul> <li>pemirolast potassium (Alamast)</li> <li>nedocromil sodium (Alocril)</li> <li>lodoxamide tromethamine (Alomide)</li> <li>loteprednol etabonate (Alrex)</li> <li>emadastine difumarate (Emadine)</li> <li>olopatadine (Pataday)</li> </ul>

#### **Ophthalmic Glaucoma Medications**

Tier 1 products are covered with no authorization necessary

Tier 2 authorization requires:

- Comprehensive dilated eye exam within the last 365 day period, and
- FDA-approved indication, and
- Trial of a Tier 1 product for a minimum of 4 weeks with inadequate results within the last 90 days, or
- · Documented adverse effect, drug interaction, or contraindication to Tier 1 products, or
- Unique FDA-approved indication for which Tier 1 medications are not indicated

Beta-Blockers			
Tier 1	Tier 2		
<ul> <li>levobunolol (Betagan)</li> <li>timolol maleate (Betimol, Istalol, Timoptic, Timoptic Ocudose, Timoptic XE)</li> <li>betaxolol (Betoptic 0.5%)</li> <li>dorzolamide/timolol (Cosopt)</li> <li>carteolol (Ocupress)</li> <li>metipranolol (OptiPranolol)</li> </ul>	<ul> <li>betaxolol (Betoptic S)</li> <li>brimonidine/timolol (Combigan)</li> <li>timolol maleate (Timoptic 0.5% dropperette)</li> </ul>		
Prostaglandin Analogs			
Tier 1	Tier 2		
<ul> <li>travoprost (Travatan, Travatan Z)</li> <li>latanoprost (Xalatan)</li> </ul>	• bimatoprost (Lumigan)		
Adrenergic Agonists			
Tier 1	Tier 2		

• dipivefrin (Propine)	
Alpha-2 Adren	ergic Agonists
Tier 1	Tier 2
• brimonidine 0.2%	<ul> <li>brimonidine (Alphagan P 0.1%,0.15%)</li> <li>apraclonidine (Iopidine 1%)</li> </ul>
Carbonic Anhyo	lrase Inhibitors
Tier 1	Tier 2
<ul> <li>dorzolamide/timolol (Cosopt)</li> <li>dichlorphenamide (Daranide)</li> <li>acetazolamide (Diamox)</li> <li>methazolamide (Neptazane)</li> <li>*(Indicates Available Oral Products)</li> </ul>	<ul> <li>brinzolamide (Azopt)</li> <li>dorzolamide (Trusopt)</li> </ul>
Cholinergic Agonists/Cl	holinesterase Inhibitors
Tier 1	Tier 2
<ul> <li>pilocarpine (Isopto Carpine, Pilopine HS 0.5%, 1%,2%,4%,6%)</li> </ul>	<ul> <li>carbachol (Isopto, Miostat 1.5%, 3%)</li> <li>echothiophate iodide (Phospholine lodide)</li> </ul>

#### **Ophthalmic Anti-Infective/Steroid Combinations**

**PA Criteria:** 

- Used for pre-operative/post-operative prophylaxis
- Prescription written by optometrist / ophthalmologist
- tobramycin/dexamethasone (Tobradex)
- tobramycin/loteprednol (Zylet)
- sulfacetamide/prednisolone (Blephamide)
- gentamicin/prednisolone (Pred-G)
- neomycin/polymyxin/Bac/Hydrocortisone Ointment
- neomycin/polymyxin-B/prednisolone (Poly-Pred)
- neomycin/polymyxin-B/hydrocortisone (Cortisporin)
- neomycin/polymyxin-B/dexamethasone (Maxitrol)
- Prior Authorization form

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#### Anti-Ulcer

- Prior Authorization required for:
- ranitidine (Zantac) capsules, effervescent forms and,
- lansoprazole (Prevacid) granules and solutabs forms.
- lansoprazole/naproxen (Prevacid NapraPac)
- esomeprazole IV (Nexium IV)

Tier 2 authorization requires:

- Documented trial of a Tier 1 medication with inadequate results or adverse effect, or
- Documented contraindication to the Tier 1 medications, or
- Documented FDA-approved indication for which Tier 1 products are not indicated
- Prior Authorization form

Tier 1	Tier 2
<ul> <li>dexlansoprazole (Kapidex)</li> <li>omeprazole (Prilosec) 20mg capsules</li> <li>lansoprazole (Prevacid) capsules *BID dosing requires PA</li> </ul>	<ul> <li>rabeprazole sodium (Aciphex)</li> <li>esomeprazole magnesium (Nexium)</li> <li>omeprazole (Prilosec) 40mg capsules</li> <li>prantoprazole sodium (Protonix)</li> </ul>

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#### PA criteria:

- Chronic Idiopathic Constipation in males and females, or Irritable bowel syndrome in females 18 years of age and older who meet the following criteria:
  - Have documentation that constipating therapies for other disease states have been discontinued (excluding opioid pain medications for cancer patients).
  - Documented and updated Colon Screening. (>50 years of age)
- Hydration and treatment attempts with a minimum of three alternate products must be documented.
- Initial approval for 12 weeks of therapy. An additional year approval may be granted if physician documents member is responding well to treatment.
- Quantity limit of 100 units for a 50 day supply.

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If you have questions please call the Pharmacy Help Desk at (800) 522-0114 (9 option 4 or (405) 522-6205 (9 option 4.

# EXHIBIT F

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### JEFFREY LEON HALFORD, D.O. 2/22/2019

IN THE DISTRICT COURT OF CLEVELAND COUNTY 1 2 STATE OF OKLAHOMA STATE OF OKLAHOMA, ex rel., 3 ) MIKE HUNTER, ATTORNEY GENERAL ) 4 OF OKLAHOMA, ) 5 Plaintiff, 6 -vs-) No. CJ-2017-816 PURDUE PHARMA, L.P., et al., 7 Defendants. 8 ) CONFIDENTIAL 9 10 11 12 VIDEO DEPOSITION OF JEFFREY LEON HALFORD, D.O. 13 TAKEN ON BEHALF OF THE DEFENDANTS 14 IN TULSA, OKLAHOMA 15 16 ON FEBRUARY 22, 2019 17 18 COMMENCING AT 10:19 A.M. 19 20 21 22 INSTASCRIPT, LLC 101 PARK AVENUE, SUITE 910 OKLAHOMA CITY, OKLAHOMA 73102 23 (405) 605-6880 24 www.instascript.net 25 REPORTED BY: KIM GLOVER, CSR, RPR, RMR, CLR

> (405) 605-6880 instaScript schedule@instascript.net

## JEFFREY LEON HALFORD, D.O. 2/22/2019

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(405) 605-6880 instaScript schedule@instascript.net

1	A Yes.
2	<b>Q</b> Okay. Are those risks to your
3	knowledge disclosed on the labels of the individual
4	opioids that you have had occasion to prescribe?
5	MR. HILL: Objection, form.
6	THE WITNESS: Yeah. It's
7	disclosed on labels. It's common knowledge in
8	medicine and medical school and residency and all of
9	our training.
10	<b>Q</b> (By Mr. Curran) Okay. When did you
11	first learn about the risks commonly associated with
12	opioids?
13	<b>A</b> Well, it's something you sort of learn
14	about as an child. I grew up in the '80s, Nancy
15	Reagan saying "Just Say No" to most medication,
16	illegal drugs certainly.
17	So it's something that's part of the
18	culture, but in medical school you learn about it more
19	specifically, more data. Learn about it a lot more in
20	internship and residency with much more specificity
21	because we're actually prescribing the medication with
22	our name on the prescription.
23	In medical school it's all sort of
24	theory and woo woo. When you first write, you know,
25	that prescription, you have to take it very seriously.

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1 And so, you know, it's just a 2 growing knowledge base throughout my career. I still 3 learn about these topics and these kinds of things 4 every day. 5 0 To your understanding are all doctors 6 taught that? 7 MR. HILL: Objection, form. 8 THE WITNESS: Taught what? 9 Q (By Mr. Curran) About the relative 10 potential for addiction resulting from opioids. 11 MR. HILL: Objection, form. It's 12 for all doctors. 13 THE WITNESS: Well, yeah. I mean, 14 I would imagine that all doctors are taught, you know, 15 as part of basic science and basic clinical medicines 16 the associated risks of not only opioids but every 17 medication we prescribe. 18 Most doctors -- I don't know if 19 the general public knows this or understands it, but 20 most doctors when we prescribe anything -- doesn't 21 matter if it's aspirin, or a high blood pressure drug 22 or an opiate, we read about it. We read about it from 23 multiple sources. 24 Drugs that I prescribe 10,000 25 times many -- almost every time I prescribed it, I

1	will pull up on my little database on my iPhone the
2	associated mechanism of action, the associated common
3	side effects because I want to inform the patient,
4	things that might happen, whether it's nausea or rash
5	or whatever, and I want to prepare them for that and,
6	you know, explain to them what might happen so it's
7	not a surprise to them when they suddenly stop the
8	truck.
9	I will always or commonly look at
10	the associated, you know, consequences of taking any
11	drug I prescribe.
12	<b>Q</b> Which leads me to ask: How do you use
13	and prescribe opioids in your practice?
14	MR. HILL: Objection, form.
15	THE WITNESS: Well, approximately
16	and I don't have the exact number here, but I'm
17	guessing it's 95% plus of my patients that come to us
18	at Pain Management of Oklahoma have been treated
19	chronic treated for their chronic pain, again 95%
20	of them with opiates for probably an average of five
21	years.
22	It is a rare patient indeed at our
23	practice that comes having never taken an opioid or
24	hasn't taken one in the past hasn't been prescribed
25	one in the past year. I would guess that that makes

1	But if it's something I'm particularly interested in,
2	a new drug or a new, you know, medical device or
3	whatever, and it's, you mean, germane to my current
4	practice, I will reluctantly schedule a 30 minute or
5	so lunch with this person.
6	And they may, during that period, offer
7	me their typical, you know, marketing stuff which
8	usually ends up in the trash. But I'll read it
9	politely in there and listen to their pitch and ask
10	questions. Almost always ask for subsequent
11	literature, medical literature references that
12	validate anything they might be saying.
13	Q Why?
14	A Because I don't trust anything they
15	would say. I take it with a very small grain of salt.
16	I usually just sort of think of what they are telling
17	me as sort of an introduction and then I need to go
18	and validate or refute and research and learn about,
19	you know, whatever this is I'm interested in, if I'm
20	going to incorporate it into my practice at all.
21	<b>Q</b> Do you or does your office keep track
22	of who or how many sales reps visit you in any given
23	period of time?
24	A Not keeping track per se but, you know,
25	it may be on our calendar. I don't know.
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1	Q	Okay. Do you keep track of how often
2	they may bring	in lunch or how much that lunch costs?
3	A	Do I keep track of it, no. I would say
4	half the time w	when I do accept an engagement with a
5	rep, they are p	providing lunch and then maybe 50% of
6	the time there	is no lunch.
7	Q	Okay. How often
8	A	I don't require a lunch, for example.
9	Q	I understand. You recall them ever
10	providing anyth	ning else in the form of anything
11	else, items	promotional items, any sort of
12	A	Pens?
13	Q	That kind of stuff.
14	A	Sticky notes?
15	Q	Right.
16	A	Beyond that, no.
17	Q	Did you ever make a decision to
18	prescribe an op	pioid medication based upon what a sales
19	rep did or what	they told you?
20	Α	No.
21		MR. HILL: Form.
22	Q	(By Mr. Curran) Do you have any
23	personal knowle	edge as to any of Teva's and by Teva,
24	I mean Teva and	l Cephalon, Watson and Actavis, do you
25	have any person	hal knowledge of any of Teva's or any

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1	other company	sales or marketing practices or efforts
2	in Oklahoma?	
3	А	Repeat that, please.
4	Q	Sure. Do you have any personal
5	knowledge into	any pharmaceutical manufacturer's sales
6	or marketing p	practices in Oklahoma?
7	A	Yes.
8	Q	Okay. Other than sales reps visiting
9	you?	
10	A	Well, I see advertisements in journals,
11	for example.	
12	Q	Okay. But do you have any knowledge as
13	to where they	decide to advertise or who they decide
14	to target or v	visit?
15	A	No.
16	Q	Okay. Would it surprise you to know
17	that as a pair	management physician you are targeted
18	by opioid manu	facturers for visits?
19	А	No.
20	Q	Do you have any personal knowledge as
21	to how any sal	es representative from any
22	pharmaceutical	manufacturer is paid?
23	A	No.
24	Q	Is that anything you concern yourself
25	with?	
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1 time to bring her some dessert. I don't usually learn 2 that much. But I can think of, you know, less than 3 4 a handful, maybe two or three of those that I have 5 attended in my career. 6 One in particular I can remember was 7 when Nucynta came out. I was interested in Nucynta. It was a novel opioid, synthetic type drug. 8 Never 9 heard of it, supposedly unlike other opioids and I was 10 interested. 11 So I went to that particular lecture. 12 And I don't consider that CME. 13 **Q** Right. 14 Α That's just a marketing lecture, 15 introduction to a drug. 16 Do you recall hearing any false or 0 17 misleading statements of any of those marketing 18 lectures as you call them? 19 Α No. I don't recall --20 MR. HILL: Form. 21 THE WITNESS: -- much about it. 22 0 (By Mr. Curran) I think I know the 23 answer to this, but let me ask. Have you ever had any consulting relationship with Teva USA or Cephalon or 24 25 Watson or Actavis about opioids?

1 NO. Α 2 Or about anything else? 0 3 No. Α If I use the term "preceptorship," do 4 Q 5 you know what that is? 6 А Only as it perhaps relates to a medical 7 student. 8 Then let me just follow up. Okay. 0 9 Have you ever agreed to do a preceptorship with any Cephalon or Teva sales rep? 10 11 Α NO. 12 Or Watson or Actavis? 0 13 Α No. 14 Q Have you ever received any funds, items, meals or anything of value that you can recall 15 from any Cephalon or Teva or Watson or Actavis sales 16 representative? 17 18 Α Not that I'm aware of. 19 0 Same question as to any sales rep from 20 any pharmaceutical company? 21MR. HILL: Objection, form. 22 Any meals? THE WITNESS: 23 (By Mr. Curran) Q Yes. 24 Yes, I have received meals. Α 25 Are those the lunches you're talking Q

1 about? 2 Lunches and/or the evening -- dinner Α talk. 3 4 0 Anything other than what we've just discussed? 5 6 No. Α 7 0 Did any of those things ever influence 8 your independent medical judgment as to whether to 9 prescribe an opioid medicine for a patient? 10 MR. HILL: Objection, form. 11 THE WITNESS: Only in so much as 12 it may be an introduction to a new medication. 13 (By Mr. Curran) 0 Which you then 14 followed up and investigated yourself? 15 MR. HILL: Objection, form. 16 THE WITNESS: Yes. And sometimes 17 it's a new indication like I don't know if this is 18 exactly accurate but Cymbalta, for example, comes out 19 originally as an antidepressant and then it gets an 20 indication for neuropathic pain. 21 I may be -- I may go to a dinner 22 or have a lunch to learn about this new indication. 23 (By Mr. Curran) Okay. Have you always 0 made your own decisions as to whether or not to 24 25 prescribe opioids --

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1	A	Yes.
2	Q	based upon your own independent
3	medical judgme	ent?
4	A	Yes.
5	Q	Have you ever considered or consulted
6	any third part	y publications before you prescribed
7	opioids?	
8	A	What do you mean third party
9	publications?	
10	Q	Sure. Groups that put out articles on
11	opioid or opic	oid-related subjects.
12	A	When you say groups, do you mean the
13	New England Jo	ournal of Medicine or what do you mean?
14	Q	Sure. That's one of them. I was
15	talking partic	cularly about I had a list here that I
16	could read you	and you could tell me if you're
17	familiar with	them.
18	А	Sure.
19	Q	American Pain Foundation, the American
20	Academy of Pai	n Medicine?
21	A	Familiar with them, yes.
22	Q	The American Pain Society?
23	A	Yes.
24	Q	The American Chronic Pain Association?
25	A	Not familiar.

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1	Q	The American Geriatrics Society?
2	А	Not familiar.
3	Q	The National Pain Foundation?
4	А	Not familiar.
5	Q	The American Society of Pain Education?
6	А	Don't know.
7	Q	The Pain and Policy Studies Group?
8	А	That sounds familiar.
9	Q	Okay. Of the ones that sound familiar
10	to you, do you	recall reading anything in there that
11	you felt was f	alse or misleading?
12		MR. HILL: Objection, form.
13		THE WITNESS: I don't recall
14	reading anythi	ng in particular from any of those
15	groups.	
16	Q	(By Mr. Curran) Fair enough. Through
17	the course of	your education and career, have you
18	noticed a chan	ge in the culture of opioid prescribing?
19	A	Yeah. But I think
20	Q	How would you describe it?
21	A	The most dramatic, as I read the
22	medical litera	ture and history and opinion pieces, the
23	culture was ch	anging pretty significantly before I
24	entered medica	l school or about the time I entered
25	medical school	in '94 to '98 when I graduated.

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further agency or certification body or administrative 1 2 person in a hospital telling me that I needed to take 3 pain more seriously. To me it was sort of annoying. 4 0 It being? 5 The fact that we had to do further Α 6 documentation to treat pain as a fifth vital sign. 7 0 Did you consider it to be an actual 8 vital sign? 9 Ά No. 10 Why not? Q. 11 Because it's not vital. Α Vital 12 indicates, you know, pulse, respiration, you know, 13 circulatory system and breathing events. 14 Important perhaps but not vital? 0 15 Α Yeah. That's reasonable. 16 Did it have any -- did that phrase or Q 17 campaign have any influence on your prescribing 18 habits? 19 MR. HILL: Object to the form. 20 THE WITNESS: Not overtly that I 21 can say. 22 I can say that it prompted a lot 23 of discussion about how we treat pain, you know, 24 during my pretty influential training at Baylor and my 25 residency. It was a topic -- is a common topic.

1	Older doctors sort of grumbling about, you know, the
2	more liberalized use of opioids and younger doctors
3	arguing, "Hey we got to take this more seriously,
4	people are killing themselves because of
5	under-treatment of chronic pain."
6	I remember a talk I wasn't even sure
7	this was a real thing until I was recently putting
8	together my lecture in October about this, that there
9	was supposedly some big lawsuit in California where a
10	doctor got sued for under-treatment of pain in a
11	malpractice case, as I understand it.
12	I remember rumors about that as a young
13	impressionable resident going, "Really, I cannot
14	imagine we could get sued for under-treatment of
15	pain."
16	<b>Q</b> So what, if any, effect did the fifth
17	vital sign, the phrase, or the I don't know what
18	you call it, the emphasis, what effect, if any, did
19	that have on your prescribing?
20	MR. HILL: Objection, form.
21	THE WITNESS: I can't think of
22	anything specific of how it influenced me.
23	<b>Q</b> (By Mr. Curran) To your knowledge, did
24	it influence the way hospitals or administrators
25	addressed the treatment of pain?

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1	A I think it did.
2	<b>Q</b> How so to your knowledge?
3	A Well, yeah, to my knowledge, you know,
4	from my reading of the medical literature and medical
5	opinion pieces, you know, that phrase was adopted by
6	the certifying body, the Joint Commission.
7	Q Joint Commission?
8	A Joint Commission, as I understand it
9	I think it's called the Joint Commission as the
10	certifying body for Medicare users to certify
11	hospitals for appropriate Medicare payments.
12	And, you know, if you have ever spent
13	any time working in a hospital, whether it's a janitor
14	or a physician, you have to take the Joint Commission
15	very seriously because your boss and your employer
16	take the Joint Commission very seriously.
17	And if there is a mock survey, you take
18	it very seriously. If there is a real survey you take
19	it even more seriously And there's hours and hours of
20	preparedness, again from the janitor to the nurses to
21	the physicians to be able to respond to questions that
22	the Joint Commission, you know, people may come and
23	talk to you about on the spur of the moment.
24	<b>Q</b> How does that affect you, the pain
25	management doctor?

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1	reason for that was because it wasn't effective in my
2	experience and from my reading of the literature. It
3	wasn't appropriate for my management of my patients,
4	and I wanted it to be, because it's a non-opioid.
5	You know, wouldn't it be great if we
6	just treated patient's depression and we got rid of
7	their chronic pain and we had some non-opioid thing to
8	help their chronic pain or have something that could
9	lower their opioid dependence?
10	Man, I wanted that to be true, and she
11	tried. She came every month, and probably multiple
12	times a month.
13	You know, I rarely prescribed it, and
14	my partners equally the same. We would have
15	conversations about this. We were like, "We wish this
16	drug would work."
17	My point is is that all the marketing
18	effort in the world for Cymbalta, at least on me and
19	my practice they could have spent one billion
20	dollars on me marketing Cymbalta and it would not have
21	changed my marketing practices one bit, and it did
22	not.
23	<b>Q</b> And you think that's the way it's
24	supposed to work; right?
25	A Yes.

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1	<b>Q</b> So you certainly wouldn't at least want
2	to acknowledge if in any way those marketing efforts
3	did influence you in some way, shape, or degree;
4	right?
5	MR. CURRAN: Object to the form.
6	MR. BURNS: Object to the form.
7	MR. JOHNSON: Same objection.
8	THE WITNESS: I don't mind
9	agreeing that they influence me in some way, shape, or
10	degree, but I don't I don't think they change
11	fundamentally how I practice, me, personally. I can't
12	speak about anybody else in particular.
13	<b>Q</b> (By Mr. Hill) You can set that
14	document aside, Doctor.
15	Doctor, Exhibit 7 to your deposition
16	has been placed in front of you. It begins with the
17	Bates number PDD1782004399. It is identified as a
18	November 6th, 2000, memorandum with the subject
19	"Rationale for Partners Against Pain Spinoff."
20	Do you see that?
21	A Yes.
22	<b>Q</b> I told you I was going to do something,
23	so I'm going to keep that statement and then we'll
24	move to the specific things that I wanted to look at.
25	You saw a moment ago we looked at

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1	Partners Against Pain Materials identified in one of
2	the Purdue marketing plans. Do you remember that?
3	A Yes.
4	<b>Q</b> And we talked about how marketing
5	directly advertising directly to patients
6	influences those patients when it comes to drugs;
7	right?
8	A Yes.
9	<b>Q</b> If you flip to the second page, Doctor.
10	A (Complies)
11	<b>Q</b> You see at the top of the page, reading
12	from the first page, the document says, "The ultimate
13	goal of Partners Against Pain is to positively impact
14	Purdue Pharma's top line growth by creating quote
15	'pull through' end quote for pain management products
16	among the 45 million Americans living in pain today.
17	This can be accomplished through a concerted education
18	effort to," and then it lists, going on to the next
19	page, four separate things.
20	Do you see that?
21	A Yes.
22	MR. BURNS: Object to the form.
23	MR. CURRAN: Object to the form.
24	<b>Q</b> (By Mr. Hill) Do you see that, at the
25	top of the second page, one of the concerted education

1 Norco or Lortab at the time or Oxycodone, with, you 2 know, significant street values. 3 So I might have been persuaded to use 4 those drugs, Butrans and Nucynta, more easily, because 5 they didn't have street values and I perceived them as 6 being safer, not because a rep told me that, but 7 because I would just know that. 8 And, Doctor, my -- you know, I Sure. 0 9 started with making some representations to you, telling you about what this lawsuit is about. 10 11 Yeah. Α 12 I understand what you have told me 0 13 today and, frankly, I respect it, and I know you're 14 speaking for yourself about what was -- what could or 15 couldn't influence you, knowingly, anyways. 16 But seeing what you have seen here and 17 seeing what wasn't disclosed about who was doing what, 18 do you also think it's reasonable to believe that 19 maybe it wasn't you but some doctors who were super targets, or whatever the word is, that were called on 20 21 over and over again, invited and paid to go to these 22 programs, knowingly or unknowingly were influenced by 23 the messages that these companies put forth? 24 MR. BURNS: Object to the form. 25 MR. CURRAN: Object to the form.

Object to the form, 1 MR. JOHNSON: 2 calls for speculation. 3 THE WITNESS: Yeah. I can't 4 comment on how much they were influenced or not. Ι 5 quess I would be surprised for -- for most -- for most doctors -- I was going to say reasonable doctors, but 6 7 I think most doctors are reasonable. To, again, begin any opioid on a 8 9 patient, no matter how much marketing effort they put forward, on inappropriate patients -- they may do the 10 11 conversion thing. They may be very -- my impression is the effects of marketing are very good at 12 converting from one drug to another, but not 13 14 necessarily, certainly in my case, changing how much 15 I'm prescribing a patient in terms of morphine 16 equivalents, which is the pertinent issue here, not 17 whether or not we use a brand name or not. It's how 18 much and how much associated risk is involved because 19 of those dosages. 20 So I just don't think many doctors 21 -- there's probably a few, but I just don't think the 22 vast majority of doctors are going to be influenced to start any drug, much less an opioid, for inappropriate 23

patients, no matter how good the meal was that they paid for or how cute the rep was or how many times

1 they came in the office or how many savings cards they 2 brought or how good their literature was. 3 I just -- I just don't see that 4 happening. 5 MR. HILL: I'm almost done and I'm 6 making a mess. Just kidding. 7 (By Mr. Hill) Doctor, do you know 0 8 whether physicians who are general practitioners, 9 family practitioners, just general primary care physicians, have the training or specialty in pain 10 11 management that someone like you has? 12 MR. CURRAN: Object to the form. 13 MR. BURNS: Object to the form. 14 THE WITNESS: Most of them do not get that as a primary part of their education in 15 residency, like a rehab physician would or an 16 17 anesthesiologist that has further pain training would. 18 (By Mr. Hill) Did you know that part 0 19 of the plans, two-decade-long plans -- we've looked at 20 some examples today -- in addition to targeting high 21 prescribers were to target family practitioners and 22 primary care physicians with these messages, as well? 23 Yes. Ά 24 Object to form. MR. BURNS: 25 Q (By Mr. Hill) The answer that you just

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1	gave me about what you would expect yourself or others
2	in your field, the likelihood of your being influenced
3	to start a new drug pain drug with a patient, do
4	you think that a doctor, like a primary care
5	physician, who doesn't have the background and
6	experience that you have would be more likely to be
7	influenced by this type of marketing and the message
8	that was sent out in it?
9	MR. CURRAN: Object to the form.
10	MR. BURNS: Object to the form.
11	MR. JOHNSON: Object to the form.
12	THE WITNESS: I can't say. I
13	really don't know. I know that that is part of the
14	underlying issue, I think, related to the opioid
15	crisis. I think the access to well-trained physicians
16	that do chronic pain the access is not there.
17	Most pain doctors in Tulsa, to
18	this day, would prefer to spend their day in the
19	procedure room, sticking long needles in people's
20	backs and making a lot of money doing it, rather than
21	worrying about how many morphine equivalents we're
22	giving these patients.
23	So when a primary care physician
24	is you know, has this group of patients that needs
25	chronic pain medications, but yet they've either had

1	IN THE DISTRICT COURT OF CLEVELAND COUNTY STATE OF OKLAHOMA
2	
3	STATE OF OKLAHOMA, ex reo., MIKE HUNTER, ATTORNEY GENERAL
4	OF OKLAHOMA,
5	Plaintiff,
6	vs. No. CJ-2017-816
7	(1) PURDUE PHARMA L.P.; (2) PURDUE PHARMA, INC.;
8	(3) THE PURDUE FREDERICK COMPANY;
9	(4) TEVA PHARMACEUTICALS USA, INC.;
10	(5) CEPHALON, INC.; (6) JOHNSON & JOHNSON;
11	<ul><li>(7) JANSSEN PHARMACEUTICALS, INC.;</li><li>(8) ORTHO-MCNEIL-JANSSEN</li></ul>
12	PHARMACEUTICALS, INC., a/k/a JANSSEN PHARMACEUTICALS, INC.;
13	(9) JANSSEN PHARMACEUTICALS, INC., a/k/a JANSSEN
14	PHARMACEUTICALS, INC.; (10) ALLERGAN, PLC, f/k/a
15	ACTAVIS PLC, f/k/a ACTAVIS, INC., f/k/a WATSON PHARMACEUTICALS, INC.;
16	(11) WATSON LABORATORIES, INC.; (12) ACTAVIS LLC; and
17	(13) ACTAVIS PHARMA, INC., f/k/a WATSON PHARMA, INC.
18	
19	Defendants.
20	
21	VIDEOTAPE DEPOSITION OF GARY SCHICK, M.D. TAKEN ON BEHALF OF THE DEFENDANTS
22	ON MARCH 1, 2019 AT 9:01 AM IN OKLAHOMA CITY, OKLAHOMA
23	
24	VIDEOTAPED BY: C.J. Shelton
25	REPORTED BY: Jody Graham, CSR, RPR, RMR, CRR

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1	Q Sure. I don't know that I could ask it the
2	same way. Do opioids possess any addiction potential?
3	A Yes. Obviously.
4	Q Okay. Tell me about that in your practice
5	and to your knowledge and experience?
6	A Well, in my practice it's never been really
7	that big of a problem because I don't usually give
8	them enough to let them get to a dependent state. At
9	least anymore. I mean, it was in the past I used
10	to do a little bit more of that, but I don't do that
11	now.
12	But patients do get dependent on the regular
13	dosing of the medication so that they still feel okay.
14	If they don't get their medications, they're going to
15	start feeling poorly and have withdrawal symptoms.
16	From a dependent standpoint that's I mean, that's
17	what they do.
18	I don't know where else to take that.
19	Q Sure. That's fine.
20	A That's just what they do.
21	Q Sure. So opioids can be addictive?
22	A Absolutely.
23	Q Is that a risk that is known to you
24	currently?
25	A Yes.

1	Q When did you first learn about the risks of
2	opioids?
3	A I guess medical school or even before.
4	Q Okay.
5	A I mean, just always known that they were
6	addictive.
7	Q Was that something that was taught in
8	medical school?
9	A Sure, yeah.
10	Q And when did you go to medical school again?
11	I think we talked about it briefly.
12	A '90 I graduated in '95. So '91 to '95.
13	Four years.
14	Q Is that something that's common knowledge in
15	the medical community?
16	A Yes.
17	Q And you've been in the Oklahoma medical
18	community for how many years?
19	A Well, let's see. I started off as a P.A. I
20	graduated P.A. school in 1986, I think. So I
21	practiced as a medical person since 1986 through the
22	VA before going to medical school. Before that I
23	worked in nursing homes. So, I mean, I have a couple
24	years there as well.
25	Q Okay. Then let me take a little sidetrack

1	
1	here. Tell me about your work as a P.A. and in
2	nursing homes.
3	A Well, when I was in college, to get into
4	P.A. school at the time you had to have some kind of
5	medical experience. And there was no way for me to
6	get any other kind of medical experience so I went to
7	work in a nursing home.
8	I did lots of wound care and vital signs and
9	took care of people in the nursing homes or other
10	banged up people that they took in there for
11	convalescence. That gave me medical experience that
12	so when I interviewed for P.A. school they let me in.
13	After a couple years of V.A. school I went
14	to the VA Hospital working in the inpatient rehab
15	unit. Mostly strokes, lot of amputations, brain
16	injury, spinal cord injury, stuff like that.
17	Q Okay. With your P.A. work, did that in any
18	way involve medication prescriptions?
19	A Not very much.
20	Q Okay. That wasn't
21	A I was doing mostly inpatient rehab.
22	Q Okay.
23	A We did have a lot of outpatients that we
24	followed from a spinal cord standpoint mostly, so
25	there were various medications that we used for

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