19TH JUDICIAL DISTRICT COURT FOR THE PARISH OF EAST BATON ROUGE
STATE OF LOUISIANA

NUMBER: 641638 **DIVISION "C"** SEC. 25

LOUISIANA DEPARTMENT OF HEALTH, THROUGH THE SECRETARY OF THE LOUISIANA DEPARTMENT OF HEALTH

STATE

VERSUS

SEP 20 2017

DEPUTY CLERK OF COURT

PURDUE PHARMA L.P.; PURDUE PHARMA, INC.; THE PURDUE FREDERICK COMPANY, INC.; TEVA PHARMACEUTICAL INDUSTRIES, LTD.; TEVA PHARMACEUTICALS USA, INC.; CEPHALON, INC.; JOHNSON & JOHNSON; JANSSEN PHARMACEUTICALS, INC.; ORTHO-MCNEIL-JANSSEN PHARMACEUTICALS, INC. n/k/a JANSSEN PHARMACEUTICALS, INC.; ENDO HEALTH SOLUTIONS INC.; ENDO PHARMACEUTICALS, INC.; ALLEGRAN PLC f/k/a ACTAVIS PLC; WATSON PHARMACEUTICALS, INC. n/k/a ACTAVIS, INC.; WATSON LABORATORIES, INC.; ACTAVIS LLC; ACTAVIS PHARMA, INC. f/k/a WATSON PHARMA, INC.

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PETITION FOR DAMAGES AND INJUNCTIVE RELIEF

Plaintiff, the Louisiana Department of Health, through the Secretary of the Louisiana Department of Health, files this Petition for Damages and Injunctive Relief against Defendants named herein as follows:

I. INTRODUCTION/BACKGROUND

1.

Plaintiff, the Louisiana Department of Health, through the Secretary of the Louisiana Department of Health, alleges the following:

2.

Drug manufacturers undertook an orchestrated campaign to flood Louisiana with highly-addictive and dangerous opioids ("opioid analgesic pain relievers" or "opioids") in an effort to maximize profits above the health and well-being of their customers including the healthcare systems supporting those customers. Importantly, these drug manufacturers knew prescribing doctors and other health-care providers relied upon statements and representations from these same drug manufacturers in determining treatment decisions. Instead of providing truthful representations regarding the dangerous and addictive opioid analgesic pain relievers they produce, these same drug manufacturers provided false and misleading statements unsupported by science and medical evidence in an effort to promote the purchase and widespread use of their dangerous and addictive narcotics.

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3.

As a result of these false and misleading representations concerning opioid analgesic pain relievers, these drug manufacturers caused a healthcare crisis that has had far-reaching health, financial, social, and deadly consequences in Louisiana and throughout the United States. On July 31, 2017, the Commission on Combating Drug Addiction and the Opioid Crisis ("Commission") issued an interim report recommending to the President of the United States that he declare the opioid epidemic a national emergency.[1] In that interim report, the Commission grimly declared: "Our nation is in crisis."[2] Notably, the Commission explained: "Since 1999, the number of **opioid overdoses in America have quadrupled** according to the CDC. Not coincidentally, in that same period, **the amount of prescription opioids in America have quadrupled as well**."[3]

4.

Defendants manufacture, market, and sell prescription opioid analgesic pain relievers including OxyContin, MS Contin, Dilaudid/Dilaudid HP, Butrans, Hysingla ER, and Targiniq ER, Percocet, Actiq, Fentora, Duragesic, Opana/Opana ER, Percodan, Zydone, Kadian, oxycodone, hydrodone and Norco. Historically, opioid analgesic pain relievers were considered too addictive and debilitating for the treatment of chronic pain (*e.g.*, back pain, migraines, and arthritis). Instead, opioid analgesic pain relievers were used *only* to treat short-term acute pain or for hospice (or palliative/end-of-life) care.

5.

However, by the late 1990s, and continuing today, each Defendant instituted a marketing scheme designed to persuade doctors and patients that opioid analgesic pain relievers should be used for chronic pain, creating a far broader group of patients much more likely to become addicted and suffer other adverse effects from the long-term use of opioid analgesic pain relievers. In connection with this scheme, each Defendant spent, and continues to spend, millions of dollars on promotional activities and materials that falsely deny or trivialize the risks of opioid analgesic pain relievers while overstating the benefits of using them for chronic pain. As to the risks, Defendants falsely and misleadingly, and contrary to the language of their drugs' labels: (1) downplayed the serious risk of addiction; (2) promoted the concept of "pseudo-addiction" and

[1] https://www.whitehouse.gov/sites/whitehouse.gov/files/ondcp/commission-interim-report.pdf.

[2] *Id.* at p. 1.

[3] *Id.* (emphasis added).

thus advocated that the signs of addiction should be treated with more opioid analgesic pain relievers; (3) exaggerated the effectiveness of screening tools in preventing addiction; (4) claimed that opioid dependence and withdrawal are easily managed; (5) denied the risks of higher opioid dosages; and (6) exaggerated the effectiveness of "abuse-deterrent" opioid formulations to prevent abuse and addiction. Conversely, Defendants also falsely touted the benefits of long-term use of opioid analgesic pain relievers, including the supposed ability of opioid analgesic pain relievers to improve function and quality of life, even though there was no "good evidence" to support Defendants' claims.

6.

Defendants disseminated these common messages to reverse the accepted medical understanding of opioid analgesic pain relievers. Defendants disseminated these messages directly, through their sales representatives, and in speaker groups led by physicians that Defendants recruited for their support of Defendants' marketing messages. Defendants also worked through third parties they controlled by: (a) funding, assisting, encouraging, and directing doctors, known as "key opinion leaders" ("KOLs") and (b) funding, assisting, directing, and encouraging seemingly neutral and credible professional societies and patient advocacy groups (referred to hereinafter as "Front Groups"). Defendants then worked together with those KOLs and Front Groups to taint the sources that doctors and patients relied on for ostensibly "neutral" guidance, such as treatment guidelines, Continuing Medical Education ("CME") programs, medical conferences and seminars, and scientific articles. Thus, working individually and collectively, and through these Front Groups and KOLs, Defendants persuaded doctors and patients that what they had long known, that opioid analgesic pain relievers are addictive drugs, unsafe in most circumstances for long-term use, was *untrue*. In fact, Defendants used their marketing scheme to falsely represent that the compassionate treatment of pain actually *required* widespread use of opioid analgesic pain relievers.

7.

Each Defendant knew that its misrepresentations of the risks and benefits of opioid analgesic pain relievers were not supported by or were directly contrary to scientific evidence.[4]

[4] *Guideline for Prescribing Opioids for Chronic Pain*, issued in 2016 and approved by the FDA ("2016 CDC Guideline"), available at https://www.cdc.gov/mmwr/volumes/65/rr/rr6501e1.htm.

8.

As more fully detailed below, Defendants also formed an opioid marketing enterprise (or "Cartel") for the purpose of promoting the widespread use of opioid analgesic pain relievers for chronic pain.

9.

Defendants successfully promoted (and continue to promote) the purchase and use of its dangerous and highly-addictive opioid products through dissemination of false statements despite knowledge of the danger associated with continued use of these products. As a result, opioid analgesic pain relievers are now the **most prescribed class of drugs in the United States**.[5] Annually, opioid sales generate more approximately **$11 billion in revenue** for drug companies. In an open letter to the nation's physicians in August 2016, the then-United States Surgeon General expressly connected this "urgent health crisis" to "heavy marketing of opioids to doctors . . . [m]any of [whom] were even taught – incorrectly – that opioids are not addictive when prescribed for prescribed by doctors, has resulted in a flood of prescription opioids available for illicit use or sale (referred to as "the supply"), and a population of patients physically and psychologically dependent on them (referred to as "the demand").[6] And when those patients can no longer afford or legitimately obtain opioids, they often turn to the illegal and secondary black market in order to purchase prescription opioid analgesic pain relievers or even heroin (referred to herein as "the secondary market"). The original market for opioid analgesic pain relievers "primes" the heroin market throughout the United States. According to the July 31, 2017, Commission interim report (citing reports by the Substance Abuse and Mental Health Services Administration Center for Behavioral Health and Statistics Quality), **"[f]our out of every five new heroin users"** start using heroin *after* first using prescription opioids.[7]

10.

As more fully detailed below, annually, there were **more prescriptions for opioid analgesic pain relievers than actual Louisiana residents**. Because of Defendants' actions, Louisiana is overrun with opioid analgesic pain relievers and engulfed in a public health crisis.

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[5] Centers for Disease Control and Prevention. FastStats. Therapeutic drug use. (2014). http://www.cdc.gov/nchs/fastats/drug-use-therapeutic.htm.

[6] Vivek H. Murthy, Letter from the Surgeon General, August 2016, available at http://turnthetiderx.org/.

[7] https://www.whitehouse.gov/sites/whitehouse.gov/files/ondcp/commission-interim-report.pdf.

11.

Louisiana has suffered and continues to suffer catastrophic damages from the opioid crisis. Contrary to the false propaganda published and disseminated by Defendants, opioid analgesic pain relievers represent a health crisis both nationally and in Louisiana. The supernatural addictive qualities of Defendants' products (opioid analgesic pain relievers or "opioids") and resulting impact are easily confirmed by available data. For instance, opioid analgesic pain relievers represent **289 million prescriptions written per year**.[8] As opioid dispensation and use increased, so did the number of **emergency department visits** which **increased by more than 200 percent from 2005 to 2011**.[9] Along with the dramatic increase in emergency department visits, **overdose deaths** caused by opioid analgesic pain relievers reached epic proportions in **2014** when **25,760 people died** in the United States as result of prescription drugs.[10] In addition to these direct deaths, the secondary heroin market created by the addiction to opioid analgesic pain relievers resulted in an increase of **five times** the number of heroin overdose deaths from **1,878 deaths** in 2004 to **10,574 deaths** in 2014.[11] During that time period, Defendants' drugs earned poignant street names such as: "Hillbilly Heroin" and "O.C." (OxyContin, Percodan, and Percocet); "O Bomb" and "Stop Signs" (Opana); "Murder 8," "China White," "Goodfella," and "TNT" (Actiq and Duragesic).[12]

12.

As detailed by the United States Surgeon General in November 2016, opioids manufactured by the Defendants virtually guarantee their continued detrimental use:[13]

> **Opioids** attach to opioid receptors in the brain, which leads to a release of dopamine in the nucleus accumbens, causing euphoria ("the high"), drowsiness, and **slowed breathing**, as well as reduced pain signaling (which is why they are frequently prescribed as pain relievers). Opioid addiction typically involves a pattern of: (1) intense intoxication, (2) the development of tolerance, (3) escalation in use, and (4) withdrawal signs that include profound negative

[8] Levy, B., Paulozzi, L. Mack, K.A., & Jones, C.M. (2015). Trends in opioid analgesic-prescribing rates by specialty, US, 2007-2012. *American Journal of Preventative Medicine*, 49(3), 409-413.

[9] Crane, E. H. (2013). *The CBHSQ Report: Emergency department visits involving narcotic pain relievers.* Rockville, MD: Substance Abuse and Mental Health Services Administration, Center for Behavioral Health Statistics and Quality.

[10] Centers for Disease Control and Prevention. (2016). CDC Wonder: Multiple cause of death 1999 – 2014. Retrieved from https://wonder.cdc.gov/wonder/help/mcd.html.

[11] Rudd, R. A., Aleshire, N., Zibbel, J. E., & Gladden, R. M. (2016). Increases in drug and opioid overdose deaths – United States, 2000-2014. *MMWR*, 64(50), 1378-1382.

[12] NIDA (2016) & DEA (2015).

[13] U.S. Department of Health and Human Services (HHS), Office of the Surgeon General, Facing Addiction in America: The Surgeon General's Report on Alcohol, Drugs, and Health. Washington, DC: HHS, November 2016. (Emphasis added).

> emotions and physical symptoms, such as bodily discomfort, pain, sweating, and intestinal distress and, in the most severe cases, seizures. As use progresses, the **opioid must be taken to avoid the severe negative effects that occur during withdrawal**. With repeated exposure to opioids, stimuli associated with the pleasant effects of the substances (e.g., places, persons, moods, and paraphernalia) and with the negative mental and physical effects of withdrawal can trigger **intense craving or preoccupation with use**.

Instead of honestly conveying the power and destruction inherent in continued opioid use, Defendants masked the devastating and lethal nature of their products in order to maximize profits.

13.

According to statistics published by both the Centers for Disease Control and Prevention ("CDC") and the Louisiana Commission on Preventing Opioid Abuse, annually, there are **122 opioid prescriptions for every 100 Louisianans** (*i.e.* there are more opioid prescriptions than Louisiana residents). According to the CDC, Louisiana ranked **7th in 2013**, **8th in 2014**, **8th in 2015**, and **5th in 2016** in the United States for prescription rate of opioids. Over the last six years, Louisiana averaged **39% higher than the national average** in prescription rates for opioids. Corrected data concerning overdose deaths in Louisiana resulting from opioid use in 2014 evidenced a **125% increase** from that originally published.[14]

14.

A report authored by Matrix Global Advisors, LLC estimated that opioid abuse costs Louisianans **$296 million dollars per year in healthcare costs alone**.[15] Additional costs and strains on the criminal justice system to include increased costs of enforcement and corrections are astronomical and have negatively impacted Louisiana. Unabated, these costs will continue to increase as the epidemic continues to spread.

15.

As a result of the manmade opioid epidemic, the Louisiana Department of Health ("LDH") has incurred devastating costs (damages) to its Medicaid Program. Just for the costs of medications designed and prescribed to **treat** opioid overdoses and dependence (not the amounts paid for the opioids themselves), the Louisiana Department of Health made payments of **$7,826,169.48** in **2012**, **$8,289,855.38** in **2013**, **$7,825,960.51** in **2014**, **$9,158,782.13** in **2015**,

[14] Ruhm, C.J. (2017) American Journal of Preventive Medicine. Geographic Variation in Opioid and Heroin Involved Drug Poisoning Mortality Rates. Retrieved from: http://dx.doi.org/10.1016/j.amepre.2017.06.009.

[15] Matrix Global Advisors, LLC (2014) Health Care Costs from Opioid Abuse: A State by State Analysis. Retrieved from: https://drugfree.org/wp-content/uploads/2015/Matrix_Opioidabuse_040415.pdf.

and **$12,735,803.42** in **2016**.[16] Thus, the Louisiana Department of Health made Medicaid payments totaling almost **46 million dollars** over a **five-year span** just to pay for *some* treatment costs of opioid dependence. As shown above, these Medicaid payments increased over this time span and will, undoubtedly, continue to do so given the unhindered spread of the manmade opioid epidemic.

16.

From 2007 to present, the Louisiana Department of Health incurred approximate costs totaling **$677,254,416** for treatment of opioid use and dependence. The Louisiana Department of Health incurred additional significant costs under its Behavioral Health component.

17.

From 2007 to present, collectively, the Defendants caused to be submitted approximately **2,168,427 prescriptions** for reimbursement to the Louisiana Department of Health, on behalf of the Louisiana Medicaid system, for their opioids. In turn, the Louisiana Department of Health, on behalf of the Louisiana Medicaid system, **paid $83,255,635.44 for these drugs**. Notably, these submissions and payments included but were not limited to the following:

a. the Purdue Defendants (Purdue Pharma L.P., Purdue Pharma, Inc., and The Purdue Frederick Company, Inc.) caused to be submitted approximately 12,008 prescriptions for reimbursement to the Louisiana Department of Health, on behalf of the Louisiana Medicaid system, for the Purdue Defendants' opioids. In turn, the Louisiana Department of Health, on behalf of the Louisiana Medicaid system, paid approximately $28,296,017.12 for these drugs;

b. the Actavis Defendants (Allegran PLC f/k/a Actavis PLC, Watson Pharmaceuticals, Inc. n/k/a Actavis, Inc., Watson Laboratories, Inc., Actavis LLC, and Actavis Pharma, Inc. f/k/a Watson Pharma, Inc.) caused to be submitted approximately 2,086,429 prescriptions for reimbursement to the Louisiana Department of Health, on behalf of the Louisiana Medicaid system, for the Actavis Defendants' opioids. In turn, the Louisiana Department of Health, on behalf of the Louisiana Medicaid system, paid approximately $42,128,485.80 for these drugs;

c. the Cephalon Defendants (Cephalon, Inc., Teva Pharmaceutical Industries, LTD, and Teva Pharmaceuticals USA, Inc.) caused to be submitted approximately 7,744 prescriptions for reimbursement to the Louisiana Department of Health, on behalf of the Louisiana Medicaid system, for the Cephalon Defendants' opioids. In turn, the Louisiana Department of Health, on behalf of the Louisiana Medicaid system, paid approximately $5,028,975.91 for these drugs;

d. the Janssen Defendants (Janssen Pharmaceuticals, Inc., Ortho-McNeil-Janssen Pharmaceuticals, Inc. n/k/a Janssen Pharmaceuticals, Inc., and Johnson & Johnson) caused to be submitted approximately 12,008 prescriptions for reimbursement to the Louisiana Department of Health, on behalf of the Louisiana Medicaid system, for the Janssen Defendants' opioids. In turn, the Louisiana Department of Health, on behalf of the Louisiana Medicaid system, paid approximately $4,566,342.42 for these drugs; and

[16] These figures are limited to outpatient pharmacy claims and encounters and do not include scenarios where a physician provides treatment for opioid overdose or dependence in a physician's office.

e. the Endo Defendants (Endo Health Solutions Inc. and Endo Pharmaceuticals, Inc.) Caused to be submitted approximately 11,072 prescriptions for reimbursement to the Louisiana Department of Health, on behalf of the Louisiana Medicaid system, for the Endo Defendants' opioids. In turn, the Louisiana Department of Health, on behalf of the Louisiana Medicaid system, paid approximately $5,061,604.54 for these drugs.

18.

To redress and punish these violations of law, Plaintiff seeks damages for the amounts the LDH has already paid for excessive opioid prescriptions and treatments costs as a result of those prescriptions (*e.g.*, addiction treatment costs) as well as other costs more fully detailed below. LDH also seeks an order enjoining Defendants from their unlawful conduct. LDH also seeks punitive damages, treble damages, and attorneys' fees and costs, in addition to granting any other equitable relief authorized by law and as more fully detailed below.

II. PARTIES

Plaintiff

19.

This is a civil action by the Louisiana Department of Health, through the Secretary of the Louisiana Department of Health.

Defendants

20.

PURDUE PHARMA L.P. is a limited partnership organized under the laws of Delaware. PURDUE PHARMA INC. is a New York corporation with its principal place of business in Stamford, Connecticut, and THE PURDUE FREDERICK COMPANY is a Delaware corporation with its principal place of business in Stamford, Connecticut (collectively, "Purdue").

21.

Purdue manufactures, promotes, sells, and distributes opioids such as OxyContin, MS Contin, Dilaudid/Dilaudid HP, Butrans, Hysingla ER, and Targiniq ER in the United States and Louisiana. OxyContin is Purdue's best-selling opioid. Since 2009, Purdue's annual sales of OxyContin have fluctuated between $2.47 billion and $2.99 billion, up four-fold from its 2006 sales of $800 million. OxyContin constitutes roughly 30% of the entire market for analgesic drugs (*i.e.* painkillers). In May 2007, Purdue pled guilty to felony misbranding OxyContin with

the intent to defraud or mislead in violation of Title 21, United States Code, Sections 331(a) and 333(a)(2).[17]

22.

CEPHALON, INC. is a Delaware corporation with its principal place of business in Frazer, Pennsylvania. TEVA PHARMACEUTICAL INDUSTRIES, LTD. ("Teva Ltd.") is an Israeli corporation with its principal place of business in Petah Tikva, Israel. In 2011, Teva Ltd. acquired Cephalon, Inc. TEVA PHARMACEUTICALS USA, INC. ("Teva USA") is a wholly-owned subsidiary of Teva Ltd. and is a Delaware corporation with its principal place of business in Pennsylvania. Teva USA acquired Cephalon in October 2011.

23.

Cephalon, Inc. manufactures, promotes, sells, and distributes opioids such as Actiq and Fentora in the U.S. and Louisiana. Actiq and Fentora have been approved by the FDA *only* for the "management of breakthrough cancer pain in patients 16 years of age and older who are already receiving and who are tolerant to opioid therapy for their underlying persistent cancer pain." In October 2008, Cephalon pled guilty to a criminal violation charging it with the introduction into interstate commerce of drugs that were misbranded through off-label promotion, in violation of Title 21, United States Code, Sections 333(a)(1) and 352(f)(1) for its misleading promotion of Actiq and two other drugs.[18]

24.

Teva Ltd., Teva USA, and Cephalon, Inc. work together closely to market and sell Cephalon products in the United States. Teva Ltd. conducts all sales and marketing activities for Cephalon in the United States through Teva USA and has done so since its October 2011 acquisition of Cephalon. Teva Ltd. and Teva USA hold out Actiq and Fentora as Teva products to the public. Teva USA sells all former Cephalon branded products through its "specialty medicines" division. The FDA-approved prescribing information and medication guide, which is distributed with Cephalon opioids marketed and sold in Louisiana, discloses that the guide was submitted by Teva USA, and directs physicians to contact Teva USA to report adverse events. All of Cephalon's promotional websites, including those for Actiq and Fentora, prominently display Teva Ltd.'s logo. Teva Ltd.'s financial reports list Cephalon's and Teva USA's sales as its own, and its year-end report for 2012 – the year immediately following the Cephalon acquisition –

[17] *United States v. The Purdue Frederick Company, Inc.*, (1:07-cr-00029-JPJ) (W.D. Va.).

[18] *United States v. Cephalon, Inc.*, (08-cr-00598) (E.D. Pa.).

attributed a 22% increase in its specialty medicine sales to "the inclusion of a full year of Cephalon's specialty sales." Through interrelated operations like these, Teva Ltd. operates in Louisiana and the rest of the United States through its subsidiaries Cephalon and Teva USA. The United States is the largest of Teva Ltd.'s global markets, representing 53% of its global revenue in 2015, and, were it not for the existence of Teva USA and Cephalon, Inc., Teva Ltd. would conduct those companies' business in the United States itself. Upon information and belief, Teva Ltd. directs the business practices of Cephalon and Teva USA, and their profits inure to the benefit of Teva Ltd. as controlling shareholder. (Teva Pharmaceutical Industries, Ltd., Teva Pharmaceuticals USA, Inc., and Cephalon, Inc. are referred to as "Cephalon.").

25.

JANSSEN PHARMACEUTICALS, INC. is a Pennsylvania corporation with its principal place of business in Titusville, New Jersey, and is a wholly owned subsidiary of JOHNSON & JOHNSON ("J&J"), a New Jersey corporation with its principal place of business in New Brunswick, New Jersey. ORTHO-MCNEIL-JANSSEN PHARMACEUTICALS, INC., now known as JANSSEN PHARMACEUTICALS, INC., is a Pennsylvania corporation with its principal place of business in Titusville, New Jersey. JANSSEN PHARMACEUTICA INC., now known as JANSSEN PHARMACEUTICALS, INC., is a Pennsylvania corporation with its principal place of business in Titusville, New Jersey. J&J is the only company that owns more than 10% of Janssen Pharmaceuticals' stock, and corresponds with the FDA regarding Janssen's products. Upon information and belief, J&J controls the sale and development of Janssen Pharmaceuticals' drugs and Janssen's profits inure to J&J's benefit (Janssen Pharmaceuticals, Inc., Ortho-McNeil-Janssen Pharmaceuticals, Inc., Janssen Pharmaceutical, Inc., and J&J are referred to as "Janssen.").

26.

Janssen manufactures, promotes, sells, and distributes drugs in Louisiana and the United States, including the opioid Duragesic. Before 2009, Duragesic accounted for at least $1 billion in annual sales. Until January 2015, Janssen developed, marketed, and sold the opioids Nucynta and Nucynta ER. Together, Nucynta and Nucynta ER accounted for $172 million in sales in 2014.

27.

ENDO HEALTH SOLUTIONS INC. is a Delaware corporation with its principal place of business in Malvern, Pennsylvania. ENDO PHARMACEUTICALS INC. is a wholly-owned subsidiary of Endo Health Solutions Inc. and is a Delaware corporation with its principal place of business in Malvern, Pennsylvania (Endo Health Solutions Inc. and Endo Pharmaceuticals Inc. are referred to as "Endo").

28.

Endo develops, markets, and sells prescription drugs, including the opioids Opana/Opana ER, Percodan, Percocet, and Zydone, in Louisiana and the United States. Opioids made up roughly $403 million of Endo's overall revenues of $3 billion in 2012. Opana ER yielded $1.15 billion in revenue from 2010 and 2013, and it accounted for 10% of Endo's total revenue in 2012. Endo also manufactures and sells generic opioids such as oxycodone, oxymorphone, hydromorphone, and hydrocodone products in Louisiana and the United States, by itself and through its subsidiary, Qualitest Pharmaceuticals, Inc.

29.

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 January 2013. Previous to that transaction, 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. 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.). 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. ACTAVIS LLC is a Delaware limited liability company with its principal place of business in Parsippany, New Jersey. Each of these defendants is owned by Allergan plc, which uses them to market and sell its drugs in the United States. Upon information and belief, Allergan plc exercises control over these marketing and sales efforts and profits from the sale of Allergan/Actavis products ultimately inure to its benefit (Allergan plc, Actavis plc, Actavis, Inc., Actavis LLC, Actavis Pharma, Inc.,

Watson Pharmaceuticals, Inc., Watson Pharma, Inc., and Watson Laboratories, Inc. are referred to as "Actavis.").

30.

Actavis manufactures, promotes, sells, and distributes opioids, including the branded drugs Kadian and Norco, a generic version of Kadian, and generic versions of Duragesic and Opana, in Louisiana and the United States. Actavis acquired the rights to Kadian from King Pharmaceuticals, Inc. on December 30, 2008, and began marketing Kadian in 2009.

III. JURISDICTION AND VENUE

31.

This is an action by the Louisiana Department of Health, through the Secretary of the Louisiana Department of Health. The Louisiana Department of Health, through the Secretary of the Louisiana Department of Health, brings this action based on the distinct harm suffered by the Louisiana Department of Health caused by Defendants' violations of state law and legal duties owed.

32.

This Court has personal jurisdiction over Defendants as they conduct business in Louisiana, purposefully direct or directed their actions toward Louisiana, and/or have the requisite minimum contacts with Louisiana necessary to constitutionally permit the Court to exercise jurisdiction. Furthermore, the Louisiana Department of Health alleges that the Defendants' unlawful conduct occurred, at least in part, in East Baton Rouge Parish in the State of Louisiana. As such, this Court has personal jurisdiction against Defendants and venue is proper in this Parish pursuant to LSA-R.S. 13:3201.

IV. FACTUAL ALLEGATIONS

33.

Before the 1990's, generally accepted standards of medical practice dictated that opioid analgesic pain relievers should *only be used short-term for acute pain*, pain relating to recovery from surgery, or for cancer or palliative ("hospice" or "end-of-life") care. Due to the lack of evidence that opioid analgesic pain relievers improved patients' ability to overcome pain and function, coupled with evidence of greater pain complaints as patients developed tolerance to opioid analgesic pain relievers over time and the serious risk of addiction and other side effects,

the use of opioid analgesic pain relievers for chronic pain was discouraged or prohibited. As a result, doctors generally *did not* prescribe opioids for chronic pain.

34.

To take advantage of the lucrative market for chronic pain patients and state reimbursements for prescription drugs, Defendants developed a well-funded marketing scheme employing deceptive representations and practices. Defendants used both direct marketing and unbranded advertising disseminated by *seemingly independent third parties* to spread false and deceptive statements about the risks and benefits of long-term opioid use – statements that benefited not only themselves and the third-parties who gained legitimacy when Defendants repeated those statements, but also other Defendants and opioid manufacturers. However, these statements were not only unsupported by or contrary to the scientific evidence, these statements were also contrary to pronouncements by and guidance from the United States Food and Drug Administration and the Centers for Disease Control and Prevention. In addition, Defendants targeted susceptible prescribers and vulnerable patient populations.

35.

Defendants spread their false and deceptive statements by marketing their branded opioid analgesic pain relievers directly to doctors and patients in Louisiana. Defendants also deployed seemingly unbiased and independent third parties that they controlled to spread their false and deceptive statements about the risks and benefits of opioid analgesic pain relievers for the treatment of chronic pain throughout Louisiana.

36.

Defendants' direct marketing of opioid analgesic pain relievers generally proceeded on two tracks. First, each Defendant conducted and continues to conduct advertising campaigns touting the purported benefits of their branded drugs. For example, Defendants spent more than **$14 million** on **medical journal advertising** of opioids in 2011 alone, nearly triple what they spent in 2001. This amount included **$8.3 million** by **Purdue**, **$4.9 million** by **Janssen**, and **$1.1 million** by **Endo**.

37.

A number of Defendants' branded advertisements deceptively portrayed the benefits of opioids for chronic pain. For example, Endo distributed and made available on its website opana.com a pamphlet promoting Opana ER with photographs depicting patients with physically

demanding jobs like construction worker and chef, misleadingly implying that the drug would provide long-term pain-relief and functional improvement. In 2012, Purdue ran a series of advertisements in medical journals for OxyContin called "Pain vignettes." These advertisements featured chronic pain patients and recommended OxyContin for each patient. One advertisement described a "54-year-old writer with osteoarthritis of the hands" and implied that OxyContin would help the writer work more effectively. In late 2015 and 2016, Endo and Purdue agreed to halt these misleading representations in the State of New York.

38.

Second, each Defendant promoted the use of opioids for chronic pain through "detailers" (sales representatives who visited individual doctors and medical staff in their offices) and small-group speaker programs. Defendants have not corrected this misinformation. Instead, each Defendant devoted and continues to devote massive resources to direct sales contacts with doctors. In **2014** alone, Defendants spent **$168 million** on **detailing branded opioids to doctors**. This amount is twice as much as Defendants spent on detailing in 2000. The amount includes **$108 million** spent by **Purdue**, **$34 million** by **Janssen**, **$13 million** by **Cephalon**, **$10 million** by **Endo**, and **$2 million** by **Actavis**.

39.

Defendants' detailers have been reprimanded for their deceptive promotions. A July 2010 "Dear Doctor" letter mandated by the FDA required Actavis to acknowledge to the doctors to whom it marketed its drugs that "[b]etween June 2009 and February 2010, Actavis sales representatives distributed . . . promotional materials that . . . omitted and minimized serious risks associated with [Kadian]," including the risk of "[m]isuse, [a]buse, and [d]iversion of [o]pioids" and, specifically, the risk that "[o]pioid[s] have the potential for being abused and are sought by drug abusers and people with addiction disorders and are subject to criminal diversion."

40.

Defendants also identified doctors to serve, *for payment*, on their speakers' bureaus and to attend programs with speakers and meals paid for by Defendants. These speaker programs provided: (1) an incentive for doctors to prescribe a particular opioid analgesic pain reliever (so they might be selected to promote the drug); (2) recognition and compensation for the doctors selected as speakers; and (3) an opportunity to promote the drug through the speaker to his or her

peers. These speakers give the false impression that they are providing unbiased and medically accurate presentations when they are, in fact, **presenting a script prepared by Defendants**. Upon information and belief, these presentations conveyed misleading information, omitted material information, and failed to correct Defendants' prior misrepresentations about the risks and benefits of opioid analgesic pain relievers.

41.

Defendants also employed a strategy commonly referred to as "detailing," which is a one-on-one marketing technique used to "educate" a physician about a vendor's products in hopes that the physician will prescribe the company's products more often. Defendants' detailing to doctors was and is effective. Numerous studies indicate that marketing impacts prescribing habits, with face-to-face detailing having the greatest influence. Even without such studies, Defendants purchase, manipulate, and analyze some of the most sophisticated data available in *any* industry, data available from IMS Health Holdings, Inc., to track the rates of initial prescribing and renewal by individual doctor, which in turn allows them to target, tailor, and monitor the impact of their core messages. Thus, Defendants *know* their detailing to doctors is effective.

42.

Upon information and belief, Defendants employed the same marketing plans and strategies and deployed the same messages in Louisiana as they did nationwide. Across the pharmaceutical industry, "core message" development is funded and overseen on a national basis by corporate headquarters. This comprehensive approach ensures that Defendants' messages are accurately and consistently delivered across marketing channels (including detailing visits, speaker events, and advertising) and in each sales territory. Defendants consider this high level of coordination and uniformity crucial to successfully marketing their drugs.

43.

Defendants ensure marketing consistency nationwide through national and regional sales representative training; national training of local medical liaisons, the company employees who respond to physician inquiries; centralized speaker training; single sets of visual aids, speaker slide decks, and sales training materials; and nationally coordinated advertising. Defendants' sales representatives and physician speakers were required to emphasize to prescribed talking points, sales messages, and slide decks, and supervisors rode along with them periodically to both check on their performance and compliance.

44.

Defendants also deceptively marketed opioids in Louisiana through unbranded advertising (*i.e.* advertising that promotes opioid use generally but does not name a specific opioid). This advertising was ostensibly created and disseminated by independent third parties. Defendants controlled the deceptive messages disseminated by these third parties and acted in concert with them to falsely and misleadingly promote opioids for the treatment of chronic pain by funding, directing, reviewing, editing, and distributing this unbranded advertising. Much as Defendants controlled the distribution of their "core messages" via their own detailers and speaker programs, Defendants similarly controlled the distribution of these messages in scientific publications, treatment guidelines, CMEs, and medical conferences and seminars. To this end, Defendants used third-party public relations firms to help control those messages when they originated from third-parties.

45.

Defendants also marketed through third-party, unbranded advertising to avoid regulatory scrutiny because that advertising is not submitted to and typically is not reviewed by the FDA. Defendants also used third-party, unbranded advertising to give the false appearance that the deceptive messages came from an independent and objective source. Defendants used third parties that they funded, directed, and controlled to carry out and conceal their scheme to deceive doctors and patients about the risks and benefits of long-term opioid use for chronic pain. Defendants' deceptive unbranded marketing often contradicted what they said in their branded materials reviewed by the FDA.

46.

Defendants also utilized a small circle of doctors who, upon information and belief, were selected, funded, and elevated by Defendants because their public positions supported the use of opioids to treat chronic pain. These doctors became known as "key opinion leaders" or "KOLs."

47.

Defendants paid KOLs to serve as consultants or on their advisory boards and to give talks or present CMEs, and their support helped these KOLs become respected industry experts. As they rose to prominence, these KOLs touted the benefits of opioids to treat chronic pain, repaying Defendants by advancing their marketing goals. KOLs' professional reputations

became dependent on continuing to promote a pro-opioid message, even in activities that were not directly funded by Defendants.

48.

KOLs have written, consulted on, edited, and lent their names to books and articles, and given speeches and CMEs supportive of chronic opioid therapy. Defendants created opportunities for KOLs to participate in research studies Defendants suggested or chose and then cited and promoted favorable studies or articles by their KOLs. By contrast, Defendants did not support, acknowledge, or disseminate publications of doctors unsupportive or critical of chronic opioid therapy.

49.

Defendants' KOLs also served on committees that developed treatment guidelines that strongly encourage the use of opioids to treat chronic pain, and on the boards of pro-opioid advocacy groups and professional societies that develop, select, and present CMEs. Defendants were able to direct and exert control over each of these activities through their KOLs. The 2016 CDC Guideline recognizes that treatment guidelines can "change prescribing practices.

50.

Pro-opioid doctors are one of the most important avenues that Defendants use to spread their false and deceptive statements about the risks and benefits of long-term opioid use. Defendants know that doctors rely heavily and less critically on their peers for guidance, and KOLs provide the false appearance of unbiased and reliable support for chronic opioid therapy. For example, the State of New York found in its settlement with Purdue that the Purdue website *In the Face of Pain* failed to disclose that doctors who provided testimonials on the site were **paid by Purdue** and concluded that Purdue's failure to disclose these financial connections potentially misled consumers regarding the objectivity of the testimonials.

51.

Thus, even though some of Defendants' KOLs have recently moderated or conceded the lack of evidence for many of the claims they made, those admissions did not reverse the effect of the false and deceptive statements that continue to appear nationwide and throughout the Louisiana in Defendants' own marketing as well as treatment guidelines, CMEs and other seminars, scientific articles and research, and other publications available in paper or online.

52.

Defendants utilized many KOLs, including many of the same ones. Two of the most prominent are described below.

53.

For example, Defendants used Dr. Russell Portenoy, former Chairman of the Department of Pain Medicine and Palliative Care at Beth Israel Medical Center in New York, to further their marketing campaign. Dr. Portenoy received research support, consulting fees, and honoraria from Cephalon, Endo, Janssen, and Purdue (among others), and was a paid consultant to Cephalon and Purdue.

54.

In exchange, Dr. Portenoy successfully promoted the widespread use of opioid analgesic pain relievers throughout the United States. Dr. Portenoy served on the American Pain Society ("APS") / American Academy of Pain Medicine ("AAPM") Guidelines Committees, which endorsed the use of opioid analgesic pain relievers to treat chronic pain in 1997 and 2009. Dr. Portenoy was also a member of the board of the American Pain Foundation ("APF"), an advocacy organization (a/k/a "Front Group") almost entirely funded by Defendants.

55.

Dr. Portenoy also made frequent media appearances promoting opioid analgesic pain relievers and spreading misrepresentations. For example, Dr. Portenoy appeared on *Good Morning America* in 2010 to discuss the use of opioids long-term to treat chronic pain. On this widely-viewed television program, broadcast in Louisiana and across the country, Dr. Portenoy claimed: "**Addiction**, when treating pain, is **distinctly uncommon**. If a person does not have a history, a personal history, of substance abuse, and does not have a history in the family of substance abuse, and does not have a very major psychiatric disorder, **most doctors can feel very assured that that person is not going to become addicted**."[19]

56.

Dr. Portenoy later conceded that he "gave innumerable lectures in the late 1980s and '90s about addiction that weren't true." In those lectures, Dr. Portenoy falsely claimed that **fewer than 1% of patients would become addicted to opioids**. According to Dr. Portenoy, he and other doctors promoting opioids overstated their benefits and glossed over their risks because the

[19] Good Morning America television broadcast, ABC News (Aug. 30, 2010) (emphasis added).

primary goal was to "destigmatize" opioids. Dr. Portenoy also conceded that "[d]ata about the effectiveness of opioids does not exist."[20] Portenoy candidly explained: "Did I teach about pain management, specifically about opioid therapy, in a way that reflects misinformation? Well, . . . I guess I did."[21] Defendants purchased this scientific backing in order to further market their highly-additive product for widespread use all while knowing that the propaganda was contrary to the known side effects.

57.

As another example of a KOL, Defendants used Dr. Lynn Webster, the co-founder and Chief Medical Director of Lifetree Clinical Research in Salt Lake City, Utah, to further their marketing campaign. In 2013, Dr. Webster was President and is a current board member of AAPM, a front group that ardently supports chronic opioid therapy. Dr. Webster is a Senior Editor of *Pain Medicine*, the same journal that published Endo special advertising supplements touting Opana ER. Dr. Webster was the author of numerous CMEs sponsored by Cephalon, Endo, and Purdue. At the same time, Dr. Webster was receiving significant funding from Defendants (including nearly $2 million from Cephalon).

58.

During a portion of his time as a KOL, Dr. Webster was under investigation for overprescribing by the United States Department of Justice's Drug Enforcement Agency, which raided his clinic in 2010.[22] Although the investigation ended without any criminal charges being filed in 2014, **more than 20** of Dr. Webster's former patients at the Lifetree Clinic **died of opioid overdoses**.[23]

59.

Ironically, Dr. Webster created and promoted the Opioid Risk Tool, a five question, one-minute screening tool relying on patient self-reports that purportedly allows doctors to manage the risk that their patients will become addicted to or abuse opioids. The claimed ability to pre-sort patients likely to become addicted is an important tool in giving doctors confidence to prescribe opioids long-term, and for this reason, references to screening appear in various

[20] Thomas Catan & Evan Perez, *A Pain-Drug Champion Has Second Thoughts*, WALL ST. J., Dec. 17, 2012.

[21] *Id.*

[22] http://www.medpagetoday.com/Neurology/PainManagement/37441.

[23] *See Id.*

industry-supported guidelines. Versions of Dr. Webster's Opioid Risk Tool appear on, or are linked to, websites run by Endo, Janssen, and Purdue.

60.

In 2011, Dr. Webster presented, via webinar, a program sponsored by Purdue titled, *Managing Patient's Opioid Use: Balancing the Need and the Risk.* Dr. Webster recommended use of risk screening tools, urine testing, and patient agreements as a way to prevent "overuse of prescriptions" and "overdose deaths." This webinar was available to and was intended to reach Louisiana doctors.

61.

Dr. Webster also was a leading proponent of the concept of **"pseudo-addiction,"** the notion that addictive behaviors should be seen not as warnings, but as **indications of undertreated pain**. In Dr. Webster's description, the only way to differentiate the two was to ***increase* a patient's dose of opioids**. As he and his co-author wrote in a book entitled *Avoiding Opioid Abuse While Managing Pain* (2007), a book that is still available online, when faced with signs of aberrant behavior, increasing the dose "in most cases . . . should be the clinician's first response." Notably, Endo distributed this book to doctors. Years later, Dr. Webster reversed himself, acknowledging that "[pseudo-addiction] obviously became too much of an excuse to give patients more medication."[24]

62.

Defendants also entered into arrangements with seemingly unbiased and independent patient and professional organizations to promote opioids for the treatment of chronic pain. Under the direction and control of Defendants, these "Front Groups" generated treatment guidelines, unbranded materials, and programs that favored chronic opioid therapy. They also assisted Defendants by responding to negative articles, by advocating against regulatory changes that would limit opioid prescribing in accordance with the scientific evidence, and by conducting outreach to vulnerable patient populations targeted by Defendants.

63.

Defendants funded these Front Groups and exercised control over programs and materials created by these groups by collaborating on, editing, and approving their content, and by funding their dissemination. In doing so, Defendants made sure that the Groups would generate only the

[24] John Fauber & Ellen Gabler, *Networking Fuels Painkiller Boom*, MILWAUKEE WISC. J. SENTINEL (Feb. 19, 2012).

messages Defendants wanted to distribute. Despite this, the Front Groups held themselves out as independent.

64.

Defendants Cephalon, Endo, Janssen, and Purdue utilized many Front Groups including the American Pain Society ("APS"), American Geriatrics Society ("AGS"), the Federation of State Medical Boards ("FSMB"), American Chronic Pain Association ("ACPA"), American Society of Pain Education ("ASPE"), National Pain Foundation ("NPF") and Pain & Policy Studies Group ("PPSG").

65.

Defendants utilized the American Pain Foundation ("APF") as a Front Group while opioid manufacturers paid the APF more than **$10 million** from 2007 until May 2012 when it ceased operations. Notably, Endo provided more than half that funding, and Purdue provided approximately $1.7 million to the APF.

66.

APF published articles for doctors, patients, reporters, and policymakers that touted the benefits of opioids for chronic pain and trivialized their risks, particularly the risk of addiction,[25] that opioid dependence could be easily addressed by tapering and that opioid withdrawal is not difficult,[26] doctors could increase opioid dosages indefinitely without added risk,[27] long-term opioid use improved patients' function and quality of life,[28] and Purdue's OxyContin provided 12 hours of continuous pain relief.[29] APF also launched a campaign to promote opioids for returning veterans, which has contributed to high rates of addiction and other adverse outcomes – including death – among returning soldiers. APF also engaged in a significant multimedia campaign – through radio, television and the internet – to educate patients about their "right" to

[25] American Pain Foundation's *Treatment Options: A Guide for People Living in Pain* (2007) (sponsored by **Cephalon** and Purdue) (still available online); American Pain Foundation's *A Policymaker's Guide to Understanding Pain and Its Management* (sponsored by Purdue) (still available online).

[26] American Pain Foundation's *A Policymaker's Guide to Understanding Pain and Its Management* (sponsored by **Purdue**) (still available online).

[27] American Pain Foundation's *Treatment Options: A Guide for People Living in Pain* (2007) (sponsored by Cephalon and Purdue) (still available online); American Pain Foundation's *A Policymaker's Guide to Understanding Pain and Its Management* (sponsored by Purdue) (still available online). American Pain Foundation's *A Policymaker's Guide to Understanding Pain and Its Management* (sponsored by **Purdue**) (still available online).

[28] *Responsible Opioid Prescribing* (sponsored by Endo, Cephalon and Purdue) (remains for sale online); American Pain Foundation's *Treatment Options: A Guide for People Living in Pain* (2007) (sponsored by **Cephalon and Purdue**) (still available online); CME entitled *Persistent Pain in the Older Patient* (sponsored by **Endo**).

[29] American Pain Foundation.

pain treatment, namely opioids. All of the programs and materials were available nationally and were intended to reach Louisiana residents.

67.

In addition to Perry Fine (a KOL from the University of Utah who received funding from Janssen, Cephalon, Endo, and Purdue) Russell Portenoy, and Scott Fishman (a KOL from the University of California, Davis who authored *Responsible Opioid Prescribing*, a publication sponsored by Cephalon and Purdue), all of whom served on APF's Board and reviewed its publications, another board member, Lisa Weiss, was an employee of a public relations firm that worked for both Purdue and APF.

68.

In 2009 and 2010, more than 80% of APF's operating budget came from pharmaceutical industry sources. In 2009, the APF received approximately $2.3 million from industry sources out of total income of about $2.85 million. In 2010, the APF projected receipts of roughly $2.9 million from drug companies, out of total income of about $3.5 million. By 2011, the APF was entirely dependent on incoming grants from Defendants Purdue, Cephalon, Endo, and others to avoid using its line of credit. As one of its board members, Russell Portenoy, explained, the lack of funding diversity was one of the biggest problems at the APF.

69.

Contrary to reality, the APF held itself out as an independent patient advocacy organization. The APF often engaged in grassroots lobbying against various legislative initiatives that might limit opioid prescribing, and thus the profitability of its sponsors. The APF was often called upon to provide "patient representatives" for Defendants' promotional activities, including for Purdue's *Partners Against Pain* and Janssen's *Let's Talk Pain*. In reality, the APF functioned largely as an advocate for the interests of Defendants, not patients. Indeed, as early as 2001, Purdue told the APF that the basis of a grant was Purdue's desire to "strategically align its investments in nonprofit organizations that share [its] business interests." In other words, the Defendants paid the APF to promote, market, and "legitimize" the widespread use of opioids both in the medical community and throughout the nation.

70.

In practice, the APF operated in close collaboration with opioid makers. On several occasions, representatives of the drug companies, often at informal meetings at Front Group

conferences, suggested activities and publications for the APF to pursue. The APF then submitted grant proposals seeking to fund these activities and publications, knowing that drug companies would support projects conceived as a result of these communications.

71.

The APF assisted in other marketing projects for drug companies. One project funded by another drug company, *APF Reporter's Guide: Covering Pain and Its Management* (2009), republished text that was originally created as part of the company's own training document.

72.

The same drug company made general grants, but even then it directed how the APF used them. In response to an APF request for funding to address a potentially damaging state Medicaid decision related to pain medications generally, the company representative responded, "I provided an advocacy grant to APF this year – this would be a very good issue on which to use some of that. How does that work?"

73.

The close relationship between the APF and the drug company was not unique, but mirrors relationships among the APF and Defendants.

74.

In May 2012, the United States Senate Finance Committee began an inquiry in order to determine the links, financial and otherwise, between the APF and the manufacturers of opioid painkillers. The investigation caused considerable damage to the APF's credibility as an "objective and neutral third party," and Defendants stopped funding it. Within days of being targeted by the Senate investigation, the APF's board voted to dissolve the organization "[d]ue to irreparable economic circumstances." The APF "cease[d] to exist, effective immediately."

75.

The American Academy of Pain Medicine ("AAPM") issued treatment guidelines and hosted various medical education programs essential to Defendants' deceptive marketing of chronic opioid therapy with the assistance, prompting, involvement, and funding of Defendants.

76.

For these efforts, opioid manufacturers paid AAPM more than $2.2 million since 2009. The AAPM maintained a corporate relations council, whose members paid $25,000 per year (on top of other funding) to participate. The benefits included allowing members to present

educational programs at off-site dinner symposia in connection with the AAPM's annual meeting held in Palm Springs, California, or other resort locations. The AAPM describes the annual event as an "exclusive venue" for offering education programs to doctors. Membership in the corporate relations council also allows drug company executives and marketing staff to meet with AAPM executive committee members in small settings. Defendants Endo, Purdue, Cephalon and Actavis were members of the council and presented deceptive programs to doctors who attended this annual event.

77.

Endo considers the AAPM as "industry friendly," with Endo advisors and speakers among its active members. Endo attended AAPM conferences, funded its CMEs, and distributed its publications. The conferences sponsored by the AAPM heavily emphasized sessions on opioids. AAPM's presidents have included top industry-supported KOLs Perry Fine, Russell Portenoy, and Lynn Webster. Notably, the AAPM named Dr. Webster President of the AAPM while he was under investigation by the DEA. Another past AAPM President, Dr. Scott Fishman, stated that he would place the organization "at the forefront" of teaching that "the risks of addiction are . . . small and can be managed."[30]

78.

Defendants were able to influence the AAPM through both their significant and regular funding and the leadership of pro-opioid KOLs within the organization.

79.

In addition, treatment guidelines have been particularly important in securing acceptance for chronic opioid therapy. Doctors rely upon these treatment guidelines, especially the general practitioners and family doctors targeted by Defendants, who are neither experts nor trained in the treatment of chronic pain. Treatment guidelines not only directly inform doctors' prescribing practices, but are cited throughout the scientific literature and referenced by third-party payors in determining whether they should cover treatments for specific indications. Pharmaceutical sales representatives employed by Endo, Actavis, and Purdue discussed treatment guidelines with doctors during individual sales visits.

[30] Interview by Paula Moyer with Scott M. Fishman, M.D., Professor of Anesthesiology and Pain Medicine, Chief of the Division of Pain Medicine, Univ. of Cal., Davis (2005), http://www.medscape.org/viewarticle/500829.

80.

In 1997, the AAPM and the American Pain Society jointly issued a consensus statement, *The Use of Opioids for the Treatment of Chronic Pain*, which endorsed opioids to treat chronic pain and claimed that the risk that patients would become addicted to opioids was low. The co-author of the statement, Dr. Haddox, was at the time a paid speaker for Purdue and Dr. Portenoy was the sole consultant. The consensus statement remained on AAPM's website until 2011 and remains accessible on the internet.

81.

The AAPM and APS issued their own guidelines in 2009 ("AAPM/APS Guidelines") and continued to recommend the use of opioids to treat chronic pain. Fourteen of the 21 panel members who drafted the AAPM/APS Guidelines, including KOLs Dr. Portenoy and Dr. Perry Fine of the University of Utah, received financial support from Janssen, Cephalon, Endo, and Purdue.

82.

The 2009 Guidelines promote opioids as "safe and effective" for treating chronic pain, despite acknowledging limited evidence, and conclude that the risk of addiction is manageable for patients regardless of past abuse histories. One panel member, Dr. Joel Saper, Clinical Professor of Neurology at Michigan State University and founder of the Michigan Headache & Neurological Institute, resigned from the panel because of his concerns that the 2009 Guidelines were influenced by contributions that drug companies, including Defendants, made to the sponsoring organizations and committee members. These AAPM/APS Guidelines have been a particularly effective channel of deception and have influenced not only treating physicians but also the body of scientific evidence on opioids. Notably, the Guidelines have been cited **732 times in academic literature**, were disseminated in Louisiana during the relevant time period, are still available online, and were reprinted in the *Journal of Pain*.

83.

Defendants widely referenced and promoted the 2009 Guidelines without disclosing the acknowledged lack of evidence to support them.

84.

In another "Front Group" example, Defendants combined their efforts through the Pain Care Forum ("PCF"), which began in 2004 as an APF project. PCF is comprised of representatives from opioid manufacturers (including Cephalon, Endo, Janssen, and Purdue) and

various Front Groups, almost all of which received substantial funding from Defendants. Between 2006 and 2015, this Front Group spent approximately **$880,000,000** on lobbyists and in political campaign donations. In Louisiana, the number of registered lobbyists working for members of the Pain Care Forum **ranked 4th** in the United States in **2015**.

85.

To convince doctors and patients in Louisiana that opioids can and should be used to treat chronic pain, Defendants had to convince them that long-term opioid use is both safe and helpful. Knowing that they could do so only by deceiving those doctors and patients about the risks and benefits of long-term opioid use, Defendants made claims that were not supported by or were contrary to the scientific evidence. Even though pronouncements by and guidance from the FDA and the CDC based on that evidence confirm that their claims were false and deceptive, Defendants have not corrected them, or instructed their KOLs or Front Groups to correct them, and continue to spread them today.

86.

To convince doctors and patients that opioids are safe, Defendants deceptively minimized and failed to disclose the risks of long-term opioid use, particularly the risk of addiction, through a series of misrepresentations that have been conclusively contradicted by the FDA and CDC. These misrepresentations, described below, reinforced each other and created the dangerously misleading impression that: (1) starting patients on opioids was low-risk because most patients would not become addicted, and because those who were at greatest risk of addiction could be readily identified and managed; (2) patients who displayed signs of addiction probably were not addicted and, in any event, could easily be weaned from the drugs; (3) the use of higher opioid doses, which many patients need to sustain pain relief as they develop tolerance to the drugs, do not pose special risks; and (4) abuse-deterrent opioids both prevent abuse and overdose and are inherently less addictive. Defendants have not only failed to correct these misrepresentations, they continue to make them today.

87.

First, Defendants falsely claimed that the risk of addiction is low and that addiction is unlikely to develop when opioids are prescribed, as opposed to obtained illicitly; and failed to disclose the greater risk of addiction with prolonged use of opioids. Some illustrative examples of these false and deceptive claims are described below:

a. Actavis's predecessor caused a patient education brochure to be distributed in 2007 that claimed opioid addiction is possible, but "less likely if you have never had an addiction problem." Upon information and belief, based on Actavis's acquisition of its predecessor's marketing materials along with the rights to Kadian, Actavis continued to use this brochure in 2009 and beyond.

b. Cephalon and Purdue sponsored APF's *Treatment Options: A Guide for People Living with Pain* (2007), which instructed that addiction is rare and limited to extreme cases of unauthorized dose escalations, obtaining duplicative opioid prescriptions from multiple sources, or theft. This publication is still available online.

c. Endo sponsored a website, Painknowledge.com, which claimed in 2009 that "[p]eople who take opioids as prescribed usually do not become addicted." Another Endo website, PainAction.com, stated "Did you know? Most chronic pain patients do not become addicted to the opioid medications that are prescribed for them."

d. Endo distributed a pamphlet with the Endo logo entitled *Living with Someone with Chronic Pain*, which stated that: "Most health care providers who treat people with pain agree that most people do not develop an addiction problem." A similar statement appeared on the Endo website www.opana.com.

e. Janssen reviewed, edited, approved, and distributed a patient education guide entitled *Finding Relief: Pain Management for Older Adults* (2009), which described as "myth" the claim that opioids are addictive, and asserted as fact that "[m]any studies show that opioids are rarely addictive when used properly for the management of chronic pain."

f. Janssen currently runs a website, Prescriberesponsibly.com (last updated July 2, 2015), which claims that concerns about opioid addiction are "overestimated."

g. Purdue sponsored APF's *A Policymaker's Guide to Understanding Pain & Its* Management, which claims that less than 1% of children prescribed opioids will become addicted and that pain is undertreated due to "misconceptions about opioid addiction[]." This publication is still available online.

h. Detailers for Purdue, Endo, Janssen, and Cephalon minimized or omitted any discussion with doctors of the risk of addiction; misrepresented the potential for abuse of opioids with purportedly abuse-deterrent formulations; and routinely did not correct the misrepresentations noted above.

88.

These claims (misrepresentations) are contrary to longstanding scientific evidence. As noted in the 2016 CDC Guideline endorsed by the FDA, there is "extensive evidence" of the "possible harms of opioids (including opioid use disorder [an alternative term for opioid addiction])." The Guideline points out that "[o]pioid pain medication use presents serious risks, including . . . opioid use disorder" and that "continuing opioid therapy for 3 months substantially increases risk for opioid use disorder."

89.

The FDA further exposed the falsity of Defendants' claims about the low risk of addiction when it announced changes to the labels for ER/LA opioids in 2013 and for IR opioids in 2016. In its announcements, the FDA found that "most opioid drugs have 'high potential for abuse'" and that opioids "are associated with a substantial risk of misuse, abuse, NOWS [neonatal opioid withdrawal syndrome], addiction, overdose, and death." According to the FDA, because of the "known serious risks" associated with long-term opioid use, including "risks of addiction, abuse, and misuse, even at recommended doses, and because of the greater risks of overdose and death," opioids should be used only "in patients for whom alternative treatment options" like non-opioid drugs have failed. The FDA further acknowledged that the risk is not limited to patients who seek drugs illicitly; addiction "can occur in patients appropriately prescribed [opioids]."

90.

The warnings on Defendants' own FDA-approved drug labels caution that opioids "expose[] users to risks of addiction, abuse and misuse, which can lead to overdose and death," that the drugs contain "a substance with a high potential for abuse," and that addiction "can occur in patients appropriately prescribed" opioids.

91.

Second, Defendants falsely instructed doctors and patients that the **signs of addiction are actually signs of undertreated pain** and should be treated by **prescribing more opioids**. Defendants called this phenomenon **"pseudo-addiction"** – a term coined by Dr. David Haddox, who went to work for Purdue, and popularized by Dr. Russell Portenoy, a KOL for Cephalon, Endo, Janssen, and Purdue – and falsely claimed that pseudo-addiction is substantiated by scientific evidence. Some illustrative examples of these deceptive claims are described below:

a. Cephalon and Purdue sponsored *Responsible Opioid Prescribing* (2007), which taught that behaviors such as "requesting drugs by name," "demanding or manipulative behavior," seeing more than one doctor to obtain opioids, and hoarding, are all signs of pseudo-addiction, rather than true addiction. Responsible Opioid Prescribing remains for sale online. The 2012 edition, which also remains available online, continues to teach that pseudoaddiction is real.

b. Janssen sponsored, funded, and edited the *Let's Talk Pain* website, which in 2009 stated: "pseudo-addiction . . . refers to patient behaviors that may occur when pain is under-treated . . . . Pseudo-addiction is different from

true addiction because such behaviors can be resolved with effective pain management."

c. Endo sponsored a National Initiative on Pain Control ("NIPC") CME program in 2009 titled *Chronic Opioid Therapy: Understanding Risk While Maximizing Analgesia*, which promoted pseudo-addiction by teaching that a patient's aberrant behavior was the result of untreated pain. Endo substantially controlled NIPC by funding NIPC projects; developing, specifying, and reviewing content; and distributing NIPC materials.

d. Purdue published a pamphlet in 2011 entitled *Providing Relief, Preventing Abuse*, which described pseudo-addiction as a concept that "emerged in the literature" to describe the inaccurate interpretation of [drug-seeking behaviors] in patients who have pain that has not been effectively treated."

e. Purdue sponsored a CME program entitled *Path of the Patient, Managing Chronic Pain in Younger Adults at Risk for Abuse*. In a role play, a chronic pain patient with a history of drug abuse tells his doctor that he is taking twice as many hydrocodone pills as directed. The narrator notes that because of pseudoaddiction, the doctor should not assume the patient is addicted even if he persistently asks for a specific drug, seems desperate, hoards medicine, or "overindulges in unapproved escalating doses." The doctor treats this patient by **prescribing a high-dose, long-acting opioid**.

92.

Contrary to Defendants' false propaganda, the 2016 CDC Guideline rejects the concept of pseudo-addiction. The Guideline does not recommend that opioid dosages be increased if a patient is not experiencing pain relief. Instead, the Guideline explains that "[p]atients who do not experience clinically meaningful pain relief early in treatment . . . are unlikely to experience pain relief with longer-term use," and that physicians should "reassess[] pain and function within 1 month" in order to decide whether to "minimize risks of long-term opioid use by discontinuing opioids" because the patient is "not receiving a clear benefit."

93.

Third, Defendants falsely instructed doctors and patients that addiction risk screening tools, patient contracts, urine drug screens, and similar strategies allow them to reliably identify and safely prescribe opioids to patients predisposed to addiction. These misrepresentations were especially insidious because Defendants aimed them at general practitioners and family doctors who lack the time and expertise to closely manage higher-risk patients on opioids. Defendants' misrepresentations made these doctors feel more comfortable prescribing opioids to their patients, and patients more comfortable starting on opioid therapy for chronic pain. Some illustrative examples of these deceptive claims are described below:

a. Endo paid for a 2007 supplement in the *Journal of Family Practice* written by a doctor who became a member of Endo's speaker's bureau in 2010. The supplement, entitled *Pain Management Dilemmas in Primary Care:*

Use of Opioids, emphasized the effectiveness of screening tools, claiming that patients at high risk of addiction could safely receive chronic opioid therapy using a "maximally structured approach" involving toxicology screens and pill counts.

b. Purdue sponsored a 2011 webinar, *Managing Patient's Opioid Use: Balancing the Need and Risk*, which claimed that screening tools, urine tests, and patient agreements prevent "overuse of prescriptions" and "overdose deaths."

c. As recently as 2015, Purdue represented in scientific conferences that "bad apple" patients, not opioids, are the source of the addiction crisis and that once those "bad apples" are identified, doctors can safely prescribe opioids without causing addiction.

94.

Once again, the 2016 CDC Guideline confirms the falsity of these misrepresentations. The Guideline notes that there are no studies assessing the effectiveness of risk mitigation strategies – such as screening tools, patient contracts, urine drug testing, or pill counts widely believed by doctors to detect and deter abuse – "for improving outcomes related to overdose, addiction, abuse, or misuse." As a result, the Guideline recognizes that available risk screening tools "show insufficient accuracy for classification of patients as at low or high risk for [opioid] abuse or misuse" and counsels that doctors "should not overestimate the ability of these tools to rule out risks from long-term opioid therapy."

95.

Fourth, to downplay the risk and impact of addiction and make doctors feel more comfortable starting patients on opioids, Defendants falsely claimed that opioid dependence can easily be addressed by tapering and that opioid withdrawal is not a problem, and failed to disclose the increased difficulty of stopping opioids after long-term use.

96.

For example, a CME sponsored by Endo, entitled *Persistent Pain in the Older Adult*, claimed that withdrawal symptoms can be avoided by tapering a patient's opioid dose by 10%-20% for 10 days. And Purdue sponsored APF's *A Policymaker's Guide to Understanding Pain & Its Management*, which claimed that "[s]ymptoms of physical dependence can often be ameliorated by gradually decreasing the dose of medication during discontinuation" without mentioning any hardships that might occur.

97.

Defendants deceptively minimized the significant symptoms of opioid withdrawal – which, as explained in the 2016 CDC Guideline, include drug cravings, anxiety, insomnia, abdominal

pain, vomiting, diarrhea, sweating, tremor, tachycardia (rapid heartbeat), spontaneous abortion and premature labor in pregnant women, and the unmasking of anxiety, depression, and addiction – and grossly understated the difficulty of tapering, particularly after long-term opioid use. Yet the 2016 CDC Guideline recognizes that the duration of opioid use and the dosage of opioids prescribed should be "limit[ed]" to "minimize the need to taper opioids to prevent distressing or unpleasant withdrawal symptoms" because "physical dependence on opioids is an expected physiologic response in patients exposed to opioids for more than a few days." The Guideline further states that "tapering opioids can be especially challenging after years on high dosages because of physical and psychological dependence" and highlights the difficulties, including the need to carefully identify "a taper slow enough to minimize symptoms and signs of opioid withdrawal" and to "pause[] and restart[]" tapers depending on the patient's response. The CDC also acknowledges the lack of any "high-quality studies comparing the effectiveness of different tapering protocols for use when opioid dosage is reduced or opioids are discontinued."

98.

Fifth, Defendants falsely claimed that doctors and patients could increase opioid dosages indefinitely without added risk and failed to disclose the greater risks to patients at higher dosages. The ability to escalate dosages was critical to Defendants' efforts to market opioids for long-term use to treat chronic pain because, absent this misrepresentation, doctors would have abandoned treatment when patients built up tolerance and lower dosages did not provide pain relief. Some illustrative examples are described below:

a. Actavis's predecessor created a patient brochure for Kadian in 2007 that stated, "Over time, your body may become tolerant of your current dose. You may require a dose adjustment to get the right amount of pain relief. This is not addiction." Upon information and belief, based on Actavis's acquisition of its predecessor's marketing materials along with the rights to Kadian, Actavis continued to use these materials in 2009 and beyond.

b. Cephalon and Purdue sponsored *APF's Treatment Options: A Guide for People Living with Pain* (2007), which claims that some patients "need" a larger dose of an opioid, regardless of the dose currently prescribed. The guide stated that opioids have "no ceiling dose" and are therefore the most appropriate treatment for severe pain. This guide is still available for sale online.

c. Endo sponsored a website, painknowledge.com, which claimed in 2009 that opioid dosages may be increased until "you are on the right dose of medication for your pain."

d. Endo distributed a pamphlet edited by a KOL entitled *Understanding Your Pain: Taking Oral Opioid Analgesics*, which was available during the time period of this Complaint on Endo's website. In Q&A format, it asked "If I take the opioid now, will it work later when I

really need it?" The response is, "The dose can be increased. . . . You won't 'run out' of pain relief."

e. Janssen sponsored a patient education guide entitled *Finding Relief: Pain Management for Older Adults* (2009), which was distributed by its sales force. This guide listed dosage limitations as "disadvantages" of other pain medicines but omitted any discussion of risks of increased opioid dosages.

f. Purdue's In the Face of Pain website promotes the notion that if a patient's doctor does not prescribe what, in the patient's view, is a sufficient dosage of opioids, he or she should find another doctor who will.

h. Purdue sponsored APF's *A Policymaker's Guide to Understanding Pain & Its Management*, which taught that dosage escalations are "sometimes necessary," even unlimited ones, but did not disclose the risks from high opioid dosages. This publication is still available online.

i. Purdue sponsored a CME entitled *Overview of Management Options* that is still available for CME credit. The CME was edited by a KOL and taught that NSAIDs (nonsteroidal anti-inflammatory drugs) and other drugs, but not opioids, are unsafe at high dosages.

j. Purdue presented a 2015 paper at the College on the Problems of Drug Dependence, the "the oldest and largest organization in the US dedicated to advancing a scientific approach to substance use and addictive disorders,"[31] challenging the correlation between opioid dosage and overdose.

99.

As confirmed by the FDA and CDC, these claims conflict with available scientific evidence. As the CDC explains in its 2016 Guideline, the "[b]enefits of high-dose opioids for chronic pain are not established" while the "risks for serious harms related to opioid therapy increase at higher opioid dosage." More specifically, the CDC explains that "there is now an established body of scientific evidence showing that overdose risk is increased at higher opioid dosages." The CDC adds that "there is an increased risk for opioid use disorder, respiratory depression, and death at higher dosages." Accordingly, the CDC advises doctors to "avoid increasing dosages" above 90 morphine milligram equivalents per day.

100.

The 2016 CDC Guideline reinforces earlier findings announced by the FDA. In 2013, the FDA acknowledged "that the available data do suggest a relationship between increasing opioid dose and risk of certain adverse events." For example, the FDA noted that studies "appear to credibly suggest a positive association between high-dose opioid use and the risk of overdose and/or overdose mortality."

[31] www.cpdd.org.

101.

Finally, Defendants' deceptive marketing of the so-called abuse-deterrent properties of some of their opioids has created false impressions that these opioids can curb addiction and abuse. Indeed, in a 2014 survey of 1,000 primary care physicians, nearly half reported that they believed abuse-deterrent formulations are inherently less addictive.[32]

102.

More specifically, Defendants made misleading claims about the ability of their "abuse-deterrent opioid formulations" to deter abuse. For example, Endo's advertisements for the 2012 reformulation of Opana ER falsely claimed that it was designed to be crush resistant, in a way that suggested it was more difficult to abuse. To the contrary, the FDA warned in a 2013 letter that there was no evidence Endo's design "would provide a reduction in oral, intranasal or intravenous abuse." Moreover, Endo's own concealed studies showed that Opana ER could still be ground and chewed. The 2016 CDC Guideline states that "[n]o studies" support the notion that "abuse-deterrent technologies [are] a risk mitigation strategy for deterring or preventing abuse," noting that the technologies – even when they work – "do not prevent opioid abuse through oral intake, the most common route of opioid abuse, and can still be abused by nonoral routes."

103.

These numerous, longstanding misrepresentations of the risks of long-term opioid use spread by Defendants successfully convinced doctors and patients to discount those risks.

Defendants Grossly Overstated the Benefits of Chronic Opioid Therapy

104.

To convince doctors and patients that opioids should be used to treat chronic pain, Defendants also had to persuade them that there was a significant upside to long-term opioid use. But as the 2016 CDC Guideline makes clear, there is "insufficient evidence to determine the long-term benefits of opioid therapy for chronic pain." In fact, the CDC found that "[n]o evidence shows a long-term benefit of opioids in pain and function versus no opioids for chronic pain with outcomes examined at least 1 year later (with most placebo-controlled randomized trials $\leq$ 6 weeks in duration)" and that other treatments were more or equally beneficial and less harmful than long-term opioid use. The FDA also recognized the lack of evidence to support

[32] Catherine S. Hwang, *et al.*, *Prescription Drug Abuse: A National Survey of Primary Care Physicians*, 175(2) JAMA INTERN. MED. 302-4 (Dec. 8, 2014).

long-term opioid use. In 2013, the FDA stated that it was "not aware of adequate and well-controlled studies of opioids use longer than 12 weeks." Despite this, Defendants falsely and misleadingly touted the benefits of long-term opioid use and falsely and misleadingly suggested that these benefits were supported by scientific evidence. Not only have Defendants failed to correct these false and deceptive claims, they continue to make them today.

105.

For example, Defendants falsely claimed that long-term opioid use improved patients' function and quality of life. Some illustrative examples are described below:

a. Actavis distributed an advertisement that claimed that the use of Kadian to treat chronic pain would allow patients to return to work, relieve "stress on your body and your mental health," and help patients enjoy their lives.

b. Endo distributed advertisements that claimed that the use of Opana ER for chronic pain would allow patients to perform demanding tasks like construction work or work as a chef and portrayed seemingly healthy, unimpaired subjects.

c. Janssen sponsored and edited a patient education guide entitled *Finding Relief: Pain Management for Older Adults* (2009) – which states as "a fact" that "opioids may make it easier for people to live normally." The guide lists expected functional improvements from opioid use, including sleeping through the night, returning to work, recreation, sex, walking, and climbing stairs.

d. Purdue ran a series of advertisements for OxyContin in 2012 in medical journals entitled "Pain vignettes," which were case studies featuring patients with pain conditions persisting over several months and recommending OxyContin for them. The advertisements implied that OxyContin improves patients' function.

e. *Responsible Opioid Prescribing* (2007), sponsored and distributed by Cephalon, Endo and Purdue, taught that relief of pain by opioids, by itself, improved patients' function. The book remains for sale online.

f. Cephalon and Purdue sponsored APF's *Treatment Options: A Guide for People Living with Pain* (2007), which counseled patients that opioids "give [pain patients] a quality of life we deserve." The guide was available online until APF ceased operations in 2012.

g. Endo's NIPC website painknowledge.com claimed in 2009 that with opioids, "your level of function should improve; you may find you are now able to participate in activities of daily living, such as work and hobbies, that you were not able to enjoy when your pain was worse." Elsewhere, the website touted improved quality of life (as well as "improved function") as benefits of opioid therapy. The grant request that Endo approved for this project specifically indicated NIPC's intent to make misleading claims about function, and Endo closely tracked visits to the site.

h. Endo was the sole sponsor, through NIPC, of a series of CMEs titled *Persistent Pain in the Older Patient*, which claimed that chronic opioid therapy has been "shown to reduce pain and improve depressive symptoms and cognitive functioning." The CME was disseminated via webcast.

i. Janssen sponsored, funded, and edited a website, *Let's Talk Pain*, in 2009, which featured an interview edited by Janssen claiming that opioids allowed a patient to "continue to function." This video is still available today on YouTube.

j. Purdue sponsored the development and distribution of APF's *A Policymaker's Guide to Understanding Pain & Its Management*, which claimed that "multiple clinical studies" have shown that opioids are effective in improving daily function, psychological health, and health-related quality of life for chronic pain patients." The Policymaker's Guide was originally published in 2011 and is still available online today.

k. Purdue's, Cephalon's, Endo's, and Janssen's sales representatives have conveyed and continue to convey the message that opioids will improve patient function.

106.

These claims are unsupported in scientific literature. Most recently, the 2016 CDC Guideline approved by the FDA concluded that "there is no good evidence that opioids improve pain or function with long-term use, and . . . complete relief of pain is unlikely." (Emphasis added). The CDC reinforced this conclusion throughout its 2016 Guideline:

a. "No 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 . . . ."

b. "Although opioids can reduce pain during short-term use, the clinical evidence review found insufficient evidence to determine whether pain relief is sustained and whether function or quality of life improves with long-term opioid therapy."

c. "[E]vidence is limited or insufficient for improved pain or function with long-term use of opioids for several chronic pain conditions for which opioids are commonly prescribed, such as low back pain, headache, and fibromyalgia."

107.

The CDC also noted that the risks of addiction and death "can cause distress and inability to fulfill major role obligations."

108.

The 2016 CDC Guideline was not the first time a federal agency repudiated Defendants' claim that opioids improved function and quality of life. In 2010, the FDA warned Actavis, in response to its advertising described in Paragraph 39, that "[w]e are not aware of substantial evidence or substantial clinical experience demonstrating that the magnitude of the effect of the drug [Kadian] has in alleviating pain, taken together with any drug-related side effects patients may experience . . . results in any overall positive impact on a patient's work, physical and

mental functioning, daily activities, or enjoyment of life."[33] And in 2008, the FDA sent a warning letter to an opioid manufacturer, making it clear "that [the claim that] patients who are treated with the drug experience an improvement in their overall function, social function, and ability to perform daily activities . . . has not been demonstrated by substantial evidence or substantial clinical experience."

109.

Defendants also falsely and misleadingly emphasized or exaggerated the risks of competing products like NSAIDs (nonsteroidal anti-inflammatory drugs), so that doctors and patients would, instead, use opioids for the treatment of chronic pain. Once again, these misrepresentations by Defendants contravene pronouncements by and guidance from the FDA and CDC based on the scientific evidence. Indeed, the FDA changed the labels for ER/LA opioids in 2013 and IR opioids in 2016 to state that opioids should only be used as a last resort "in patients for which alternative treatment options" like non-opioid drugs "are inadequate." And the 2016 CDC Guideline states that NSAIDs, not opioids, should be the first-line treatment for chronic pain, particularly arthritis and lower back pain.

110.

In addition, Purdue misleadingly promoted OxyContin as being unique among opioids in providing 12 continuous hours of pain relief with one dose. In fact, OxyContin does not last for 12 hours, a fact that Purdue has known at all times relevant to this action. According to Purdue's own research, OxyContin wears off in under six hours in one quarter of patients and in under 10 hours in more than half. This is because OxyContin tablets release approximately 40% of their active medicine immediately, after which release tapers. This triggers a powerful initial response, but provides little or no pain relief at the end of the dosing period, when less medicine is released. This phenomenon is known as "end of dose" failure, and the FDA found in 2008 that a "substantial number" of chronic pain patients taking OxyContin experience it. This not only renders Purdue's promise of 12 hours of relief false and deceptive, it also makes OxyContin more dangerous because the declining pain relief patients experience toward the end of each dosing period drives them to take more OxyContin before the next dosing period begins, quickly increasing the amount of drug they are taking and spurring growing dependence.

[33] Warning Letter from Thomas Abrams, Dir., FDA Div. of Mktg., Adver., & Comme'ns, to Doug Boothe, CEO, Actavis Elizabeth LLC (Feb. 18, 2010), available at http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/EnforcementActivitiesbyFDA/WarningLettersandNoticeofViolationLetterstoPharmaceuticalCcompanies/ucm259240.htm.

111.

Cephalon deceptively marketed its opioids Actiq and Fentora for chronic pain even though the FDA expressly limited their use to the treatment of cancer pain in opioid-tolerant individuals. Both Actiq and Fentora are extremely powerful fentanyl-based IR opioids. Neither drug is approved for or has been shown to be safe or effective for chronic pain. Indeed, the FDA expressly prohibited Cephalon from marketing Actiq for anything but cancer pain, and refused to approve Fentora for the treatment of chronic pain because of the potential harm, including the high risk of "serious and life-threatening adverse events." The FDA also issued a Public Health Advisory in 2007 emphasizing that Fentora should only be used for cancer patients who are opioid-tolerant and should not be used for any other conditions, such as migraines, post-operative pain, or pain due to injury.

112.

Despite this, Cephalon conducted and continues to conduct a well-funded campaign to promote Actiq and Fentora for chronic pain and other non-cancer conditions for which it was not approved, appropriate, or safe. As part of this campaign, Cephalon used CMEs, speaker programs, KOLs, journal supplements, and detailing by its sales representatives to give doctors the false impression that Actiq and Fentora are safe and effective for treating non-cancer pain. For example:

a. Cephalon paid to have a CME it sponsored, *Opioid-Based Management of Persistent and Breakthrough Pain*, published in a supplement of *Pain Medicine News* in 2009. The CME instructed doctors that "clinically, broad classification of pain syndromes as either cancer- or noncancer-related has limited utility" and recommended Actiq and Fentora for patients with chronic pain. The CME is still available online.

b. Cephalon's sales representatives set up hundreds of speaker programs for doctors, including many non-oncologists, which promoted Actiq and Fentora for the treatment of non-cancer pain.

c. In December 2011, Cephalon widely disseminated a journal supplement entitled "*Special Report: An Integrated Risk Evaluation and Mitigation Strategy for Fentanyl Buccal Tablet (FENTORA) and Oral Transmucosal Fentanyl Citrate (ACTIQ)*" to *Anesthesiology News*, *Clinical Oncology News*, and *Pain Medicine* News, three publications that are sent to thousands of anesthesiologists and other medical professionals. The Special Report openly promotes Fentora for "multiple causes of pain" – and not just cancer pain.

113.

Cephalon's deceptive marketing gave doctors and patients the false impression that Actiq and Fentora were not only safe and effective for treating chronic pain, but were also approved by the FDA for such uses.

114.

Purdue also unlawfully and unfairly failed to report or address illicit and unlawful prescribing of its drugs, despite knowing about it for years. Purdue's sales representatives have maintained a database since 2002 of doctors suspected of inappropriately prescribing its drugs. Rather than report these doctors to state medical boards or law enforcement authorities (as Purdue is legally obligated to do) or cease marketing to them, Purdue used the list to demonstrate the high rate of diversion of OxyContin (the same OxyContin that Purdue promoted as less addictive) in order to persuade the FDA to bar the manufacture and sale of generic copies of the drug because the drug was too likely to be abused. In an interview with the *Los Angeles Times*, Purdue's senior compliance officer acknowledged that in five years of investigating suspicious pharmacies, Purdue failed to take action, even where Purdue employees personally witnessed the diversion of its drugs. The same was true of prescribers; despite its knowledge of illegal prescribing, Purdue did not report until years after law enforcement shut down a Los Angeles clinic that prescribed more than 1.1 million OxyContin tablets and that Purdue's district manager described internally as "an organized drug ring." In doing so, Purdue protected its own profits at the expense of public health and safety.

115.

Like Purdue, Endo has been cited for its failure to set up an effective system for identifying and reporting suspicious prescribing. In its settlement agreement with Endo, the State of New York found that Endo failed to require sales representatives to report signs of abuse, diversion, and inappropriate prescribing; paid bonuses to sales representatives for detailing prescribers who were subsequently arrested or convicted for illegal prescribing; and failed to prevent sales representatives from visiting prescribers whose suspicious conduct had caused them to be placed on a no-call list.

116.

As a part of their deceptive marketing scheme, Defendants identified and targeted susceptible prescribers and vulnerable patient populations in the U.S., including Louisiana. For example, Defendants focused their deceptive marketing on primary care doctors, who were more likely to treat chronic pain patients and prescribe them drugs, but were less likely to be educated about treating pain and the risks and benefits of opioids and therefore more likely to accept Defendants' misrepresentations.

117.

Defendants also targeted vulnerable patient populations who tend to suffer from chronic pain (*e.g.*, elderly and veterans). Defendants targeted these vulnerable patients even though the risks of long-term opioid use were significantly greater for them. For example, the 2016 CDC Guideline observes that existing evidence shows that elderly patients taking opioids suffer from elevated fall and fracture risks, greater risk of hospitalization, and increased vulnerability to adverse drug effects and interactions. The Guideline therefore concludes that there are "special risks of long-term opioid use for elderly patients" and recommends that doctors use "additional caution and increased monitoring" to minimize the risks of opioid use in elderly patients. The same holds true for veterans, who are more likely to use anti-anxiety drugs (benzodiazepines) for post-traumatic stress disorder, which interact dangerously with opioids.

118.

Defendants made, promoted, and profited from their misrepresentations about the risks and benefits of opioids for chronic pain even though they knew that their misrepresentations were false and deceptive. The history of opioids, as well as research and clinical experience over the last 20 years, established that opioids were highly addictive and responsible for a long list of very serious adverse outcomes. The FDA and other regulatory bodies warned Defendants of this adverse outcomes, and Defendants had access to scientific studies, detailed prescription data, and reports of adverse events, including reports of addiction, hospitalization, and deaths – all of which made clear the harms from long-term opioid use and that patients are suffering from addiction, overdoses, and death in alarming numbers. More recently, the FDA and CDC issued pronouncements based on the medical evidence that conclusively expose the known falsity of Defendants' misrepresentations, and Endo and Purdue recently entered agreements prohibiting them from making some of the same misrepresentations described in this Complaint in New York.

119.

Moreover, at all times relevant to this Petition, Defendants took steps to avoid detection and fraudulently concealed their deceptive marketing and unlawful, unfair, and fraudulent conduct. For example, Defendants disguised their own role in the deceptive marketing of chronic opioid therapy by funding and working through third parties like Front Groups and KOLs. Defendants intentionally hid behind the assumed credibility and objectivity of these individuals

and organizations and relied on them to endorse the accuracy and integrity of Defendants' false and deceptive statements about the risks and benefits of long-term opioid use for chronic pain.

120.

In addition, Defendants concealed their role in shaping, editing, and approving the content of information and materials disseminated by these third parties. In reality, Defendants exerted considerable influence on these promotional and "educational" materials in emails, correspondence, and meetings with KOLs, Front Groups, and public relations companies that were not, and have not yet become, public. For example, painknowledge.org, which is run by the NIPC, failed to disclose Endo's involvement. Other Defendants, such as Purdue and Janssen, operated similar websites that masked their own direct role.

121.

Finally, Defendants manipulated their promotional materials and the scientific literature to provide the illusion of legitimacy and to make it appear that these items were accurate, truthful, and supported by objective evidence when they were not. Further, Defendants distorted the meaning or import of studies they cited and offered them as evidence for propositions the studies did not support.

122.

Thus, Defendants successfully concealed from the medical community, patients, and health care payers facts sufficient to arouse suspicion of the claims that the LDH now asserts. LDH did not know of the existence or scope of Defendants' industry-wide fraud and could not have acquired such knowledge earlier through the exercise of reasonable diligence.

123.

Defendants' misrepresentations deceived doctors and patients about the risks and benefits of long-term opioid use. Studies also reveal that many doctors and patients are not aware of or do not understand these risks and benefits. Indeed, patients often report that they were not warned they might become addicted to opioids prescribed to them. As reported in January 2016, a 2015 survey of more than 1,000 opioid patients found that 4 out of 10 were not told opioids were potentially addictive.[34]

[34] Hazelden Betty Ford Foundation, *Missed Questions, Missed Opportunities* (Jan. 27, 2016), available at: http://www.hazeldenbettyford.org/about-us/news-and-media/pressrelease/doctors-missing-questions-that-could-prevent-opioid-addiction.

124.

Defendants' deceptive marketing scheme caused and continues to cause doctors in Louisiana to prescribe opioids for chronic pain conditions such as back pain, headaches, arthritis, and fibromyalgia. Absent Defendants' deceptive marketing scheme, these doctors would not have prescribed as many opioids. Defendants' deceptive marketing scheme also caused and continues to cause patients to purchase and use opioids for their chronic pain believing they are safe and effective. Absent Defendants' deceptive marketing scheme, fewer patients would be using opioids long-term to treat chronic pain, and those patients using opioids would be using less of them.

125.

Defendants' deceptive marketing has caused and continues to cause the prescribing and use of opioids to explode. Indeed, this dramatic increase in opioid prescriptions and use corresponds with the dramatic increase in Defendants' spending on their deceptive marketing scheme. Defendants' spending on opioid marketing totaled approximately **$91 million** in **2000**. By **2011**, that spending dramatically increased to **$288 million**.

126.

The escalating number of opioid prescriptions written by doctors who were deceived by Defendants' deceptive marketing scheme is the cause of a correspondingly dramatic increase in opioid addiction, overdose, and death throughout the United States and Louisiana. In August 2016, then-U.S. Surgeon General Vivek Murthy published an open letter to be sent to physicians nationwide, enlisting their help in combating this "urgent health crisis" and linking that crisis to deceptive marketing. There, he wrote that the push to aggressively treat pain, and the "devastating" results that followed, had "coincided with heavy marketing to doctors . . . [m]any of [whom] were even taught – incorrectly – that opioids are not addictive when prescribed for legitimate pain."

127.

Scientific evidence demonstrates a strong correlation between opioid prescriptions and opioid abuse. In a 2016 report, the CDC explained that "[o]pioid pain reliever prescribing has quadrupled since 1999 and has increased in parallel with [opioid] overdoses." Patients receiving prescription opioids for chronic pain account for the majority of overdoses. For these reasons,

the CDC concluded that efforts to rein in the prescribing of opioids for chronic pain are critical "to reverse the epidemic of opioid drug overdose deaths and prevent opioid-related morbidity."

128.

Contrary to Defendants' misrepresentations, most opioid addiction begins with legitimately *prescribed* opioids, and therefore could have been prevented had Defendants' representations to prescribers been truthful. In 2011, 71% of people who abused prescription opioids got them through friends or relatives, not from "pill mills," drug dealers or the internet.[35] Numerous doctors and substance abuse counselors note that many of their patients who misuse or abuse opioids started with legitimate prescriptions, confirming the important role that doctors' prescribing habits have played in the opioid epidemic.

129.

Defendants' creation of a virtually limitless opioid market, through false and deceptive advertising and other unlawful and unfair conduct, significantly harmed LDH and communities throughout Louisiana. Defendants' success in extending the market for opioids to new patients and chronic pain conditions created an abundance of drugs available for non-medical and criminal use and fueled a new wave of addiction and injury. Estimates suggest that 60% of the opioids that are abused come, directly or indirectly, through doctors' prescriptions.[36]

130.

Law enforcement agencies have increasingly associated prescription drug abuse with violent and property crimes. Despite strict federal regulation of prescription drugs, local law enforcement agencies are faced with increasing diversion from legitimate sources for illicit purposes, including: doctor shopping, forged prescriptions, falsified pharmacy records, and employees who steal from their place of employment. The opioid epidemic has prompted a growing trend of crimes against pharmacies including robbery and burglary. In fact, a 2005 study by The Center on Addiction and Substance Abuse at Columbia University revealed that, by that time, 20.9% of pharmacies nationwide had stopped stocking certain medications such as OxyContin and Percocet, in order to protect themselves from robbery. This ongoing diversion of prescription narcotics creates a lucrative marketplace.

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[35] *See* U.S. Dep't of Health & Human Servs., *2011 National Survey on Drug Use and Health* (Sept. 2012).

[36] Nathaniel P. Katz, *Prescription Opioid Abuse: Challenges and Opportunities for Payers*, Am. J. Managed Care (Apr. 19 2013), at 5 ("The most common source of abused [opioids] is, directly or indirectly, by prescription."), *available at* http://www.ajmc.com/publications/issue/2013/2013-1-vol19-n4/Prescription-Opioid-Abuse-Challenges-and-Opportunities-for-Payers

131.

The costs and consequences of opioid addiction are staggering. Prescription opioid misuse, abuse and overdose have an enormous impact on the health and safety of individuals as well as communities at large, as the consequences of this epidemic reach far beyond the individual who is addicted. Some of the repercussions for individuals include job loss, loss of custody of children, physical and mental health problems, homelessness and incarceration.[37]

132.

Defendants knew and should have known about these harms that their wrongful conduct caused. Defendants closely monitored their sales and the habits of prescribing doctors. Their sales representatives, who visited doctors and attended CMEs, knew which doctors were receiving their messages and how they were responding. Defendants also had access to and monitored government and other data that tracked the explosive rise in opioid use, addiction, injury, and death. They knew and intended that their misrepresentations would persuade doctors to prescribe and patients to use their opioids for chronic pain.

133.

Defendants' actions are not permitted nor excused by the fact that their drug labels (with the exception of the Actiq/Fentora labels) may have allowed or did not exclude the use of opioids for chronic pain. FDA approval of opioids for certain uses did not allow Defendants to misrepresent the risks and benefits of opioids. Indeed, Defendants' misrepresentations were directly contrary to pronouncements by and guidance from the FDA based on the medical evidence and their own labels.

134.

Nor is Defendants' causal role broken by the involvement of doctors. Defendants' marketing efforts were ubiquitous and highly persuasive. Their deceptive messages tainted virtually every source doctors could rely on for information and prevented them from making informed treatment decisions. Defendants were also able to harness and hijack what doctors wanted to believe – namely, that opioids represented a means of relieving their patients' suffering and of practicing medicine more compassionately. Defendants touted their products as medical breakthrough and preyed upon doctors wanting to believe that they were giving patients the most modern and safe care available.

[37] *See* Section I.

135.

As referenced above, from 2007 to present, the Louisiana Department of Health incurred approximate costs totaling $677,254,416 for treatment of opioid use and dependence.

136.

While the use of opioids has taken an enormous toll on the Louisiana Department of Health, Defendants made blockbuster profits as further detailed in Section I.

V. CAUSES OF ACTION

137.

The Louisiana Department of Health specifically **declines and does not assert any federal law cause of action** with respect to the Defendants' actions.

Violations of Louisiana Medical Assistance Programs Integrity Law ("MAPIL")

138.

Pursuant to Louisiana Code of Civil Procedure article 853, the Louisiana Department of Health incorporates by reference all previous allegations in the preceding paragraphs as if fully set forth herein.

139.

This action is brought pursuant to La. Rev. Statute 46:438.3 and other laws which allow the Louisiana Department of Health to recover damages, penalties, interest, attorney fees, and costs for the conduct resulting in the submission of false and fraudulent claims to the medical assistance programs. Defendants have engaged in the following acts, among others, in violation of Section 438.3:

a. knowingly presenting or causing false or fraudulent claims to be presented and submitted to the medical assistance programs by unlawfully marketing opioids as detailed herein;

b. knowingly engaging in misrepresentations related to the safety and efficacy of opioids as part of an attempt to obtain and to obtain payment from medical assistance programs funds as detailed herein;

c. as part of sophisticated scheme knowingly causing false claim submissions for reimbursement to be filed for highly addictive prescription drugs with the intent that the addicted patients will use more of the drugs causing more false claims to be filed;

d. conspiring to defraud, or attempting to defraud, the medical assistance programs through misrepresenting the safety and efficacy of opioids as detailed herein; and

e. obtaining, or attempting to obtain, payment from medical assistance programs for false or fraudulent claims as detailed herein.

140.

The Louisiana Department of Health's alleged actual damages resulting from the foregoing acts are in excess of one thousand dollars. Each violation of this Section is considered a separate violation.

141.

The Louisiana Department of Health is entitled to collect actual damages for monies paid that would otherwise not have been paid had defendants promoted, marketed, and sold opioids in compliance with the law. (LSA-R.S. 46:438.6(A)). Additionally, the Louisiana Department of Health is entitled to the civil fine described in LSA-R.S. 46:438.6(B). Additionally, the Louisiana Department of Health is entitled to the civil penalties under LSA-R.S. 46:438.6(C). Additionally, the Louisiana Department of Health is entitled to an award of costs, expenses, fees, interest, and attorney fees as set forth in LSA-R.S. 46:438.6(D).

Violations of Louisiana Racketeering Act
(LSA-R.S. 15:1351 *et seq.*)

142.

Defendants Purdue, Janseen, Cephalon, and Endo (collectively, "Racketeering Defendants") unlawfully misappropriated, converted, and obtained by false pretenses a thing of value (property) belonging to the Louisiana Department of Health to include Medicaid payments made for medically unnecessary opioids prescribed and dispensed for chronic pain. Accordingly, the Racketeering Defendants' actions constitute theft in violation of LSA-R.S. § 14:67(A), to wit: the misappropriation or taking of anything of value which belongs to another, either without the consent of the other to the misappropriation or taking, or by means of fraudulent conduct, practices, or representations. Also, the Racketeering Defendants conspired with others known and unknown to misappropriate, convert, and obtain by false pretenses, and attempted to misappropriate, convert, and obtain by false pretenses the money rightfully belonging to the Louisiana Department of Health in the form of Medicaid funding held and administered by the Louisiana Department of Health. Accordingly, the Racketeering Defendants' actions constitute conspiracy to commit theft, theft and attempted theft. The Racketeering Defendants' actions also constitute Medicaid fraud in violation of LSA-R.S. § 14:70.1 as well as conspiracy and attempt to commit Medicaid fraud in violation of state law.

143.

As detailed above, the Racketeering Defendants committed various fraudulent acts which constitute fraud and a scheme to defraud. These intentional omissions of material fact and affirmative representations made by the Racketeering Defendants were false when made which included but was not limited to the acts detailed above and the following acts:

a. Marketing materials about the Racketeering Defendants' opioids, and their risks and benefits, which the Racketeering Defendants sent to health care providers located across the country and Louisiana;

b. Written representations and telephone calls between the Racketeering Defendants and Front Groups regarding representations about the Racketeering Defendants' opioids, or the use of opioids for chronic pain generally;

c. Written representations and telephone calls between the Racketeering Defendants and KOLs regarding Defendants' opioids, or the use of opioids for chronic pain generally;

d. Hundreds of e-mails between the Racketeering Defendants and the Front Groups agreeing to or effectuating the implementation of the opioid marketing scheme;

e. Hundreds of e-mails between the Racketeering Defendants and KOLs agreeing to or effectuating the implementation of the opioid marketing scheme;

f. Hundreds of communications between the Front Groups and publications, groups drafting treatment guidelines and the media effectuating the implementation of the opioid marketing scheme;

g. Hundreds of communications between the KOLs and publications, groups drafting treatment guidelines and the media effectuating the implementation of the opioid marketing scheme;

h. Written and oral communications directed to State agencies and private insurers throughout Louisiana that fraudulently misrepresented the risks of benefits of using opioids for chronic pain; and

i. Receipts of increased profits which represented the wrongful proceeds of the scheme.

144.

The Racketeering Defendants' theft, conspiracy to commit theft, attempted theft, misappropriation, fraud, Medicaid fraud, conspiracy to commit Medicaid fraud, and attempted Medicaid fraud were each the proximate cause of the Louisiana Department of Health's damages as detailed herein. These violations occurred through the execution of the Racketeering Defendants' scheme using omissions of material fact and affirmative misrepresentation to perpetrate the theft, attempted theft, misappropriation, fraud, Medicaid fraud, conspiracy to commit Medicaid fraud, and attempted Medicaid fraud upon the Louisiana Department of Health

to include the numerous unjustified Medicaid payments by the Louisiana Department of Health for the ultimate benefit of the Racketeering Defendants.

145.

In addition, these fraudulent acts are all in violation of the Louisiana Racketeering Act (LSA-R.S. §§ 15:1351 et seq.). **The Louisiana Department of Health specifically declines and does not assert any federal law cause of action with respect to the Racketeering Defendants' actions**.

146.

The Louisiana Department of Health seeks damages for the Racketeering Defendants' theft, conspiracy to commit theft, attempted theft, misappropriation, fraud, Medicaid fraud, conspiracy to commit Medicaid fraud, and attempted Medicaid fraud, scheme to defraud, and fraudulent conduct, practices, and representations including without limitation all damages, fees, and costs it has incurred or will incur as a result of the Racketeering Defendants' actions, which must be trebled under LSA-R.S. § 15:1356(E).

147.

The Louisiana Department of Health also seeks attorney's fees and litigation and investigative costs incurred in this matter pursuant to LSA-R.S. § 15:1356(E).

148.

The "Opioid Marketing Enterprise" consisted of the Racketeering Defendants named herein, the remaining Defendants named herein, the Front Groups detailed above, KOLs detailed above, and others to include but not limited to employees of entities associated with the Racketeering Defendants. Further, the Opioid Marketing Enterprise existed as an "enterprise" as defined in LSA-R.S. § 15:1352(B).

149.

The Opioid Marketing Enterprise existed as an association in fact and included unlawful as well as lawful enterprises as defined in LSA-R.S. § 15:1352(B).

150.

While the Racketeering Defendants participated in the Opioid Marketing Enterprise, the Racketeering Defendants also existed separate and distinct from the Opioid Marketing Enterprise.

151.

The Racketeering Defendants maintained an interest and control of the Opioid Marketing Enterprise and also conducted and participated in the conduct of the Opioid Marketing Enterprise's affairs through a pattern of racketeering activity.

152.

The Racketeering Defendants' control and participation in the Opioid Marketing Enterprise were necessary for the successful activity in which the Racketeering Defendants engaged that included but was not limited to the acts detailed above and the following acts:

a. the Racketeering Defendants created a body of deceptive and unsupported medical and popular literature about opioids that: (a) understated the risks and overstated the benefits of long-term use; (b) appeared to be the result of independent, objective research; and (c) was thus more likely to be relied upon by physicians, patients, and payors;

b. the Racketeering Defendants selected, cultivated, promoted, and paid the KOLs based solely on their willingness to communicate and distribute Defendants' messages about the use of opioids for chronic pain;

c. the Racketeering Defendants provided substantial opportunities for KOLs to participate in research studies on topics Defendants suggested or chose, with the predictable effect of ensuring that many favorable studies appeared in the academic literature;

d. the Racketeering Defendants paid KOLs to serve as consultants or on their advisory boards and to give talks or present CMEs, typically over meals or at conferences;

e. the Racketeering Defendants disseminated many of their false, misleading, imbalanced, and unsupported statements through unbranded materials that appeared to be independent publications from Front Groups;

f. the Racketeering Defendants sponsored CME programs put on by Front Groups that focused exclusively on the use of opioids for chronic pain;

g. the Racketeering Defendants developed and disseminated pro-opioid treatment guidelines;

h. the Racketeering Defendants encouraged Front Groups to disseminate their pro-opioid messages to groups targeted by Defendants, such as veterans and the elderly, and then funded that distribution;

i. the Racketeering Defendants concealed their relationship to and control of Front Groups and KOLs from the Louisiana Department of Health and the public at large; and

j. the Racketeering Defendants intended that Front Groups and KOLs would distribute promotional and other materials that claimed opioids could be safely used for chronic pain.

153.

The Front Groups also participated in the conduct of the affairs of the Opioid Marketing Enterprise, directly or indirectly, in the following ways:

a. The Front Groups promised to, and did, make representations regarding Defendants' opioids that were consistent with Defendants' messages themselves;

b. The Front Groups distributed promotional and other materials which claimed that opioids could be safely used for chronic pain, and the benefits of using opioids for chronic pain outweighed the risks; and

c. The Front Groups concealed their connections to Defendants.

154.

The KOLs also participated in the conduct of the affairs of the Opioid Marketing Enterprise, directly or indirectly, in the following ways:

a. The KOLs promised to, and did, make representations regarding Defendants' opioids that were consistent with Defendants' messages themselves;

b. The KOLs distributed promotional and other materials which claimed that opioids could be safely used for chronic pain, and the benefits of using opioids for chronic pain outweighed the risks; and

c. The KOLs concealed their connections to and sponsorship by Defendants.

155.

The Opioid Marketing Enterprise had an ascertainable structure separate and apart from the pattern of racketeering activity in which the Racketeering Defendants engaged.

156.

The Racketeering Defendants and the other members of the Opioid Marketing Enterprise shared in the fruits of its predicate acts detailed above. The association in fact Opioid Marketing Enterprise, the Racketeering Defendants, and other members of the Opioid Marketing Enterprise had a formal, ongoing relationship that functioned as a continuing unit, pursuing a course of conduct as set forth above, with a common or shared purpose, and continuity of structure and personnel.

157.

The Racketeering Defendants and those employed by or associated with the Opioid Marketing Enterprise conducted the affairs of the Opioid Marketing Enterprise through a pattern of racketeering activity in violation of LSA-R.S. § 15:1353(C) and have conspired to violate Section 15:1353(C) in violation of Section 15:1353(D) as detailed above.

158.

The Racketeering Defendants and those employed by or associated with the Opioid Marketing Enterprise violated Section 15:1353(D), inasmuch as they knowingly, intentionally,

and unlawfully aided and abetted each other and the Opioid Marketing Enterprise and conspired to conduct and participate, directly or indirectly, in the conduct of the affairs of the Enterprise, through the pattern of racketeering activity described herein.

159.

With respect to the activities alleged and detailed herein, the Opioid Marketing Enterprise sought to aid and abet and actually did aid and abet a transaction to violate La. R.S. § 15:1353(C) and specifically LSA-R.S. § 14:67 (theft), § 14:26 (conspiracy to commit theft), § 14:27 (attempted theft), LSA-R.S. § 14:70.1 (Medicaid fraud), § 14:26 (conspiracy to commit Medicaid fraud), and § 14:27 (attempted Medicaid fraud).

160.

The Opioid Marketing Enterprise's scheme to defraud resulted in severe financial losses to the Louisiana Department of Health.

161.

The Opioid Marketing Enterprise's misrepresentations constitute tortious and illegal acts as defined by Louisiana law including but not limited to violations of LSA-R.S. § 14:67 (theft), § 14:26 (conspiracy to commit theft), § 14:27 (attempted theft), LSA-R.S. § 14:70.1 (Medicaid fraud), § 14:26 (conspiracy to commit Medicaid fraud), and § 14:27 (attempted Medicaid fraud).

162.

The violations set forth herein constitute "racketeering activity" within the meaning of LSA-R.S. § 15:1353, by the members of the Opioid Marketing Enterprise committing, conspiring to commit, and/or attempting to commit the Title 14 offenses alleged herein with at least two such acts of racketeering activity, as described herein, having occurred within the past five years.

163.

The Opioid Marketing Enterprise's racketeering activities or predicate acts are related and also amount to continuing criminal activity which occurred over an extended period of time.

164.

As a result of the actions undertaken by the Opioid Marketing Enterprise, the Louisiana Department of Health is entitled to recover pursuant to LSA-R.S. § 15:1353(E) three times the actual damages sustained, attorney fees in the trial and appellate courts and costs of investigation and litigation reasonably incurred.

Fraud

165.

Pursuant to Louisiana Code of Civil Procedure article 853, the Louisiana Department of Health incorporates by reference all previous allegations in the preceding paragraphs as if fully set forth herein.

166.

Defendants made numerous fraudulent misrepresentations as detailed herein.

167.

Defendants engaged in repeated fraudulent acts and practices, thus committing fraud against the Louisiana Department of Health, pursuant to Louisiana Civil Code article 2315 (as defined in Louisiana Civil Code article 1953). The Louisiana Department of Health specifically declines and does not assert any contractual fraud claim; instead, the Louisiana Department of Health asserts only a delictual fraud claim under this cause of action.

Negligent Misrepresentation

168.

Pursuant to Louisiana Code of Civil Procedure article 853, the Louisiana Department of Health incorporates by reference all previous allegations in the preceding paragraphs as if fully set forth herein.

169.

For reasons set forth above, Defendants made negligent misrepresentations to the Louisiana Department of Health and others pursuant to Louisiana Civil Code articles 2315 and 2316. There existed at all relevant times a legal duty owed to the Louisiana Department of Health by the Defendants to accurately warn of the efficacy and side effects of opioid analgesic pain relievers. Defendants breached this duty as set forth above. The Louisiana Department of Health reasonably relied upon Defendants' representations. As an actual and proximate result of Defendants' misrepresentations, and the Louisiana Department of Health's reasonable reliance thereof, the Louisiana Department of Health has been damaged as detailed above.

170.

The Louisiana Department of Health is entitled to judgment against Defendants for restitution, attorney's fees and costs for the losses incurred by the Louisiana Department of Health as a direct and proximate cause of Defendants' misrepresentations.

Redhibition

171.

Pursuant to Louisiana Code of Civil Procedure article 853, the Louisiana Department of Health incorporates by reference all previous allegations in the preceding paragraphs as if fully set forth herein.

172.

Pursuant to Louisiana Civil Code 2520, *et seq.*, through the manufacture, marketing, and sale of OxyContin, MS Contin, Dilaudid/Dilaudid HP, Butrans, Hysingla ER, and Targiniq ER, Percocet, Actiq, Fentora, Duragesic, Opana/Opana ER, Percodan, Zydone, Kadian, oxycodone, hydrocodone and Norco, Defendants warranted to the Louisiana Department of Health, Louisiana patients, medical assistance programs and government payors that OxyContin, MS Contin, Dilaudid/Dilaudid HP, Butrans, Hysingla ER, and Targiniq ER, Percocet, Actiq, Fentora, Duragesic, Opana/Opana ER, Percodan, Zydone, Kadian, oxycodone, hydrocodone and Norco were free of any redhibitory effects.

173.

By virtue of the acts alleged above, Defendants had reason to know that the Louisiana Department of Health, patients, their insurers, public health care providers, prescribers, public entities, medical assistance programs and government payors were purchasing and using OxyContin, MS Contin, Dilaudid/Dilaudid HP, Butrans, Hysingla ER, and Targiniq ER, Percocet, Actiq, Fentora, Duragesic, Opana/Opana ER, Percodan, Zydone, Kadian, oxycodone, hydrocodone and Norco for the treatment of unapproved indications or for ineffective treatment. Therefore, pursuant to La. C.C. art. 2520, Defendants warranted to the Louisiana Department of Health, Louisiana patients, their insurers, public health care providers, prescribers, public entities, medical assistance programs and government payors that OxyContin, MS Contin, Dilaudid/Dilaudid HP, Butrans, Hysingla ER, and Targiniq ER, Percocet, Actiq, Fentora, Duragesic, Opana/Opana ER, Percodan, Zydone, Kadian, oxycodone, hydrocodone and Norco were for those particular purposes.

174.

OxyContin, MS Contin, Dilaudid/Dilaudid HP, Butrans, Hysingla ER, and Targiniq ER, Percocet, Actiq, Fentora, Duragesic, Opana/Opana ER, Percodan, Zydone, Kadian, oxycodone, hydrocodone and Norco contain redhibitory defects unknown and undiscoverable to the

Louisiana Department of Health, but for Defendants' false representations and omissions regarding unapproved indications and uses for OxyContin, MS Contin, Dilaudid/Dilaudid HP, Butrans, Hysingla ER, and Targiniq ER, Percocet, Actiq, Fentora, Duragesic, Opana/Opana ER, Percodan, Zydone, Kadian, oxycodone, hydrodone and Norco, Louisiana healthcare professionals would not have prescribed OxyContin, MS Contin, Dilaudid/Dilaudid HP, Butrans, Hysingla ER, and Targiniq ER, Percocet, Actiq, Fentora, Duragesic, Opana/Opana ER, Percodan, Zydone, Kadian, oxycodone, hydrodone and Norco for such unapproved indications and uses, and consequently, the Louisiana Department of Health would not have purchased and/or paid for OxyContin, MS Contin, Dilaudid/Dilaudid HP, Butrans, Hysingla ER, and Targiniq ER, Percocet, Actiq, Fentora, Duragesic, Opana/Opana ER, Percodan, Zydone, Kadian, oxycodone, hydrodone and Norco.

175.

The redhibitory defects existed at the time OxyContin, MS Contin, Dilaudid/Dilaudid HP, Butrans, Hysingla ER, and Targiniq ER, Percocet, Actiq, Fentora, Duragesic, Opana/Opana ER, Percodan, Zydone, Kadian, oxycodone, hydrodone and Norco were purchased and/or paid for by the Louisiana Department of Health, and the Louisiana Department of Health had no knowledge of the redhibitory defects when it paid for OxyContin, MS Contin, Dilaudid/Dilaudid HP, Butrans, Hysingla ER, and Targiniq ER, Percocet, Actiq, Fentora, Duragesic, Opana/Opana ER, Percodan, Zydone, Kadian, oxycodone, hydrodone and Norco and it could not have reasonably discovered the hidden redhibitory defects in OxyContin, MS Contin, Dilaudid/Dilaudid HP, Butrans, Hysingla ER, and Targiniq ER, Percocet, Actiq, Fentora, Duragesic, Opana/Opana ER, Percodan, Zydone, Kadian, oxycodone, hydrodone and Norco.

176.

Defendants breached their warranty of redhibition and as a direct result of this breach of warranty, the Louisiana Department of Health has suffered and will continue to suffer damages.

177.

Pursuant to La. C.C. art. 2545, Defendants are liable to the Louisiana Department of Health for the return of the price with interest from the time it was paid for, reimbursement of the reasonable expenses occasioned by the sale, and for damages, including any consequential damages for medical care and expenses related to the undisclosed adverse effects and side effects of OxyContin, MS Contin, Dilaudid/Dilaudid HP, Butrans, Hysingla ER, and Targiniq ER,

Percocet, Actiq, Fentora, Duragesic, Opana/Opana ER, Percodan, Zydone, Kadian, oxycodone, hydrodone and Norco in a total amount to be determined at trial, as well as reasonable attorney fees to be set by the Court.

Unjust Enrichment

178.

Pursuant to Louisiana Code of Civil Procedure article 853, the Louisiana Department of Health incorporates by reference all previous allegations in the preceding paragraphs as if fully set forth herein.

179.

Alternatively, the Louisiana Department of Health asserts that by receiving recoveries for overpayments/overcharges for prescriptions which were reimbursed by Louisiana Medicaid, Defendants have been enriched without cause at the expense of the Louisiana Department of Health. Pursuant to Louisiana Civil Code article 2298, Defendants are obligated to restore to Louisiana Department of Health the portion of any payments for OxyContin, MS Contin, Dilaudid/Dilaudid HP, Butrans, Hysingla ER, and Targiniq ER, Percocet, Actiq, Fentora, Duragesic, Opana/Opana ER, Percodan, Zydone, Kadian, oxycodone, hydrodone and Norco, opioid analgesic pain relievers. attributable to prescriptions reimbursed by Louisiana Medicaid.

180.

It would be inequitable for Defendants to be permitted to retain any of the overcharges for OxyContin, MS Contin, Dilaudid/Dilaudid HP, Butrans, Hysingla ER, and Targiniq ER, Percocet, Actiq, Fentora, Duragesic, Opana/Opana ER, Percodan, Zydone, Kadian, oxycodone, hydrodone and Norco, opioid analgesic pain relievers, derived from Defendants' unfair and unconscionable methods, acts and trade practices alleged in this Petition.

181.

Defendants should be compelled to disgorge for the benefit of Plaintiff all unlawful or inequitable proceeds received by Defendants.

182.

Plaintiff has no adequate remedy at law.

183.

The Louisiana Department of Health alleges that under La. C.C. art. 2298, Defendants have been unjustly enriched and, thus, Plaintiff is entitled to an award for costs, expenses, fees, and attorney fees.

VI. PRAYER FOR RELIEF

WHEREFORE, the Louisiana Department of Health prays that its Petition for Damages and Injunctive Relief be deemed good and sufficient and that, after due proceedings are had hereon, judgment be rendered in the Plaintiff's favor and against each and every Defendant, jointly severally and *in solido*, finding these Defendants liable and indebted to the Louisiana Department of Health for:

a. for judgement in favor of the Louisiana Department of Health and against Defendants under Louisiana's Medical Assistance Programs Integrity Law, LSA-R.S. § 46:438.6 for actual damages incurred by the Louisiana Department of Health as a result of Defendants' violations of Section 46:438.6, a civil fine in the amount of three times the Louisiana Department of Health's actual damages sustained as a result of Defendants' violations of Section 46:438.6, and interest at the maximum rate of legal interest provided by LSA-R.S. § 13:4202 from the date the violations occurred to the date of repayment, in a total amount to be determined at trial;

b. for judgment in favor of the Louisiana Department of Health and against Defendants, under Louisiana's Medical Assistance Programs Integrity Law, LSA-R.S. § 46:438.6 for actual damages incurred by the Louisiana Department of Health as a result of Defendants' violations of Section 46:438.6, a civil monetary penalty of eleven thousand dollars ($11,000.00) for each violation, and interest at the maximum rate of legal interest provided by LSA-R.S. § 13:4202 from the date the violations occurred to the date of repayment;

c. for judgment in favor of the Louisiana Department of Health and against Defendants, under Louisiana's Medical Assistance Programs Integrity Law, LSA-R.S. § 46:438.6(D) for all costs, expenses and fees related to investigations and proceedings associated with the violations alleged herein, including attorney fees;

d. for judgment in favor of the Louisiana Department of Health against the Racketeering Defendants for actual damages in an amount to be proven at trial, plus treble damages, attorney fees, interests, and costs as provided by La. R.S. § 15:1353(E);

e. for judgment in favor of the Louisiana Department of Health and against Defendants, under Louisiana's Fraud laws, for actual damages, restitution, disgorgement, and attorney fees and costs;

f. for judgment favor of the Louisiana Department of Health and against Defendants, under Louisiana's Redhibition law, La C.C. art. 2545, for restitution and judicial interest, as well as for reimbursement of reasonable expenses occasioned by the sale, and for damages and reasonable attorney fees and costs;

g. for judgment in favor of the Louisiana Department of Health and against Defendants, under Louisiana's Negligent Misrepresentation laws, for damages, reasonable attorney fees, and costs;

h. for judgment in favor of the Louisiana Department of Health and against Defendants, under La. C.C. art. 2298, that Defendants have been unjustly enriched and are liable to the Louisiana Department of Health for compensation to the extent that Defendants have been unjustly enriched, for costs, expenses, fees, and attorney fees;

i. for all damages sustained by the Louisiana Department of Health in such amount as is proven at trial, together with prejudgment interest;

j. injunctive relief enjoining Defendants from, directly or indirectly through KOLs, Front Groups or other third parties, continuing to misrepresent the risks and benefits of the use of opioids for chronic pain, and from continuing to violate Louisiana law; and

k. judicial interest from the date of the judicial demand; and

l. such other and further legal, general, and equitable relief that the Court deems necessary, justified, and proper under the circumstances of this matter.

Finally, the Louisiana Department of Health demands that the claims asserted herein be adjudicated by jury trial.

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PLEASE HOLD SERVICE:

PURDUE PHARMA L.P.
Through the Long Arm Statute

PURDUE PHARMA, INC.
Through the Long Arm Statute

THE PURDUE FREDERICK COMPANY, INC.
Through the Long Arm Statute

TEVA PHARMACEUTICAL INDUSTRIES, LTD.
Through the Long Arm Statute

TEVA PHARMACEUTICALS USA, INC.
Through the Long Arm Statute

CEPHALON, INC.
Through the Long Arm Statute

JOHNSON & JOHNSON
Through the Long Arm Statute

CIV

☐ 01-DAMAGES
☐ 02-CONTRACT
☐ 03-PRISONER
☐ 04-EXEC
☐ 05-SUIT
☐ 06-EVI
☐ 07-WORKMAN'S COMP
☐ 08-JUDICIAL REVIEW
☐ 09 PROPERTY RIGHTS
☑ 10-INJUNCTION MANDAMUS
☐ 11-COMM. FIRE
☐ 12-PUBLIC SERV. COMM.
☐ 13-OTHER PARTITIONS
☐ 18-
☐ 19-
☐ 20-

JANSEEN PHARMACEUTICALS, INC.
Through the Long Arm Statute

ORTHO-MCNEIL-JANSSEN PHARMACEUTICALS, INC. n/k/a JANSSEN PHARMACEUTICALS, INC.
Through the Long Arm Statute

ENDO HEALTH SOLUTIONS INC.
Through the Long Arm Statute

ENDO PHARMACEUTICALS, INC.
Through the Long Arm Statute

ALLEGRAN PLC f/k/a ACTAVIS PLC
Through the Long Arm Statute

WATSON PHARMACEUTICALS, INC. n/k/a ACTAVIS, INC.
Through the Long Arm Statute

WATSON LABORATORIES, INC.
Through the Long Arm Statute

ACTAVIS LLC
Through the Long Arm Statute

ACTAVIS PHARMA, INC. f/k/a WATSON PHARMA, INC.
Through the Long Arm Statute