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S.C. SUPREME COURT

EXHIBIT 2

**COMMONWEALTH OF KENTUCKY
JOHNSON COUNTY CIRCUIT COURT
CIVIL DIVISION ____**

CASE NO. _____

PAINTSVILLE HOSPITAL COMPANY, LLC; JENNIE
STUART MEDICAL CENTER, INC.; HARDIN
MEMORIAL HOSPITAL; T.J. SAMSON COMMUNITY
HOSPITAL; SAINT JOSEPH HEALTH SYSTEM, INC.;
FLAGET HEALTHCARE, INC.; HOSPITAL OF
LOUISA, INC.; and JACKSON HOSPITAL
CORPORATION.

PLAINTIFFS

v.

**COMPLAINT
JURY TRIAL DEMANDED**

AMNEAL PHARMACEUTICALS, LLC; AMNEAL
PHARMACEUTICALS, INC.; AMNEAL
PHARMACEUTICALS OF NEW YORK LLC; IMPAX
LABORATORIES, LLC; TEVA PHARMACEUTICAL
INDUSTRIES, LTD.; TEVA PHARMACEUTICALS
USA, INC.; CEPHALON, INC.; WATSON
LABORATORIES, INC.; WARNER CHILCOTT
COMPANY, LLC; ACTAVIS PHARMA, INC. f/k/a
WATSON PHARMA INC.; ACTAVIS SOUTH
ATLANTIC LLC; ACTAVIS ELIZABETH LLC;
ACTAVIS MID ATLANTIC LLC; ACTAVIS TOTOWA
LLC; ACTAVIS LLC; ACTAVIS KADIAN LLC;
ACTAVIS LABORATORIES UT, INC.; ACTAVIS
LABORATORIES FL, INC.; JOHNSON & JOHNSON;
JANSSEN PHARMACEUTICALS, INC.; ORTHO-
MCNEIL-JANSSEN PHARMACEUTICALS, INC. n/k/a
JANSSEN PHARMACEUTICALS, INC.; JANSSEN
PHARMACEUTICA, INC. n/k/a JANSSEN
PHARMACEUTICALS, INC.; NORAMCO, INC.;
TASMANIAN ALKALOIDS PTY. LTD.; ABBVIE,
INC.; ABBOTT LABORATORIES; ABBOTT
LABORATORIES, INC.; ASSERTIO THERAPEUTICS,
INC.; ENDO HEALTH SOLUTIONS, INC.; ENDO
PHARMACEUTICALS, INC.; PAR
PHARMACEUTICAL, INC.; PAR
PHARMACEUTICALS COMPANIES, INC.;

DEFENDANTS

MALLINCKRODT, LLC; MALLINCKRODT PLC;
SPECGX LLC; ALLERGAN PLC; ALLERGAN
FINANCE, LLC; ALLERGAN SALES, LLC;
ALLERGAN USA, INC.; ANDA, INC.; H.D. SMITH,
LLC f/k/a H.D. SMITH WHOLESALE DRUG CO.;
SMITH DRUG COMPANY; HENRY SCHEIN, INC.;
KVK-TECH, INC.; PRACTICE FUSION, INC.;
ALLSCRIPTS HEALTHCARE SOLUTIONS, INC.;
AMERISOURCEBERGEN DRUG CORPORATION;
CARDINAL HEALTH, INC.; THE KROGER CO.;
KROGER LIMITED PARTNERSHIP I; KROGER
LIMITED PARTNERSHIP II; CVS HEALTH
CORPORATION; CVS PHARMACY, INC.;
KENTUCKY CVS PHARMACY, L.L.C.; RITE AID OF
KENTUCKY, INC.; WALGREENS BOOTS
ALLIANCE, INC.; WALGREEN CO.; WALGREEN
EASTERN CO., INC.; WAL-MART INC.; and WAL-
MART STORES EAST, LP.

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Presiding Judge: HON. JOHN DAVID PRESTON (624234)

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PRAYER FOR RELIEF 360

JURY DEMAND 360

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“The opioid epidemic is the deadliest drug crisis in American history, and Appalachia has suffered the consequences more than perhaps any other region,” Attorney General William P. Barr announced in a press release on April 17, 2019.¹

The decade of the 1990s was the era of the blockbuster drug, the billion-dollar pill, and a pharmaceutical sales force arms race was part of the excess of the time ... A pharmaceutical Wild West emerged. Salespeople stampeded into offices. They made claims that helped sell the drugs to besieged doctors. Those claims also lead years later to blockbuster lawsuits and criminal cases against their companies.²

COMPLAINT

Plaintiffs Paintsville Hospital Company, LLC, Jennie Stuart Medical Center, Inc., Hardin Memorial Hospital, T.J. Samson Community Hospital, Saint Joseph Health System, Inc., Flaget Healthcare, Inc., Hospital Of Louisa, Inc., and Jackson Hospital Corporation bring this Complaint against Defendants Amneal Pharmaceuticals, LLC; Amneal Pharmaceuticals, Inc.; Amneal Pharmaceuticals of New York LLC; Impax Laboratories, LLC; Teva Pharmaceutical Industries, Ltd.; Teva Pharmaceuticals USA, Inc.; Cephalon, Inc.; Watson Laboratories, Inc.; Warner Chilcott Company, LLC; Actavis Pharma, Inc. f/k/a Watson Pharma Inc.; Actavis South Atlantic LLC; Actavis Elizabeth LLC; Actavis Mid Atlantic LLC; Actavis Totowa LLC; Actavis LLC; Actavis Kadian LLC; Actavis Laboratories UT, Inc.; Actavis Laboratories FL, Inc.; Johnson & Johnson; Janssen Pharmaceuticals, Inc.; Ortho-McNeil-Janssen Pharmaceuticals, Inc. n/k/a Janssen Pharmaceuticals, Inc.; Janssen Pharmaceutica, Inc. n/k/a Janssen Pharmaceuticals, Inc.; Noramco, Inc.; Tasmanian Alkaloids Pty. Ltd.; AbbVie, Inc.; Abbott Laboratories; Abbott

¹ Press Release, U.S. Dep’t of Justice, Appalachian Regional Prescription Opioid (ARPO) Strike Force Takedown Results in Charges Against 60 Individuals, Including 53 Medical Professionals (Apr. 17, 2019), available at <https://www.justice.gov/opa/pr/appalachian-regional-prescription-opioid-arpo-strike-force-takedown-results-charges-against>

² Sam Quinones, *Dreamland: The True Tale of America’s Opiate Epidemic* at 133 (Bloomsbury Press 2015) (“Dreamland”).

Laboratories, Inc.; Assertio Therapeutics, Inc.; Endo Health Solutions, Inc.; Endo Pharmaceuticals, Inc.; Par Pharmaceutical, Inc.; Par Pharmaceuticals Companies, Inc.; Mallinckrodt, LLC; Mallinckrodt Plc; SpecGx LLC; Allergan Plc; Allergan Finance, LLC; Allergan Sales, LLC, Allergan USA, Inc.; Anda, Inc.; H.D. Smith, LLC f/k/a H.D. Smith Wholesale Drug Co.; Smith Drug Company; Henry Schein, Inc.; KVK-Tech, Inc.; Practice Fusion, Inc.; Allscripts Healthcare Solutions, Inc.; AmerisourceBergen Drug Corporation; Cardinal Health, Inc.; The Kroger Co.; Kroger Limited Partnership I; Kroger Limited Partnership II; CVS Health Corporation; CVS Pharmacy, Inc.; Kentucky CVS Pharmacy, L.L.C.; Rite Aid of Kentucky, Inc.; Walgreens Boots Alliance, Inc.; Walgreen Co.; Walgreen Eastern Co., Inc.; Wal-Mart Inc.; and Wal-Mart Stores East, LP (collectively “Defendants”) under the Kentucky Consumer Protection Act (the “KCPA”) as codified at K.R.S § 367.170(1); Nuisance; Negligence; Wanton Negligence; Negligence *Per Se*; Fraud; Civil Conspiracy; and Unjust Enrichment seeking judgment against Defendants and in favor of Plaintiffs; compensatory damages; treble damages; punitive damages; pre-judgment and post-judgment interest; cost of suit; and equitable relief, including injunctive relief and alleges as follows:

I. INTRODUCTION

A. The Opioid Crisis in Kentucky

1. Plaintiffs operate hospitals located throughout Kentucky. The service areas of Plaintiffs’ hospitals have been hit hard by the opioid crisis.

2. No state has been hit harder by the opioid epidemic than Kentucky.³

³ *Confronting the Opioid Epidemic*, University of Kentucky, available at <http://www.uky.edu/president/opioid>.

3. The opioid epidemic poses an ongoing crisis in Kentucky. Opioid use has had tragic consequences for communities across Kentucky. Thousands of Kentucky residents have died from opioid overdoses, and many thousands more suffer from opioid use disorders and related health conditions.

4. During the period from 2006 to 2014, approximately 2,452,373,586 pills of hydrocodone and oxycodone were supplied to Kentucky.⁴ That is enough pills for all of the 4,339,367 Kentuckians⁵ to each have approximately 565 pills.

5. The rate of overdose deaths involving opioid prescriptions in Kentucky rose steadily from 1.0 deaths per 100,000 persons in 1999 to 10.2 deaths per 100,000 persons in 2017.⁶ According to the CDC, in 2015, Kentucky and Ohio shared the 2nd highest overdose rate in the country. Data from 2013 onward shows that Kentucky has the 3rd highest drug overdose mortality rate in the country.⁷ Altogether, between 2012 and 2016, drug overdoses caused a total of 5,822 deaths in Kentucky. In 2017, there were 1,565 fatal drug overdoses in Kentucky, which is an increase to approximately 130 deaths per month. According to the National Institute on Drug Abuse, Kentucky has double the overdose rate of the national average.

6. Drug overdoses have become the leading cause of accidental death in Kentucky. In 2015, 102 opioid prescriptions were written for every 100 Kentucky residents, which was 1.5 times the national average. Kentucky's overdose fatalities, which were already high, increased

⁴ *Drilling into the DEA's pain pill database*, Washington Post, Jan. 17, 2019, available at <https://www.washingtonpost.com/graphics/2019/investigations/dea-pain-pill-database/>.

⁵ 2010 Demographic Profile Census, Kentucky, U.S. Census Bureau, available at https://factfinder.census.gov/faces/nav/jsf/pages/community_facts.xhtml?src=bkml.

⁶ National Institute on Drug Abuse, Virginia Opioid Summary, (last updated March 2019), available at <https://www.drugabuse.gov/opioid-summaries-by-state/kentucky-opioid-summary>

⁷ See <http://www.healthyamericans.org/reports/drugabuse2013/release.php?stateid=KY>.

dramatically in 2015. Overdose deaths of Kentucky residents, regardless of where the death occurred, and non-residents who died in Kentucky, numbered 1,249 in 2015.⁸ In 2015, drug overdoses accounted for 51.17% of Kentucky's statewide accidental deaths, more than motor vehicle accidents, fire, drowning and gunshot wounds combined. In 2015, opioids accounted for 46.63% of the statewide total of drug related fatal overdose victims.⁹ In 2016, the number of lives lost statewide to drug overdoses was nearly five-times that of car accidents.

7. Opioid abuse has reached epidemic levels in Kentucky. From February 1, 2016, to January 31, 2017, pharmacies in Kentucky filled prescriptions for 307,234,816 doses of Schedule II prescription drugs, which breaks down to 69 doses of Schedule II narcotics for every man, woman, and child in Kentucky. The progression from prescription opioids to the use of illicit drugs, particularly injectable heroin, is well documented, with approximately 75% of heroin users reporting that their initial drug use was through prescription.¹⁰ As Kentucky citizens who become addicted to prescription opioids have predictably migrated to illicit, but less expensive, opioids, namely heroin and fentanyl, overdoses have dramatically increased. Opioid-overdose

⁸ 2015 Overdose Fatality Report, Kentucky Office of Drug Control Policy, *available at* <https://odcp.ky.gov/Documents/2016%20ODCP%20Overdose%20Fatality%20Report%20Final.pdf>.

⁹ 2015 Annual Report, Office of the Kentucky State Medical Examiner, *available at* <https://odcp.ky.gov/Reports/2016%20annual%20report.pdf>.

¹⁰ Theodore J. Cicero, PhD et al., *The Changing Face of Heroin Use in The United States: A Retrospective Analysis of The Past 50 Years*, JAMA Psychiatry (2014); 71(7):821-826, doi:10.1001/jamapsychiatry.2014.366, *available at* <https://jamanetwork.com/journals/jamapsychiatry/fullarticle/1874575>.

reversal drug naloxone was administered in four out of every seven Emergency Medical Services runs; and on average, seven response calls per day were to drug-related incidents.¹¹

8. Opioids have endangered public health in Kentucky even beyond addiction and overdose. Addicts who are not killed by drug addiction experience a variety of health consequences (including non-fatal overdoses) and engage in a variety of risky drug-seeking behaviors. Widespread drug addiction imposes costs on the community including health care and substance abuse treatment costs – a substantial portion of which were provided by Plaintiffs – as well as other costs borne by the community, increased costs and burdens imposed on the criminal justice system and the costs associated with the lost productivity of addicts.¹² Since 2017, Kentucky Attorney General has brought nine lawsuits against opioid manufacturers, distributors and pharmacies for flooding Kentucky communities with dangerous prescription drugs.¹³

9. A study by the American Enterprise Institute concluded that, in 2015, Kentucky’s “cost per capita” resulting from the opioid crisis was \$2,412,¹⁴ or approximately \$10.5 billion total.

10. Children have been especially vulnerable to the opioid epidemic. Along with overdose deaths, the number and rate of neonatal abstinence syndrome (“NAS”) – a condition

¹¹ New Online Tool Uses Data to Show Impact of Opioids, (Oct. 9, 2016), *available at* <https://nkyhealth.org/2016/10/09/new-onlinetool-uses-data-to-show-impact-of-opioids/?search=opioid>.

¹² Alex Brill & Scott Ganz, *The Geographic Variation in the Cost of the Opioid Crisis*, at 1-4, Am. Enter. Inst. (Mar. 20, 2018), *available at* https://www.aei.org/wp-content/uploads/2018/03/Geographic_Variation_in_Cost_of_Opioid_Crisis.pdf

¹³ Office of the Kentucky Attorney General, *Litigation Against Pharmaceutical Industry*, <https://ag.ky.gov/fighting-drug-abuse/litigation>

¹⁴ Alex Brill & Scott Ganz, *The Geographic Variation in the Cost of the Opioid Crisis*, at 1-4, American Enter. Inst. (Mar. 20, 2018), *available at* https://www.aei.org/wp-content/uploads/2018/03/Geographic_Variation_in_Cost_of_Opioid_Crisis.pdf.

suffered by babies born to mothers addicted to opioids – has also increased dramatically in Kentucky. Kentucky has had one of the highest rates of pregnant women using opioids in the country. In 2014, Kentucky had the third-highest rate of pregnant women with opioid use disorder. In just one 12-month period, between August 1, 2014 and July 31, 2015, 1,234 infants in Kentucky were born addicted to opioids, more than 100 newborns per month. The number of NAS cases in Kentucky totaled 1,115 in 2016 based on hospital discharge data.¹⁵ In 2017, the number of babies born with NAS in Kentucky had increased by 375% since 2007. These infants usually will spend weeks in neonatal intensive care units while they painfully withdraw from the drugs – a process so painful that it traps many adults on opioids. Research has indicated that these children are likely to suffer from continued serious neurologic and cognitive impacts, including hyperactivity, attention deficit disorder, lack of impulse control, and a higher risk of future addiction. When untreated, NAS can be life-threatening.

11. Children are also left orphaned by multiple generations of family members lost to addiction.¹⁶ As of June 2017, there were over 8,000 children in foster care in Kentucky, compared to 6,000 in 2012, most commonly because of parent's abuse of drugs or alcohol. According to one foster-parent recruiter, the increasing number of children in foster care in

¹⁵ Kentucky Department of Public Health Division of Maternal and Child Health, *Annual Report, Neonatal Abstinence Syndrome In Kentucky*, (Jan. 2018), available at <https://chfs.ky.gov/agencies/dph/dmch/Documents/DPHNASReport2016.pdf>

¹⁶ Opioids orphan kids in Kentucky, Dec. 12, 2014, available at <https://www.cnn.com/2012/12/14/health/kentucky-overdoses/>.

Ashland, Kentucky has reached a “crisis point” as a result of the opioid epidemic.¹⁷ Children are also injured by the removal from their homes due to opioid abuse and opioid dependence.

12. Kentucky has seen an increase in blood-borne diseases caused by intravenous drug use, including hepatitis C (HCV) and human immunodeficiency (HIV). Intravenous use of opioids, which has been a particular problem with easy-to-inject Opana ER, has led to a surge in HCV in the state and created a risk of an even broader epidemic. Kentucky and other states in the central Appalachian region of the country experienced a 364% increase in reported acute HCV among individuals aged 30 years old or below between 2006 and 2012.¹⁸ Among the 220 U.S. counties identified by the CDC as the most vulnerable to HIV and HCV infections among people who inject drugs in the context of the national opioid epidemic, 54 were in Kentucky, primarily in rural communities.¹⁹ If untreated, hepatitis C continues to be transmitted, including in childbirth, and can ultimately cause liver cancer, fibrosis, or cirrhosis, and is the leading cause of liver transplants in the country.

13. The widespread use of opioids and corresponding increases in addiction and abuse have led to increased emergency room visits, emergency responses to overdoses, and emergency medical technicians’ administration of naloxone—an antidote to opioid overdose. In Louisville, the police force administered 123 doses of naloxone in just the first six weeks of 2017

¹⁷ States hit hard by opioid crisis see increase in foster care kids, North Jefferson News, Jan. 19, 2017.

¹⁸ Jon E. Zibbell, PhD et al., *Increases in Hepatitis C Virus Infection Related to Injection Drug Use Among Persons Aged ≤ 30 Years—Kentucky, Tennessee, Virginia, and West Virginia, 2006–2012*, Morbidity and Mortality Weekly Report (May 2015); 64(17):453–58, available at <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4584548/>.

¹⁹ Michelle Van Handel et al., *County-Level Vulnerability Assessment for Rapid Dissemination of HIV or HCV Infections Among Persons Who Inject Drugs, United States, 2016* JAIDS 73(3):323–331, (Nov. 2016), doi: 10.1097/QAI.0000000000001098, available at <https://insights.ovid.com/pubmed?pmid=27763996>.

— representing approximately three overdoses each day. It also has resulted in dramatic growth in drug-related crimes. There have been increases in domestic violence, robberies, burglaries, and thefts, among other crimes across Kentucky. An estimated 90% of defendants in Floyd County are prosecuted for crimes related to prescription drug abuse or diversion.

14. Over the last decade, Kentucky has lost over 11,000 coal mining jobs, according to the Kentucky Department of Energy. When the mining industry plummeted, other local businesses were also forced to close. The collapse of the coal industry forced many of the town's residents into joblessness and triggered a sense of hopelessness, which exacerbated the opioid crisis in the region. Abuse of prescription pain medication is especially widespread among the growing ranks of out-of-work miners, who were often prescribed opioid medications to deal with the rigors of the job.

15. From 2006 to 2014, certain Defendants and their co-conspirators topped the ARCOS data lists for the number of hydrocodone and oxycodone opioid pills that were tracked entering Kentucky from distributors: AmerisourceBergen Drug (584,198,415 pills); Cardinal Health (328,472,955 pills); Walgreen Co. (276,846,260 pills); Walmart (185,434,100 pills); and from manufacturers: Actavis Pharma, Inc. (1,047,559,999 pills); SpecGx LLC (716,919,264 pills); Par Pharmaceutical (435,584,240 pills); Amneal Pharmaceuticals LLC (81,686,293 pills); and Purdue Pharma LP (45,208,206 pills).

16. Across Kentucky, families and communities face heartbreaking tragedies that cannot be adequately conveyed by statistics, and they have faced them all too often. Many grieving families have been financially tapped out by the costs of repeated cycles of addiction treatment programs; others have lost hope and given up. The increasing number of cases takes both a physical and mental toll on investigators, first-responders, and hospitals such as Plaintiffs.

B. The Opioid Crisis Nationally

17. The United States is in the midst of an opioid epidemic caused by Defendants' unlawful marketing, sale, and distribution of opioids that has resulted in opioid dependence, criminal activity, serious health issues, and the loss of life.²⁰ According to the Centers for Disease Control and Prevention ("CDC"), from 1999 to 2014, the sales of opioids in the U.S. nearly quadrupled, but there was no overall change in the amount of pain that Americans reported.²¹

18. The United States constitutes 4.6% of the world's population, but consumed 80% of the world's opioid supply in 2011.²² According to the Centers for Disease Control and Prevention ("CDC"), from 1999 to 2014, the sales of opioids in the U.S. nearly quadrupled, but there was no overall change in the amount of pain that Americans reported.²³

19. It is undisputed that opioids are both addictive and deadly. Between 1999 and 2014, more than 165,000 Americans died of opioid overdose.²⁴ Deaths related to opioids are

²⁰ As used herein, the term "opioid" refers to the entire family of opiate drugs including natural, synthetic, and semi-synthetic opiates.

²¹ Centers for Disease Control and Prevention, *Prescribing Data*, available at <https://www.cdc.gov/drugoverdose/data/prescribing.html>, (last accessed August 1, 2018).

²² Donald Teater, Nat'l Safety Council, *The Psychological and Physical Side Effects of Pain Medications*, available at <https://www.colorado.gov/pacific/sites/default/files/Psychological%20and%20Physical%20Side%20Effects%20Teater%20NSC.pdf> (citing Daneshvari R. Solanki et al., *Monitoring Opioid Adherence in Chronic Pain Patients: Assessment of Risk of Substance Abuse*, PAIN PHYSICIAN JOURNAL, 14:E119-E131, (2011), available at <https://www.painphysicianjournal.com/current/pdf?article=MTQ0NQ%3D%3D&journal=60>).

²³ Centers for Disease Control and Prevention, *Prescribing Data*, available at <https://www.cdc.gov/drugoverdose/data/prescribing.html>, (last accessed Aug. 1, 2018).

²⁴ Deborah Dowell et al., *CDC Guideline for Prescribing Opioids for Chronic Pain – United States, 2016*, 65(1) Morbidity and Mortality Weekly Report (Mar. 2016), at 2, available at <https://www.cdc.gov/mmwr/volumes/65/rr/pdfs/rr6501e1.pdf> ("Dowell, CDC Guideline").

accelerating. In 2011, the CDC declared that opioid deaths had reached “epidemic levels.”²⁵ That year, 11,693 people died of opioid overdoses.²⁶ Since then, opioid deaths have *more than quadrupled*, reaching 47,600 Americans in 2017—more than ten times the number of Americans who died in the entire Iraq War.²⁷

20. According to the CDC, opioid overdoses killed more than 45,000 people over a 12-month timeframe that ended in September 2017. It is already the deadliest drug epidemic in American history.²⁸ If current trends continue, lost lives from opioid overdoses will soon represent the vast majority of all drug overdose deaths in the United States.

²⁵ Press Release, Centers for Disease Control and Prevention: Prescription Painkiller Overdoses at Epidemic Levels (Nov. 1, 2011), *available at* https://www.cdc.gov/media/releases/2011/p1101_flu_pain_killer_overdose.html (“Prescription Painkiller Overdoses at Epidemic Levels”).

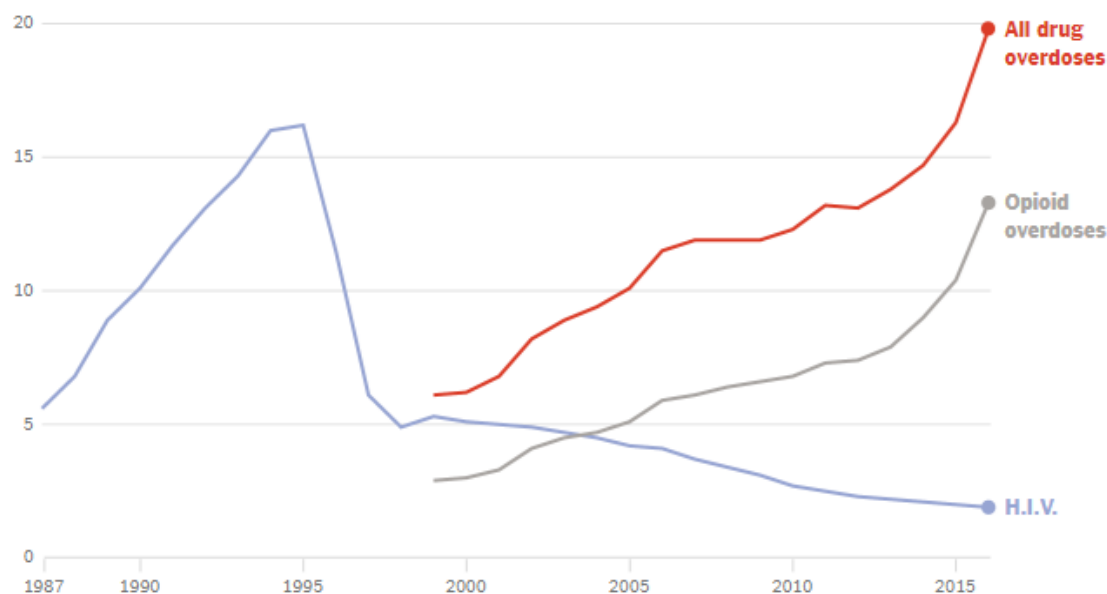
²⁶ Li Hui Chen et al., *Drug-poisoning Deaths Involving Opioid Analgesics: United States, 1999-2011*, 166 NCHS Data Brief (Sept. 2014), *available at* <https://www.cdc.gov/nchs/data/databriefs/db166.pdf>.

²⁷ U.S. Dep’t of Health and Human Services, *What is the U.S. Opioid Epidemic?* (Jan. 2019), <https://www.hhs.gov/opioids/about-the-epidemic/index.html>; German Lopez, *2017 was the worst year ever for drug overdose deaths in America*, VOX, Aug. 16, 2018, *available at* <https://www.vox.com/science-and-health/2018/8/16/17698204/opioid-epidemicoverdose-deaths-2017>.

²⁸ The Editorial Board, *An Opioid Crisis Foretold*, THE NEW YORK TIMES (April 21, 2018), *available at* <https://www.nytimes.com/2018/04/21/opinion/an-opioid-crisis-foretold.html>.

Lost Lives

Deaths in the U.S. per 100,000 people



Note: Drug overdose data available since 1999. Source: Centers for Disease Control and Prevention | By THE NEW YORK TIMES.²⁹

21. Between the start of the century and the year 2014, opioid-related death rates have increased by 200%, with 14% of that increase occurring between 2013 and 2014.

22. The opioid epidemic is killing scores of individuals each and every day and is having a similarly drastic impact on the total cost of medical care.

23. A particular tragedy of the opioid epidemic is that it has caused law-abiding citizens who experience routine injuries to become dependent on opioids, and, in many cases, has resulted in the total ruination of their lives.

24. The opioid epidemic is “directly related to the increasingly widespread misuse of powerful opioid pain medications.”³⁰ In many cases, heroin abuse starts with prescription opioid

²⁹ *Id.*

dependence. An inflated volume of opioids invariably leads to increased diversion and abuse. Indeed, there is a “parallel relationship between the availability of prescription opioid analgesics through legitimate pharmacy channels and the diversion and abuse of these drugs and associated adverse outcomes.”³¹ For most people who misuse opioids, the source of their drugs can typically be found in the excess supply of drugs in the community, beyond what is needed for legitimate medical purposes. Filling an opioid prescription is a significant risk factor for overdose.³²

25. According to the CDC, the United States is currently seeing the highest overdose death rate ever recorded.³³ Aside from overdose, long-term opioid use is associated with a significant increase in mortality from other causes.³⁴ As opioid-related deaths increase, the life expectancy in the United States decreases.³⁵

³⁰ See Robert M. Califf, *et al.*, *A Proactive Response to Prescription Opioid Abuse*, 374 N. Eng. J. Med. 1480 (Apr. 14, 2016), doi: 10.1056/NEJMSr1601307, available at <https://www.nejm.org/doi/full/10.1056/NEJMSr1601307> (“Califf *et al.*”).

³¹ Dart, Richard C., *et al.*, *Trends in Opioid Analgesic Abuse and Mortality in the United States*, 372 N. Eng. J. Med. 241 (2015), DOI: 10.1056/NEJMSa1406143, available at <https://www.nejm.org/doi/full/10.1056/nejmsa1406143>.

³² Dowell, CDC Guideline, *supra* n. 24, at 22-24.

³³ Jessica Glenza, *Opioid crisis: overdoses increased by a third across US in 14 months*, says CDC, The GUARDIAN (March 6, 2018), available at <https://www.theguardian.com/us-news/2018/mar/06/opioid-crisis-overdoses-increased-by-a-third-across-us-in-14-months-says-cdc>.

³⁴ Wayne A. Ray, *et al.*, *Prescription of Long-Acting Opioids and Mortality in Patients With Chronic Noncancer Pain*, 315(22):2415-2423, JAMA (Jun. 2016), doi:10.1001/jama.2016.7789, available at <https://jamanetwork.com/journals/jama/fullarticle/2528212>.

³⁵ National Center for Health Statistics, *Life Expectancy*, available at <https://www.cdc.gov/nchs/fastats/life-expectancy.htm>, (last accessed August 1, 2018); Centers for Disease Control and Prevention, U.S. drug overdose deaths continue to rise; increase fueled

26. On October 28, 2017, the President of the United States declared the opioid crisis a public health emergency.³⁶

27. This suit takes aim at the primary cause of the opioid crisis: A False Narrative marketing scheme, in which the Supply Chain Defendants joined and conspired, involving the false and deceptive marketing of prescription opioids, which was designed to dramatically increase demand for and sale of opioids and opioid prescriptions.

28. On the demand side, the Defendants who manufacture, sell and market opioid pain killers (the “Marketing Defendants and Purdue³⁷”) precipitated the crisis. These opioids have various brand names and generic names, and include OxyContin, fentanyl, hydrocodone, oxycodone, and others mentioned in this Complaint. Through a massive marketing campaign premised on false and incomplete information, the Marketing Defendants and Purdue engineered a dramatic shift in how and when opioids are prescribed by the medical community and used by patients.

29. The Marketing Defendants and Purdue relentlessly and methodically—but untruthfully—asserted that the risk of opioid dependence was low when opioids were used to treat chronic pain and overstated the benefits and trivialized the risk of the long-term use of opioids. Contrary to these assertions, opioids are extremely addictive. Studies have found

by synthetic opioids, (March 18, 2018), *available at* <https://www.cdc.gov/media/releases.2018/p0329-drug-overdose-deaths.html>.

³⁶ Julie Hirschfeld Davis, *Trump Declares Opioid Crisis a ‘Health Emergency’ but Requests No Funds*, THE NEW YORK TIMES (Oct. 26, 2017), *available at* <https://www.nytimes.com/2017/10/26/us/politics/trump-opioid-crisis.html>.

³⁷ The Purdue entities and individuals described in this Section are Co-Conspirators with the other Defendants charged in this Complaint. They are not charged as Defendants.

diagnosed opioid dependence rates in primary care settings as high as 26%.³⁸ Among opioid users who received four prescriptions in a year, 41.3% meet diagnostic criteria for a lifetime opioid-use disorder.³⁹ Because opioids cause tolerance and dependence, patients who take the drugs for even a short time become a physiologically captured market. According to the U.S. Department of Health and Human Services, more than two million Americans are opioid-dependent.⁴⁰ The difficulty in stopping use is particularly true for patients first prescribed an extended release opioid. Patients who initiated treatment on an extended release opioid – such as OxyContin – have a 27.3% likelihood to be using opioids one year later, and a 20.5% likelihood of using opioids three years later.⁴¹

30. Opioids pose high risks for children and adolescents. Most of the use in this population is off-label as opioids are not approved for children. Use of prescription opioid pain medication before high school graduation is associated with a 33% increase in the risk of later opioid misuse. The misuse of opioids in adolescents strongly predicts the later onset of heroin

³⁸ Dowell, CDC Guideline, *supra* n. 24, at 22-24.

³⁹ Joseph A. Boscarino, *et al.*, *Opioid-Use Disorder Among Patients on Long-Term Opioid Therapy: Impact of Final DSM-5 Diagnostic Criteria on Prevalence and Correlates*, 6:83-91, Substance Abuse and Rehabilitation (Aug. 2015), available at <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4548725/>; see also Joseph A. Boscarino, *et al.*, *Prevalence of Prescription Opioid-Use Disorder Among Chronic Pain Patients: Comparison of the DSM-5 vs. DSM-4 Diagnostic Criteria*, 30(3):185-94, *Journal of Addictive Diseases* (Sept. 2011), available at <https://www.ncbi.nlm.nih.gov/pubmed/21745041> (showing a 34.9% lifetime opioid use disorder).

⁴⁰ U.S. Dept. of Health and Human Services, *What is the U.S. Opioid Epidemic?* (Jan. 2019), available at <https://www.hhs.gov/opioids/about-the-epidemic/index.html>.

⁴¹ Anuj Shah *et al.*, *Characteristics of Initial Prescription Episodes and Likelihood of Long-Term Opioid Use – United States, 2006-2015*, 66(10):265-269, *Morbidity and Mortality Weekly Report* (Mar. 2017), available at <https://www.cdc.gov/mmwr/volumes/66/wr/mm6610a1.htm>.

use.⁴² Nonetheless, the 2016 CDC guidelines found that there have been significant increases in opioid prescribing for children and adolescents, for conditions such as headaches and sports injuries.

31. The Marketing Defendants' and Purdue's goal was simple: dramatically increase sales by convincing doctors to prescribe opioids not only for the kind of severe pain associated with cancer or short-term post-operative pain, but also for common chronic pain, such as back pain and arthritis. They did this even though they knew that opioids were addictive and subject to abuse, and that their claims regarding the risks, benefits, and superiority of opioids for long-term use were untrue and unfounded.

32. The Supply Chain Defendants saw the profit potential in opioid sales, participated in the conspiracy by ignoring their legal responsibilities, and flooded affected areas with opioids while knowing they were contributing to, and profiting from, widespread opioid dependence and human misery. The Supply Chain Defendants, through their willingness to uncritically supply whatever quantities of opioids pharmacies ordered, normalized overprescribing and caused widespread proliferation and availability of these dangerous drugs throughout communities in Kentucky.

33. Defendants succeeded. Opioid abuse has quickly become one of the nation's most pressing health management issues, not only because of its toll on patients, but increasingly because of the financial impact on hospitals and the rest of the healthcare system.⁴³

⁴² Dowell, CDC Guideline, *supra* n. 24.

⁴³ Jennifer Bresnick, *Hospitals Face Higher Costs, More ED Visits from Opioid Abuse*, HEALTHIT Analytics (Dec. 21, 2016), available at <https://healthitanalytics.com/news/hospitals-face-higher-costs-more-ed-visits-from-opioid-abuse> (last accessed on August 1, 2018).

34. The Marketing Defendants and Purdue and the Supply Chain Defendants extract billions of dollars of revenue from the opioid-dependent American public while hospitals sustain billions of dollars in losses caused as a result of the reasonably foreseeable consequences of the opioid dependence epidemic. In fact, Defendants depend on hospitals to mitigate the health consequences of their illegal activities – at no cost to Defendants – thereby permitting Defendants to perpetuate their wrongful scheme. Defendants knew that but for the hospitals providing at least some aspect of a safety net, the number of overdose deaths and other related health consequences arising from opioid dependence would have been far greater than actually occurred, and the public outcry and political backlash threatening their profitmaking activities would have been swifter and far more certain.

35. The Marketing Defendants and Purdue and Supply Chain Defendants have continued their wrongful, intentional, and unlawful conduct, despite their knowledge that such conduct has caused and/or is continuing to cause a national, state, and local opioid epidemic.

36. The deceptive marketing campaign of the Marketing Defendants and Purdue substantially contributed to an explosion in the use of opioids across the country. Approximately 20% of the population between the ages of 30 and 44, and nearly 30% of the population over 45 have used opioids. Opioids are the most common treatment for chronic pain, and 20% of office visits now include an opioid.

37. The sharp increase in opioid use resulting from Defendants' conduct has led directly to a dramatic increase in opioid abuse, dependence, overdose, and death throughout the United States, including Kentucky. Representing the NIH's National Institute of Drug Abuse in hearings before the Senate Caucus on International Narcotics Control in May 2014, Dr. Nora

Volkow explained that “aggressive marketing by pharmaceutical companies” is “likely to have contributed to the severity of the current prescription drug abuse problem.”⁴⁴

38. In August 2016, then U.S. Surgeon General Vivek Murthy published an open letter to physicians nationwide, enlisting their help in combating this “urgent health crisis” and linking that crisis to deceptive marketing. 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.”⁴⁵

39. In a 2016 report, the CDC explained that “[o]pioid prescribing has quadrupled since 1999 and has increased in parallel with [opioid] overdoses.”⁴⁶ Patients receiving opioids for chronic pain account for the majority of overdoses. For these reasons, the CDC concluded that efforts to rein in the use of opioids for chronic pain are critical “to reverse the epidemic of opioid drug overdose deaths and prevent opioid-related morbidity.”⁴⁷

⁴⁴ *America’s Addiction to Opioids: Heroin and Prescription Drug Abuse*, U.S. Senate, Caucus on International Narcotics Control, 113th Cong., at 3 (May 14, 2014) (statement). Testimony of Dr. Nora D. Volkow, Director, National Institute on Drug Abuse, *available at* <https://www.drugabuse.gov/about-nida/legislative-activities/testimony-to-congress/2014/americas-addiction-to-opioids-heroin-prescription-drug-abuse>.

⁴⁵ Letter from Vivek H. Murthy, M.D., U.S. Surgeon General, *available at* <http://www.turntheridex.org/> (last accessed July 23, 2018).

⁴⁶ Rose A. Rudd, *et al.*, Centers for Disease Control and Prevention, Increases in Drug and Opioid Overdose Deaths – United States, 2000-2014, 64(50); 1378-82, Morbidity and Mortality Weekly Report, *available at* <https://www.cdc.gov/mmwr/preview/mmwrhtml/mm6450a3.htm> (“2000-2014 Increases in Drug and Opioid Overdose Deaths”).

<https://www.cdc.gov/mmwr/preview/mmwrhtml/mm6450a3.htm>.

⁴⁷ *Id.*

40. Defendants' practice of continually filling opioid prescriptions, including from suspicious prescribers, and failing to report suspicious orders of opioids has enabled an oversupply of opioids to communities, including in the communities that Plaintiffs serve. The Supply Chain Defendants had financial incentives to distribute higher volumes of opioids and not to report suspicious orders or guard against diversion. Wholesale drug distributors acquire pharmaceuticals, including opioids, from manufacturers at an established wholesale acquisition cost. Discounts and rebates from this cost may be offered by manufacturers based on market share and volume. As a result, higher volumes may decrease the cost per pill to distributors. Decreased cost per pill in turn, allows wholesale distributors to offer more competitive prices, or alternatively, pocket the difference as additional profit.

41. Further, either explicitly or implicitly, all Defendants in this action worked together to stifle the reporting of suspicious orders. This is because even one defection and reporting to the DEA could have reduced the overall quantity of opioids allowed to be dispensed within the United States. Therefore, to ensure that profits remained artificially high, the Defendants worked together to ensure oversupply of the market.

42. The widespread use of opioids and corresponding increases in opioid dependence and abuse have led to increased emergency room visits, emergency responses to overdoses, and emergency medical technicians' administration of naloxone—the antidote to opioid overdose.

43. As communities work to restore their lives, the opioid epidemic continues to outpace their efforts.

C. The Impact of Opioids on Kentucky Hospitals

44. Hospitals—legally and morally—are compelled to act and treat patients with opioid-related conditions⁴⁸ and, as a result, are directly and monetarily damaged by the opioid epidemic. In addition to the cost of the opioid drugs themselves, hospitals have incurred and continue to incur millions of dollars in damages for the costs of unreimbursed, uncompensated and/or undercompensated care as a result of the unlawful marketing, distribution, and sale of opioids. Arguably, more than any other institution, hospitals directly and monetarily bear the brunt of the opioid crisis.

45. Because of defendants’ conduct, the opioid epidemic is placing an increasing strain on the overburdened health care system in Kentucky.

46. Plaintiffs are struggling from the relentless and crushing financial burdens caused by the epidemic of opioid dependence.

47. The effects of the opioid epidemic on hospitals may soon become even worse. The coverage rules under the Affordable Care Act (“ACA”) are in transition, thus creating the possibility of increased costs for hospitals for treatment of opioid-dependent patients admitted under the Emergency Medical Treatment and Labor Act (“EMTALA”), 42 U.S.C. § 1395dd.⁴⁹

⁴⁸ “Opioid-related conditions” include but are not limited to opioid addiction and overdose; psychiatric and mental health treatment; NAS or other opioid-related conditions of newborns; illnesses associated with opioid use, such as endocarditis, hepatitis-C, and HIV; surgical procedures that are more complex and expensive due to opioid addiction; illnesses or conditions claimed by a person with opioid addiction in order to obtain an opioid prescription; and any other condition identified in Plaintiffs’ records as related to opioid use and abuse.

⁴⁹ American Hospital Association, *AHA Priorities to Address the Opioid Crisis*, <https://www.aha.org/guidereports/2018-03-02-aha-priorities-address-opioid-crisis>, (last accessed August 1, 2018).

48. As a result of these statutes, hospitals in Kentucky must admit opioid-dependent patients who present themselves in need of intensive care or who display symptoms of mental illness. In addition, if an opioid-dependent patient is pregnant, and presents herself for treatment, hospitals also have to provide care for both the opioid-dependent mother and her opioid-dependent baby. As a result of the opioid dependence epidemic, including in the areas Plaintiffs serve, opioid-dependent patients routinely occupy beds in hospitals, including hospitals operated by Plaintiffs. Opioid-dependent mothers and babies routinely present themselves for admission at ERs and occupy beds in the NICUs, including those operated by Plaintiffs. Many of those patients have no insurance and do not pay for their care.

49. Plaintiffs encounter patients with opioid dependence on a daily basis. They must try to help patients who have serious medical conditions that require extra care and expense because the patient is dependent on opioids.

50. The statistics are startling. Adult hospitalizations due substantially to opioid-related medical conditions doubled from 2000 to 2012. From 2005 to 2014, emergency department visits exhibited a 99.4% cumulative increase.⁵⁰

51. Between 2005 and 2014 there was a dramatic increase nationally in hospitalizations involving opioids: the rate of opioid-related inpatient stays increased 64%, and the rate of opioid-related emergency department (“ED”) visits nearly doubled.⁵¹

⁵⁰ *Id.*

⁵¹ Audrey J. Weiss, *et al.*, *Patient Characteristics of Opioid-Related Inpatient Stays and Emergency Department Visits Nationally and by State, 2014* (June 2017), available at <https://www.hcup-us.ahrq.gov/reports/statbriefs/sb224-Patient-Characteristics-Opioid-Hospital-Stays-ED-Visits-by-State.pdf>.

52. The average health care costs for those diagnosed with an opioid use disorder were eight times higher than those without an opioid use disorder.⁵²

53. The cost to hospitalize opioid-dependent patients has more than tripled in a decade, up to nearly \$15 billion in 2012. Similarly, the number of patients hospitalized due to the effects of these drugs surged by more than 72% in 2012, although overall hospitalizations during that time stayed relatively flat.⁵³

54. Private insurance covers only a portion of those costs. The burden is carried by hospitals, patients, and government programs.⁵⁴ In 2012, hospitals provided almost \$15 billion for opioid-related inpatient care, more than double of what they billed in 2002.⁵⁵ A substantial portion of these costs were under-insured or unreimbursed, uncompensated, and/or undercompensated.

55. In 2012, an average hospital stay for a patient with an opioid-related condition cost about \$28,000 and only about 20% of the hospital stays related to those incidents were covered by private insurance. The number increased to \$107,000 if there was an associated infection, with merely 14% covered by insurance.⁵⁶

⁵² Alen G. White, PhD, *et al.*, *Direct Costs of Opioid Abuse in an Insured Population in the United States*, published in *Journal of Managed Care Pharmacy*, Vol. 11, No. 6, at 469 (July/August 2005), available at <http://www.amcp.org/data/jmcp/3.pdf>.

⁵³ Marty Stempniak, *Opioids Add to a Sharp Rise in Hospitalizations, Costs*, (May 5, 2016), <https://www.hhnmag.com/articles/7231-opioids-contribute-to-a-sharp-rise-in-hospitalizations-health-care-costs>, (last accessed on July 11, 2018).

⁵⁴ *Id.*

⁵⁵ Shefali Luthra, *Opioid Epidemic Fueling Hospitalizations, Hospital Costs*, KAISER HEALTH NEWS (May 2, 2016), available at <https://khn.org/news/opioid-epidemic-fueling-hospitalizations-hospital-costs/>.

⁵⁶ *Id.*

56. Patients with opioid dependence-related histories (medically and psychosocially) often cannot get treatment at skilled nursing facilities if they are discharged by hospitals. In Kentucky, there is nowhere for these patients to go other than hospitals due to the behavioral and security issues that are often associated with those who are dependent on opioids. As a result, they wind up staying in hospitals longer, resulting in the cost of care going up.

57. The cost of treating opioid overdose victims in hospital intensive care units jumped 58% in a seven-year span. Between 2009 and 2015, the average cost of care per opioid overdose admission increased from \$58,000 to \$92,400. This was during a period when the overall medical cost escalation was about 19%. This cost increase also highlights a troubling trend: overdose patients are arriving in worse shape, requiring longer stays and a higher level of treatment.⁵⁷

58. Pregnant women and their children have been significantly impacted by the opioid epidemic. There are negative consequences of drug use for pregnant women including increased risks of assault and abuse, miscarriage, and contracting hepatitis or HIV. Each year, thousands of infants are exposed to opioids while in the womb. Infants who are chronically exposed to opioids and other drugs will often experience a constellation of withdrawal signs after birth, collectively referred to as NAS.

59. The rates of opioid abuse during pregnancy have increased nationally and in Kentucky. There has been an almost four-fold increase in admissions to NICUs for NAS over the past decade: from seven cases per 1,000 NICU admissions in 2004, to 27 cases per 1,000 NICU admissions in 2012. Costs have been increasing rapidly.

⁵⁷ Casey Ross, *The Cost of Treating Opioid Overdose Victims is Skyrocketing*, STAT NEWS (August 11, 2017), available at <https://www.statnews.com/2017/08/11/opioid-overdose-costs/>.

60. NAS is such a problem in Kentucky that the Kentucky General Assembly enacted KRS § 211.676, which requires the reporting of NAS cases to the Department for Public Health, and KRS § 211.678, which calls for an annual report of de-identified, aggregate statistical data from this reporting.

61. The misconduct of Marketing Defendants and Purdue, Supply Chain Defendants, and others prompted Kentucky health care providers to prescribe, patients to take, and payors to cover opioids for the treatment of chronic pain. Through their marketing, the Marketing Defendants and Purdue and Supply Chain Defendants overcame barriers to widespread prescribing of opioids for chronic pain with deceptive messages about the risks, benefits, and sustainability of long-term opioid use. These harms were compounded by supplying opioids beyond what the market could bear, funneling so many opioids into Kentucky communities that the only logical conclusion was that the product was being diverted and used illicitly. The massive quantities of opioids that flooded into Kentucky as a result of Defendants' wrongful conduct has devastated communities across this State, including the communities served by Plaintiffs.

D. Financial Impact of Defendants' Activities on Plaintiffs

62. Plaintiffs have treated, and continue to treat, numerous patients for opioid-related conditions, including: (1) opioid overdose; (2) opioid dependence; (3) hepatitis C, HIV and other infections occurring as a result of intravenous drug use; (4) neonatal treatment in their NICU for babies born opioid-dependent, for which treatment is specialized, intensive, complex, lengthy and highly expensive; and (5) psychiatric and related treatment for patients with opioid dependence who present in need of mental health treatment programs.

63. Plaintiffs have incurred and continue to incur substantial unreimbursed, uncompensated, and/or undercompensated costs for their treatment of patients with opioid-

related conditions. These patients with opioid-related conditions seek treatment from Plaintiffs as a proximate result of the opioid epidemic created and engineered by Defendants. As a result, Plaintiffs' monetary losses with respect to treatment of these patients were and are foreseeable to Defendants and were and are the proximate result of Defendants' acts and omissions specified herein.

64. Plaintiffs also have incurred and continue to incur operational costs in the form of surgical procedures and other care that have been and are more complex and expensive than would otherwise be the case if the patients were not opioid affected. Surgical procedures on opioid affected patients have been and are complicated and costly and require special protective measures and related prescription drugs.

65. Additionally, individuals with opioid dependence have presented and continue to present themselves to Plaintiffs claiming to have illnesses and medical problems in an effort to obtain opioids. Plaintiffs have incurred and continue to incur operational costs related to the time and expenses in diagnosing, testing, and otherwise attempting to treat these individuals.

66. Increased numbers of opioid-dependent patients have continued to cause substantial financial burden on Plaintiffs. Plaintiffs have borne substantial reimbursement shortages when they have continued to treat opioid-dependent patients with opioid-related conditions or comorbidities. Plaintiffs' effective treatment of all patients has been affected by their treatment of opioid-dependent patients.

67. The costs incurred by Plaintiffs are the direct and proximate result of the opioid epidemic created and engineered by Defendants.

68. Because opioids are very dangerous and highly addictive drugs, it was foreseeable to Defendants that the increase in the use of opioids would result in a corresponding epidemic of

patients with opioid-related conditions going to hospitals for treatment, including to Plaintiffs. It was foreseeable to Defendants that Plaintiffs would suffer substantial monetary losses because of the opioid epidemic, because hospitals are on the front line of treatment for these patients and must bear the additional costs of treatment.

69. Plaintiffs have purchased and continue to purchase and administer opioids marketed and sold by Defendants. Defendants have marketed and continue to market their opioid products directly to Plaintiffs, their pharmacy representatives and their doctors. Defendants directly marketed their opioid products through the False Narrative campaign. Plaintiffs are direct customers and victims of Defendants' false, deceptive, and unfair marketing of opioids described hereafter.

70. Plaintiffs have purchased opioids from Defendants, have used them as falsely and deceptively marketed by Defendants, and have suffered damages as a direct and proximate result of Defendants' acts and omissions as described in this Complaint.

71. Plaintiffs would not have purchased the quantity of opioids they had from Defendants had they known the truth about Defendants' false marketing scheme, *i.e.* that Defendants' claims regarding the risks, benefits, and superiority of opioids for long-term use were untrue and unfounded, as described herein.

72. Plaintiffs bring this civil action to recover monetary losses that they have incurred as a direct and proximate result of Defendants' false, deceptive, unfair marketing and distribution of opioids. Such economic damages were foreseeable to Defendants and were sustained because of Defendants' unlawful actions and omissions.

73. Plaintiffs bring this suit against the manufacturers of opioids. The manufacturers aggressively pushed highly addictive, dangerous opioids, falsely representing to doctors that

patients would only rarely succumb to drug dependence. These pharmaceutical companies aggressively advertised to and persuaded hospitals and their doctors to purchase and prescribe highly addictive, dangerous opioids, and turned patients into opioid-dependent patients for their own corporate profit. Such actions were unlawful.

74. Plaintiffs also bring this suit against the Supply Chain Defendants of these highly addictive drugs. In addition to participating in the False Narrative campaign, the Supply Chain Defendants (along with the Manufacturers) unlawfully breached their legal duties under Kentucky law to monitor, detect, investigate, report, and refuse to fill suspicious orders of opiates, which enabled the manufacturers' deceptive advertising to increase sales and distribution of their products to hospitals, including Plaintiffs.

E. The Role of Defendants in Causing and Perpetuating the Opioid Crisis

75. The Marketing Defendants' and Purdue's push to increase opioid sales worked. Through publications and websites, endless streams of sales representatives, "education" programs, and other means, the Marketing Defendants and Purdue dramatically increased their sales of opioids and reaped billions of dollars of profit as a result. Since 1999, the amount of opioids sold in the U.S. has nearly quadrupled. In 2016, 289 million prescriptions for opioids were filled in the U.S.—enough to medicate every adult in America around the clock for a month.

76. On the supply side, the crisis was fueled and sustained by those involved in the supply chain of opioids, including manufacturers and distributors, who failed to maintain effective controls over the distribution of opioids, and who instead have actively sought to evade such controls. Defendants have contributed substantially to the opioid crisis by selling and distributing far greater quantities of opioids than they know should be necessary for legitimate medical uses, while failing to report, and take steps to halt, suspicious orders when they were

identified, thereby exacerbating the oversupply of such drugs and fueling an illegal secondary market.

77. From the day they made the pills to the day those pills were consumed in each community, the Marketing Defendants and Purdue had control over the information regarding addiction they chose to spread and emphasize as part of their massive marketing campaign. By providing misleading information to doctors about addiction being rare and opioids being safe even in high doses, then pressuring those doctors into prescribing their products by arguing, among other things, that no one should be in pain, especially chronic pain, the Marketing Defendants and Purdue created a population of opioid-dependent patients who sought opioids at never-before-seen rates. The scheme worked, although perversely, and through it the Marketing Defendants and Purdue caused their profits to soar as more and more people became dependent on opioids.

78. Defendants systematically and repeatedly disregarded the health and safety of the public. Charged by law to monitor and report dangerous behavior, they failed to do so in favor of maximizing corporate profits and increasing their market share.

79. Corporate greed and callous indifference to the known, serious potential for human suffering and death have caused this public health crisis. Defendants unleashed a healthcare crisis that has had far-reaching financial and social consequences in this country, including opioid dependence and death.

80. The Marketing Defendants and Purdue 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 thus advocated that the signs of addiction should be treated with more opioids; (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; (6) promoted the falsehood that long-term opioid use improves functioning; (7) misrepresented the effectiveness of time-released dosing, and, in particular, the effectiveness of a version of OxyContin that purportedly provided twelve hours of pain relief; and (8) exaggerated the effectiveness of “abuse-deterrent” opioid formulations to prevent abuse, addiction and death.

81. The Marketing Defendants and Purdue disseminated these common messages to reverse the popular and medical understanding of opioids. They disseminated these messages directly, through their sales representatives, and in speaker groups led by physicians who were recruited by and paid by the Marketing Defendants and Purdue for their support of the Marketing Defendants’ and Purdue’s marketing messages.

82. The Marketing Defendants and Purdue also worked through third parties they controlled by: (a) funding, assisting, encouraging, and directing doctors, known as “key opinion leaders” (“KOLs”) and (b) creating, funding, assisting, directing, and/or encouraging seemingly neutral and credible professional societies and patient advocacy groups (hereinafter “Front Groups”). The Marketing Defendants and Purdue then worked together with those KOLs and Front Groups to profoundly influence, and at times control, 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, the Marketing Defendants and Purdue persuaded doctors and patients that what they had long known – that opioids are addictive drugs, unsafe in most circumstances for long-term use – was untrue, and quite the opposite, that the compassionate treatment of pain *required* opioids.

83. Each Marketing Defendant and Purdue knew that its misrepresentations of the risks and benefits of opioids were not supported by or were directly contrary to the scientific evidence. Indeed, the falsity of each Defendant's misrepresentations has been confirmed by the U.S. Food and Drug Administration ("FDA") and the CDC, including by CDC's *Guideline for Prescribing Opioids for Chronic Pain*, issued in 2016 and approved by the FDA.⁵⁸

84. The Supply Chain Defendants facilitated the supply of far more opioids than could have been justified to serve the legal and appropriate market. The failure of Supply Chain Defendants to Maintain effective controls, and to investigate, report, and take steps to halt orders that they knew or should have known were suspicious, breached both their statutory and common law duties.

85. For over a decade, the Supply Chain Defendants aggressively sought to bolster their revenue, increase profit, and grow their share of the prescription painkiller market by unlawfully and surreptitiously increasing the volume of opioids they sold. However, Supply Chain Defendants are not permitted to engage in a limitless expansion of their sales through the unlawful sales of regulated painkillers. Rather, as described below, multiple sources impose duties on the Supply Chain Defendants to maintain effective controls against diversion and to prevent oversupply into the illicit market.

86. As facilitated and caused by Supply Chain Defendants' actions, opioids' distribution has skyrocketed.

⁵⁸ See Centers for Disease Control and Prevention, *Guideline for Prescribing Opioids For Chronic Pain*, available at https://www.cdc.gov/drugoverdose/pdf/guidelines_factsheet-a.pdf (last accessed August 1, 2018); Pat Anson, *FDA Endorses CDC Opioid Guidelines*, PAIN NEWS NETWORK (Feb. 4, 2016), available at <https://www.painnewsnetwork.org/stories/2016/2/4/fda-endorses-cdc-opioid-guidelines>.

II. JURISDICTION AND VENUE

87. This Court has subject matter jurisdiction pursuant to KRS § 23A.010.

88. The Court has personal jurisdiction over Defendants because at all relevant times Defendants engaged in substantial business activities in Kentucky and purposefully directed their actions towards Kentucky, voluntarily submitted to the jurisdiction of Kentucky when obtaining a manufacturer or distributor license and have the requisite minimum contacts with Kentucky necessary to constitutionally permit this Court to exercise jurisdiction.

89. Venue is proper in Johnson County on multiple grounds: (a) under KRS § 452.450 for the reason that one or more of Defendants has a place of business in the Commonwealth or has an agent who resides in the Commonwealth and such Defendant(s) has committed tortious conduct in Johnson County; (b) under KRS § 452.460 for the reason that the injuries to Plaintiffs occurred, in part, in Johnson County; (c) for Defendants subject to Kentucky's long-arm jurisdiction, under KRS 454.210(4) for the reason that one of the Plaintiff hospitals has legal residence in Johnson County and, for all Plaintiff hospitals, because Defendants' tortious conduct occurred, in part, in Johnson County; (d) under KRS § 367.190(1) for the reason that unlawful methods, acts and/or practices of Defendants were committed in Johnson County; or (e) under KRS § 452.480 for the reason that one or more of Defendants reside or may be summoned in Johnson County.

90. This action is non-removable because there is incomplete diversity of residents and no substantial federal question is presented.

III. PARTIES

A. Plaintiffs

91. Plaintiff Paintsville Hospital Company, LLC is a Kentucky limited liability company with its principal business office located in Paintsville, Kentucky. Quorum Health

Investment Company, LLC, a Delaware limited liability company, is a member of Paintsville Hospital Company, LLC. Paintsville Hospital Company, LLC operates and does business as Paul B. Hall Regional Medical Center (“PBHRM”) located in Paintsville, Kentucky. PBHRM is licensed for a total of 72 acute-care beds, serving patients in Johnson County, Kentucky and surrounding areas.

92. Plaintiff Jennie Stuart Medical Center, Inc. is a Kentucky nonprofit corporation with its principal business office located in Hopkinsville, Kentucky. Jennie Stuart Medical Center, Inc. operates and does business as Jennie Stuart Medical Center located in Hopkinsville, Kentucky, a facility licensed for a total of 182 acute-care beds and 12 geriatric psychiatric beds, serving patients in Christian County, Kentucky and surrounding areas.

93. Plaintiff Hardin County, Kentucky d/b/a Hardin Memorial Hospital (“Hardin Memorial”) is a non-profit, county-owned hospital located in Elizabethtown, Kentucky whose Board of Trustees consist of members of the Hardin County Fiscal Court. Hardin Memorial is licensed for a total of 270 acute-care beds and 15 adult psychiatric beds, serving patients in Hardin County, Kentucky and surrounding areas.

94. Plaintiff T.J. Samson Community Hospital (“T.J. Samson”) is a Kentucky nonprofit corporation with its principal business office located in Glasgow, Kentucky. T.J. Samson is licensed for a total of 180 acute-care beds, serving patients in Barren County, Kentucky and surrounding areas.

95. Plaintiff Saint Joseph Health System, Inc. is a Kentucky nonprofit corporation with its principal business office located in Lexington, Kentucky. Saint Joseph Health System, Inc. operates and does business as CHI Saint Joseph Health – Saint Joseph Hospital, CHI Saint Joseph Health – Saint Joseph Berea, CHI Saint Joseph Health – Saint Joseph East, CHI Saint

Joseph Health – Saint Joseph London, and CHI Saint Joseph Health – Saint Joseph Mount Sterling. Saint Joseph Health System, Inc. is licensed for a total of 842 acute-care beds and 25 critical access beds, serving patients in Madison, Fayette, Laurel, and Montgomery counties in Central and Southern Kentucky and surrounding areas.

96. Flaget Healthcare, Inc. d/b/a Flaget Memorial Hospital (“Flaget”) is a Kentucky nonprofit corporation with its principal business office located in Lexington, Kentucky. Flaget is licensed for a total of 40 acute-care beds, serving patients in Nelson County, Kentucky and surrounding areas.

97. Plaintiff Hospital of Louisa, Inc. is a Kentucky profit corporation with its principal business office located in Louisa, Kentucky. Hospital of Louisa, Inc. operates and does business as Three Rivers Medical Center located in Louisa, Kentucky, a facility licensed for a total of 90 acute-care beds, serving patients in Lawrence County, Kentucky and surrounding areas.

98. Plaintiff Jackson Hospital Corporation is a Kentucky corporation with its principal business office located in Jackson, Kentucky. Jackson Hospital Corporation operates and does business as Kentucky River Medical Center located in Jackson, Kentucky. Kentucky River Medical Center is licensed for a total of 55 acute-care beds, serving patients in Breathitt County, Kentucky and surrounding areas.

B. Defendants and Co-Conspirators

1. Marketing Defendants and Co-Conspirators

a. Purdue

99. The Purdue entities and individuals described in this Section are Co-conspirators with the other Defendants charged in this complaint. They are not charged as Defendants.

i. Purdue Co-Conspirators⁵⁹

100. Co-conspirators Purdue Pharma L.P. (“PPL”) is a limited partnership organized under the laws of Delaware with its principal place of business in Stamford, Connecticut.

101. Co-conspirators Purdue Pharma Inc. (“PPI”) is a New York corporation with its principal place of business in Stamford, Connecticut, and is the general partner of Purdue Pharma, L.P.

102. Co-conspirators The Purdue Frederick Company, Inc. (“PFC”) is a New York corporation with its principal place of business in Stamford, Connecticut.

103. Co-conspirator Rhodes Pharmaceuticals L.P., is a limited partnership organized under the laws of Delaware with its principal place of business in Coventry, Rhode Island. Rhodes Pharmaceuticals L.P. has one general partner, Rhodes Pharmaceuticals, Inc.; and one limited partner, Coventry Technologies L.P., which holds Rhodes Pharmaceuticals L.P.’s shares. Coventry Technologies L.P. is a Delaware limited partnership with its principal place of business in Stamford, Connecticut. Its general partner is Purdue Pharma, Inc.

104. Co-conspirator Rhodes Technologies Inc. is a corporation organized under the laws of Delaware with its principal place of business in Coventry, Rhode Island. Rhodes Technologies is a Delaware general partnership with its principal place of business in Coventry, Rhode Island. Rhodes Technologies Inc. is the general partner of Rhodes Technologies and is a subsidiary of Purdue Pharma, L.P. (Rhodes Technologies and Rhodes Pharmaceuticals are collectively referred to as “Rhodes”). Rhodes manufactures and distributes generic opioids, including authorized generic versions of OxyContin and Butrans. Rhodes Technologies also

⁵⁹ Purdue Pharma Inc. and certain affiliated business entities have filed for bankruptcy protection. Plaintiffs do not intend to name any of the Purdue entities as defendants in this action, but identify them as Co-Conspirators with certain persons who are named as defendants.

manufacturers the active pharmaceutical ingredient in drugs including Purdue's OxyContin.⁶⁰ Among the drug products manufactured by Rhodes is buprenorphine, a drug used to treat opioid dependence.

105. PPL, PPI, PFC, Rhodes and their subsidiaries and affiliates (collectively, "Purdue-Co-conspirators") engaged in the manufacture, promotion, distribution, and sale of opioids nationally and in Kentucky including OxyContin, MS Contin, Dilaudid, Dilaudid-HP, Butrans, Hysingla ER and Targiniq ER.

ii. Purdue Individual Co-Conspirators

106. The following individuals, all members of the Sackler family that beneficially owns Purdue, have served on the Board of Purdue during the relevant times indicated in parenthesis:

- 107. Richard Sackler (at all pertinent times until 2018⁶¹), a resident of Florida;
- 108. Beverly Sackler (all pertinent times until 2017), a resident of Connecticut;
- 109. David Sackler (2012-18), a resident of New York;
- 110. Ilene Sackler Lefcourt (all pertinent times), a resident of New York;
- 111. Jonathan Sackler (all pertinent times), a resident of Connecticut;
- 112. Kathe Sackler (all pertinent times), a resident of Connecticut;
- 113. Mortimer D.A. Sackler (all pertinent times), a resident of New York⁶²; and

⁶⁰ At various times, Defendant Mallinckrodt also supplied Purdue with oxycodone.

⁶¹ Defendant Beverly Sackler left the Board in 2017. Defendants Richard, David and Theresa Sackler left the Board in 2018. Defendants Jonathan Sackler, Ilene Sackler Lefcourt, Kathe Sackler, and Mortimer D.A. Sackler remain on the Board.

114. Theresa Sackler (all pertinent times until 2018), a resident of the United Kingdom.

115. The foregoing individuals (collectively, the “Sackler Co-Conspirators”) controlled Purdue’s misconduct. Each of them took a seat on the Board of Directors of Purdue Pharma Inc. Together, the Sackler Co-Conspirators, at all pertinent times, constituted a majority of Board, which gave them full power over Purdue. They directed and otherwise participated in Purdue’s deceptive sales and marketing practices, sending hundreds of orders to executives and other employees.

116. While the Sackler Co-Conspirators relinquished their officer titles in or around 2003 to try to shield themselves from future criminal and civil liability, they remained Purdue’s owners, in control of its Board of Directors, and thus in firm control.

117. At all pertinent times, at least through the end of 2018, the Sackler Co-Conspirators controlled Purdue’s deceptive sales campaign. They directed the company to hire hundreds more sales representatives to visit doctors thousands more times. They insisted that sales representatives repeatedly visit the most prolific prescribers. They directed representatives to encourage doctors to prescribe more of the highest doses of opioids. They studied unlawful tactics to keep patients on opioids longer and then ordered Purdue staff to implement these unlawful tactics. They asked for detailed reports about doctors suspected of misconduct, how much money Purdue made from them, and how few of them Purdue had reported to the authorities. They sometimes demanded more detail than anyone else in the entire company, so staff had to create special reports just for them. Richard Sackler even went into the field to

⁶² References to “Mortimer D.A. Sackler” in this Complaint are to Mortimer David Alfons Sackler. Mortimer Sackler’s father, the late Mortimer D. Sackler, was also involved in Purdue Pharma during his lifetime.

promote opioids to doctors and supervise representatives face to face. In connection with a single meeting in 2011, for example, sales and marketing staff scrambled to prepare responses to questions from the Sackler Co-Conspirators as follows: Co-Conspirator Mortimer D.A. Sackler asked about launching a generic version of OxyContin to “capture more cost sensitive patients;” Co-Conspirator Kathe Sackler recommended looking at the characteristics of patients who had switched to OxyContin to see if Purdue could identify more patients to convert; and Co-Conspirator Jonathan Sackler wanted to study changes in market share for opioids, focusing on dose strength.

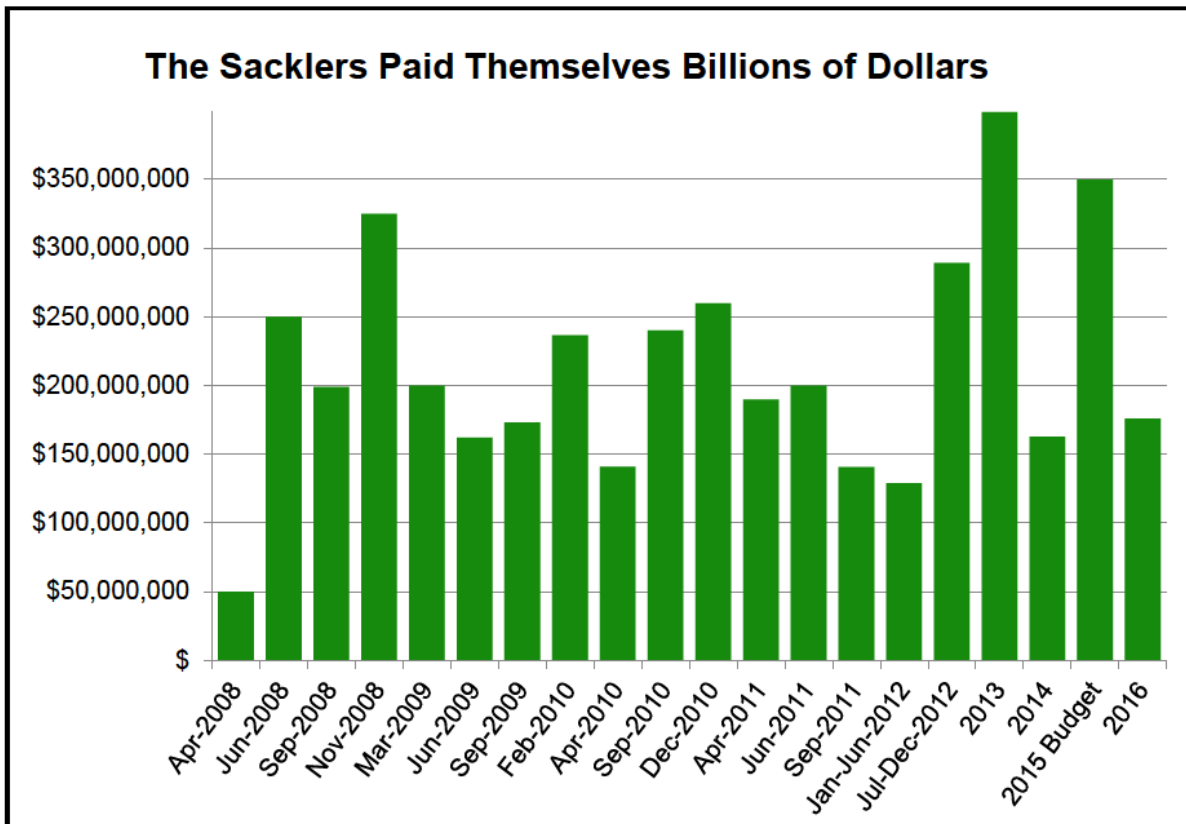
118. The Sackler Co-Conspirators’ micromanagement was so intrusive that staff begged for relief. Co-Conspirator Gasdia (identified below) wrote to the CEO: “Anything you can do to reduce the direct contact of Richard into the organization is appreciated.” To convince the Sackler Co-Conspirators to make him CEO, Co-Conspirator Landau wrote a plan that he titled: “SACKLER PHARMA ENTERPRISE.” He started by admitting that the Sackler Co-Conspirators in fact controlled the company like chief executive officers. The family ran “the global Sackler pharmaceutical enterprise ... with the Board of Directors serving as the ‘de-facto’ CEO.”

119. The Sackler Co-Conspirators concealed their extensive involvement at all costs. In 2000, the Sackler Co-Conspirators were warned that a reporter was “sniffing about the OxyContin abuse story.” The Sackler Co-Conspirators put the threat on the agenda for the next Board meeting and began covering their tracks. They planned a response that “deflects attention away from the company owners.” More recently, in November 2016, staff prepared statements to the press denying the Sackler Co-Conspirators’ involvement in Purdue. Their draft claimed: “Sackler family members hold no leadership roles in the companies owned by the family trust.”

A staff member reviewing the draft knew what was up and commented with apparent sarcasm: “Love the ... statement.” Staff eventually told the press: “Sackler family members hold no management positions.” Some employees worried about the deception. When journalists asked follow-up questions about the Sackler Co-Conspirators, communications staff deliberated about whether to repeat the “no management positions” claim. They double-checked that Purdue’s top lawyers had ordered the statement. Then they arranged for one of the Sackler Co-Conspirators’ foreign companies to issue it, so U.S. employees would not be blamed: “The statement will come out of Singapore.”

120. Most of all, the Sackler Co-Conspirators cared about money. Millions of dollars were not enough. They wanted billions. They cared more about money than about patients, or their employees, or the truth. In 1999, when employee Michael Friedman reported to Co-Conspirator Richard Sackler that Purdue was making more than \$20,000,000 per week, Richard replied immediately, at midnight, that the sales were “not so great.” “After all, if we are to do 900M this year, we should be running at 75M/month. So it looks like this month could be 80 or 90M. Blah, humbug. Yawn. Where was I?” Missives of this nature from Richard to Purdue’s ostensible management were a routine, if not daily, occurrence. There was no such thing as enough.

121. From the money that Purdue collected as a result of its wrongful conduct, they paid themselves and their family billions of dollars. From the 2007 convictions (of certain Purdue officers) until 2018, the Sackler Co-Conspirators voted dozens of times to pay out Purdue’s opioid profits to their family - in total ***more than four billion dollars***.



122. When the Sackler Co-Conspirators directed Purdue to pay their family, they knew and intended that they were paying themselves from opioid sales in Kentucky. Purdue and the Sackler Co-Conspirators tracked revenue from Kentucky.

123. In order to enhance their own and Purdue's social standing and prestige, the Sackler Co-Conspirators endowed many cultural, educational and scientific institutions, many of which bear their family name, including many academic programs at Harvard University and Tufts University in Massachusetts, the New York Academy of Sciences, Columbia University, Dia Art Foundation, the Metropolitan Museum of Art and the Guggenheim art museum, all in New York, London's Victoria and Albert Museum, and the Louvre in Paris. There is a Sackler gallery at the Princeton University Art Museum and Sackler museums at Harvard University and Peking University in Beijing. The Sackler Co-Conspirators and their relatives include many prominent New York and international socialites.

124. Co-Conspirators John Stewart (CEO from 2007 to 2013), Mark Timney (2014 to 2017), a resident of Connecticut, and Co-Conspirator Craig Landau (2017 to the present), a resident of Connecticut, each directed Purdue's deception as CEO of Purdue Pharma Inc. and Russell Gasdia, a resident of Massachusetts and Vice President of Sales and Marketing for Co-Conspirator Purdue Pharma L.P. at all pertinent times until June 2014, carried out the misconduct. The Co-Conspirators named in this paragraph are collectively referred to as the "Purdue Officer Co-Conspirators."

125. The Sackler Co-Conspirators and the Purdue Officer Co-Conspirators are collectively referred to as the "Purdue Individual Co-Conspirators." Purdue Co-Conspirators and Purdue Individual Co-Conspirators are collectively referred to as "Purdue."

126. The Purdue Co-Conspirators all actively participated in the common law torts and statutory violations of Purdue and benefited therefrom. The tortious conduct of the Purdue Individual Co-Conspirators was not, and could not have been, through the exercise of due diligence, known to the public until their conduct was detailed in recent court filings by the Attorney General of Massachusetts.

127. 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, including to Plaintiffs. OxyContin is Purdue's best-selling opioid. Since 2009, Purdue's annual nationwide 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 (painkillers).

128. In 2007, Purdue settled criminal and civil charges against it for misbranding OxyContin and agreed to pay the United States \$635 million – one of the largest settlements with

a drug company for marketing misconduct. In the same year, Purdue settled with 27 states for its Consumer Protection Act violations regarding Purdue's extensive off-label marketing of OxyContin and Purdue's failure to adequately disclose abuse and diversion risks associated with the drug. None of this stopped Purdue. In fact, Purdue continued to create the false perception that opioids were safe and effective for long-term use, even after being caught, by using unbranded marketing methods to circumvent the system. In short, Purdue paid the fine when caught and then continued business as usual, deceptively marketing and selling billions of dollars of opioids each year. Substantially all of the Sackler Co-Conspirators (all of those except David Sackler) were heavily involved in the conduct that led to the fines and criminal convictions in 2007. The misconduct of Richard, Beverly, Ilene, Jonathan, Kathe, Mortimer, and Theresa Sackler was particularly unfair, deceptive, unreasonable, and unlawful because they already had been given a second chance. From the 1990s until 2007, they directed a decade of misconduct, which led to criminal convictions, court judgment, and commitments that Purdue would not deceive doctors and patients again. That background confirms that their misconduct since 2007 was knowing, purposeful, reckless, and intentional.

129. Each of the Purdue Individual Co-Conspirators acted directly and through agents to transact business and cause injury in Kentucky.

130. Purdue employed scores of sales representatives in Kentucky to promote Purdue's opioids in Kentucky and sold hundreds of millions of dollars of opioids in Kentucky.

131. The Sackler Co-Conspirators and Purdue Officer Co-Conspirators voted for and/or directed sales representatives to go door-to-door, making thousands of visits to doctors in Kentucky. Although they did not knock on the doors to clinics and family practices themselves, these individuals voted for and/or ordered sales representatives to deceptively promote Purdue's

dangerous drugs in person, as a central facet of their deceptive marketing scheme that killed hundreds of people in Kentucky.

132. The Sackler Co-Conspirators and Purdue Officer Co-Conspirators voted for and/or directed payments to Kentucky doctors to promote Purdue's drugs.

133. The Sackler Co-Conspirators and Purdue Officer Co-Conspirators all directed the dissemination of tens of thousands of copies of unfair or deceptive marketing materials to doctors and other health care providers throughout Kentucky for the purpose of getting more and more prescribers to put their patients on Purdue's drugs for longer and longer periods of time at higher and higher doses. These individuals voted for and/or managed a chain-of-command causing these mailings in Kentucky because they meant increased sales and profits for the Sackler Co-Conspirators and their executives.

134. This misconduct caused tortious injury in Kentucky by killing hundreds of people and injuring many more.

b. Cephalon and Associated Companies

135. Defendant Cephalon, Inc. is a Delaware corporation with its principal place of business in Frazer, Pennsylvania. Teva Ltd. Acquired Cephalon in October 2011, and Cephalon Inc. became a wholly owned subsidiary of Defendant Teva Ltd.

136. Defendant Teva Pharmaceutical Industries, Ltd. ("Teva Ltd.") is an Israeli corporation with its principal place of business in Petah Tikva, Israel. Teva Ltd. is traded on the New York Stock Exchange (NYSE: TEVA). In its 2018 Form 10-K filed with the Securities and Exchange Commission, Teva Ltd. stated that it is the leading generic drug company in the United States. Teva Ltd. operates globally, with significant business transactions in the United States. In 2018, its gross profit from North American operations was \$4.979 million.

137. Teva Pharmaceuticals USA, Inc. (“Teva USA”) is a Delaware corporation with its principal place of business in North Wales, Pennsylvania, and is a wholly owned subsidiary of Teva, Ltd.

138. Teva USA and Cephalon, Inc. work together closely to market and sell Cephalon products in the United States. Since its acquisition of Cephalon in October 2011, Teva USA has conducted all sales and marketing activities for Cephalon in the United States, through its “specialty medicines” division. Teva USA and Cephalon, Inc. worked together to manufacture, promote, sell, and distribute opioids such as Actiq and Fentora in the United States. Teva USA holds out Actiq and Fentora as Teva products to the public. The FDA-approved prescribing information and medication guide, which is distributed with Cephalon opioids, 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, display Teva Ltd.’s logo.⁶³

139. Teva USA’s parent company, Teva Pharmaceuticals Industries, Ltd. lists Cephalon and Teva USA’s sales as its own on its financial reports, and its year-end report for 2012 – the year immediately following the Cephalon acquisition – attributed a 22% increase in its specialty medicine sales to “the inclusion of a full year of Cephalon’s specialty sales,” including sales of Fentora.⁶⁴ Actiq has been approved by the FDA only for the “management of breakthrough cancer pain in patients 16 years and older with malignancies who are already receiving and who are tolerant to around-the-clock opioid therapy for the underlying persistent

⁶³ *E.g.*, ACTIQ, available at <http://www.actiq.com/> (displaying logo at bottom-left) (last accessed August 1, 2018).

⁶⁴ Teva Ltd., Annual Report (Form 20-F), at 62 (Feb. 12, 2013), available at http://annualreports.com/HostedData/AnnualReportArchive/t/NASDAQ_TEVA_2012.pdf.

cancer pain.”⁶⁵ Fentora has been approved by the FDA only for the “management of breakthrough pain in cancer patients 18 years of age and older who are already receiving and who are tolerant to around-the-clock opioid therapy for their underlying persistent cancer pain.”⁶⁶ In 2008, Cephalon pled guilty to a criminal violation of the Federal Food, Drug and Cosmetic Act for its misleading promotion of Actiq and two other drugs, and agreed to pay a \$425 million fine.⁶⁷

140. Teva USA also sells generic opioids in the United States, including generic opioids previously sold by Allergan plc, whose generics business Teva Ltd., Teva USA’s parent company based in Israel, acquired in August 2016.

141. Teva USA and Cephalon Inc. are collectively referred to herein as “Cephalon.”

142. From 2000 forward, Cephalon has made thousands of payments to physicians nationwide, including in Kentucky, ostensibly for activities including participating on speakers’ bureaus, providing consulting services, assisting in post-marketing safety surveillance and other services, many of whom were not oncologists and did not treat cancer pain, but, in fact, these activities were used by Cephalon to deceptively promote and maximize the use of opioids.

⁶⁵ *Highlights of Prescribing information, ACTIQ® (fentanyl citrate) oral transmucosal lozenge, CII (2009), ACTIQ PI/Med Guide, available at https://www.accessdata.fda.gov/drugsatfda_docs/label/2009/020747s030lbl.pdf* (last accessed August 1, 2018).

⁶⁶ *Highlights of Prescribing Information, FENTORA® (fentanyl citrate) buccal tablet, CII (2011), available at https://www.accessdata.fda.gov/drugsatfda_docs/label/2012/021947s015lbl.pdf* (last accessed August 1, 2018).

⁶⁷ Press Release, U.S. Dep’t of Justice, Biopharmaceutical Company, Cephalon, to Pay \$425 Million & Enter Plea to Resolve Allegations of Off-Label Marketing (Sept. 29, 2008), <https://www.justice.gov/archive/opa/pr/2008/September/08-civ-860.html>.

c. Actavis Entities

143. Defendant Allergan plc (“Allergan”) is a public limited company incorporated in Ireland with its principal place of business in Dublin, Ireland. Shares of Allergan are traded on the New York Stock Exchange (NYSE: AGN). In its 2018 Form 10-K filed with the SEC, Allergan plc stated that it does business in the United States through its U.S. Specialized Therapeutics and U.S. General Medicine segments, which generated nearly 80% of the company’s \$15.8 billion in net revenue during the year ended December 31, 2018.

144. Before the entities defined below as Actavis were sold to Teva Ltd. in August 2016, Actavis was part of the same corporate family as Allergan and sold and marketed opioids as part of a coordinated strategy to sell and market the branded and generic opioids of Allergan and Actavis. In October 2012, the Actavis Group was acquired by Watson Pharmaceuticals, Inc., and the combined company changed its name to Actavis, Inc. as of January 2013, and then to Actavis plc in October 2013. In October 2013, Actavis plc (n/k/a Allergan plc) acquired Warner Chilcott plc pursuant to a transaction agreement dated May 19, 2013. Actavis plc (n/k/a Allergan plc) was established to facilitate the business combination between Actavis, Inc. (n/k/a Allergan Finance, LLC) and Warner Chilcott plc. Following the consummation of the October 1, 2013 acquisition, Actavis, Inc. (n/k/a Allergan Finance, LLC Inc.) and Warner Chilcott plc became wholly-owned subsidiaries of Actavis plc (n/k/a Allergan plc). Pursuant to the transaction, each of Actavis, Inc.’s common shares were converted into one Actavis plc share. Further, Actavis plc (n/k/a Allergan plc) was the “successor issuer” to Actavis, Inc. and Warner Chilcott. Actavis plc acquired Allergan, Inc. in March 2015, and the combined company thereafter changed its name to Allergan plc.

145. Defendant Allergan Finance, LLC (f/k/a Actavis, Inc., f/k/a Watson Pharmaceuticals, Inc.) is a limited liability company incorporated in Nevada and headquartered in Madison, New Jersey. Allergan Finance, LLC is a wholly-owned subsidiary of defendant Allergan plc. In 2008, Actavis, Inc. (n/k/a Allergan Finance, LLC), acquired the opioid Kadian through its subsidiary, Actavis Elizabeth LLC, which had been the contract manufacturer of Kadian since 2005. Since 2008, Kadian's label has identified the following entities as the manufacturer or distributor of Kadian: Actavis Elizabeth LLC, Actavis Kadian LLC, Actavis Pharma, Inc., and Allergan USA, Inc. Currently, Allergan USA, Inc. is contracted with UPS SCS, Inc. to distribute Kadian on its behalf.

146. Defendant Allergan Sales, LLC is incorporated in Delaware and headquartered in Irvine, California. Allergan Sales, LLC is the current New Drug Application ("NDA") holder for Kadian, and in 2016, Allergan Sales, LLC held the Abbreviated New Drug Applications ("ANDAs") for Norco. Allergan Sales, LLC is the wholly-owned subsidiary of Allergan plc. The Norco ANDAs are currently held by Allergan Pharmaceuticals International Limited, which is incorporated in Ireland.

147. Defendant Allergan USA, Inc. is incorporated in Delaware and headquartered in Madison, New Jersey. Allergan USA, Inc. is currently responsible for Norco and Kadian sales. Allergan USA, Inc. is a wholly-owned subsidiary of Allergan plc.

148. Defendant Allergan plc has, at all times, exercised control over these marketing and sales efforts and profits from the sale of its subsidiaries' products ultimately inure to its benefit, including those sales by Actavis during the period of its ownership and control by Allergan. Allergan is or has been in the business of manufacturing, selling, promoting, and/or

distributing both brand name and generic opioids throughout the United States, including to Plaintiffs.

149. Defendant Watson Laboratories, Inc. (“Watson”) is a Nevada corporation with its principal place of business in Corona, California. Watson Laboratories, Inc. was sold to Teva Pharmaceutical Industries Ltd. as part of Allergan plc’s 2016 sale of its generic businesses to Teva. Prior to the sale, Watson Laboratories, Inc. was a direct subsidiary of Actavis, Inc., (n/k/a Allergan Finance, LLC). Between 2000 and 2015, Watson Laboratories, Inc. held the ANDAs for Norco and was the manufacturer of the drug. Watson Laboratories, Inc. was also the ANDA holder of various generic opioids.

150. Defendant Warner Chilcott Company, LLC is a limited liability company incorporated in Puerto Rico. Since 2015, Warner Chilcott Company, LLC has been the manufacturer of Norco. Warner Chilcott Company, LLC was a subsidiary of Warner Chilcott plc until Warner Chilcott plc became a wholly owned subsidiary of Allergan plc in 2013. Warner Chilcott Company LLC was sold to Teva Pharmaceutical Industries Ltd. as part of Allergan plc’s 2016 sale of its generic businesses to Teva.

151. Defendant Actavis Pharma, Inc. (f/k/a Watson Pharma Inc.) (“Actavis Pharma”) is a Delaware corporation with its principal place of business in New Jersey.

152. Actavis Pharma was previously responsible for sales of Kadian and Norco. Actavis Pharma was sold to Teva Pharmaceutical Industries Ltd. as part of Allergan plc’s 2016 sale of its generic businesses to Teva. According to ARCOS data, from 2006 through 2014, Actavis Pharma, Inc. sold 1,047,559,999 pills of oxycodone and hydrocodone into Kentucky. Among all manufacturers, Actavis Pharma, Inc. manufactured the most oxycodone and hydrocodone pills sold into Kentucky during that eight-year period.

153. Defendant Actavis South Atlantic LLC is a Delaware limited liability company with its principal place of business in Sunrise, Florida. Actavis South Atlantic LLC was listed as the ANDA holder for oxymorphone and fentanyl transdermal. Actavis South Atlantic LLC was sold to Teva Pharmaceutical Industries Ltd. as part of Allergan plc's 2016 sale of its generic businesses to Teva.

154. Defendant Actavis Elizabeth LLC is a Delaware limited liability company with its principal place of business in Elizabeth, New Jersey. From December 19, 2005, until it purchased the medication in December 2008, Actavis Elizabeth LLC served as the contract manufacturer of Kadian for Alpharma. Actavis Elizabeth LLC held the ANDA for Kadian from 2008 to 2013. Actavis Elizabeth LLC was also the holder of ANDAs for the following opioid products: oxycodone/acetaminophen; homatropine methylbromide/hydrocodone bitartrate; morphine sulfate capsule; morphine sulfate tablet; oxycodone/hydrochloride tablet; oxycodone/ibuprofen; and oxymorphone tablet. Actavis Elizabeth LLC was sold to Teva Pharmaceutical Industries Ltd. as part of Allergan plc's 2016 sale of its generic businesses to Teva.

155. Defendant Actavis Mid Atlantic LLC is a Delaware limited liability company with its principal place of business in Parsippany, New Jersey. Actavis Mid Atlantic LLC has held the ANDA for homatropine methylbromide/hydrocodone bitartrate. Actavis Mid Atlantic LLC was sold to Teva Pharmaceutical Industries Ltd. As part of Allergan plc's 2016 sale of its generic businesses to Teva.

156. Defendant Actavis Totowa LLC is a Delaware limited liability company with its principal place of business in Parsippany, New Jersey. Actavis Totowa LLC has held the

ANDAs for the following Schedule II opioid products: oxycodone/acetaminophen; homatropine methylbromide; oxycodone/hydrochloride.

157. Defendant Actavis LLC (f/k/a Actavis Inc.) (“Actavis LLC”) is a Delaware limited liability company with its principal place of business in Parsippany, New Jersey. Defendants Actavis South Atlantic LLC, Actavis Elizabeth LLC, Actavis Mid Atlantic LLC, and Actavis Totowa LLC were all direct subsidiaries of Actavis LLC, which was an indirect subsidiary of defendant Watson. Watson, in turn, was a direct subsidiary of Actavis, Inc. (n/k/a Allergan Finance, LLC). Actavis LLC was sold to Teva Pharmaceutical Industries Ltd. as part of Allergan plc’s 2016 sale of its generic businesses to Teva.

158. Defendant Actavis Kadian LLC is a Delaware limited liability company with its principal place of business in Morristown, New Jersey. Actavis Kadian LLC has been identified on Kadian’s label as a manufacturer or distributor of Kadian. Actavis Kadian LLC was sold to Teva Pharmaceutical Industries Ltd. as part of Allergan plc’s 2016 sale of its generic businesses to Teva.

159. Defendant Actavis Laboratories UT, Inc. (f/k/a Watson Laboratories, Inc.-Salt Lake City) is a Delaware limited liability company with its principal place of business in Salt Lake City, Utah. Actavis Laboratories UT, Inc. was the Kadian NDA holder from 2013 to 2016 and was listed as the NDA holder for morphine sulfate capsule. Actavis Laboratories UT, Inc. was sold to Teva Pharmaceutical Industries Limited as part of Allergan plc’s 2016 sale of its generic businesses to Teva. Prior to the sale, Actavis Laboratories UT, Inc. was a direct subsidiary of Actavis, Inc. (n/k/a Allergan Finance, LLC).

160. Defendant Actavis Laboratories FL, Inc. (f/k/a Watson Laboratories, Inc.-Florida) is a Florida limited liability company with its principal place of business in Davie, Florida.

Actavis Laboratories FL, Inc. was a Norco ANDA holder in 2015 and was the ANDA holder of the following opioid products: hydrocodone/acetaminophen; hydrocodone/ibuprofen; oxycodone/aspirin; and hydromorphone tablet. Actavis Laboratories FL, Inc. was sold to Teva Pharmaceutical Industries Ltd. as part of Allergan plc's 2016 sale of its generic businesses to Teva. Prior to the sale, Actavis Laboratories FL, Inc. was a direct subsidiary of Andrx Corporation, which was a direct subsidiary of Actavis, Inc. (n/k/a Allergan Finance, LLC). Andrx Corporation was transferred to Teva as part of the 2016 sale.

161. Each of these Defendants and entities currently is or was previously owned by Defendant Allergan plc., which uses them to market and sell its drugs in the United States. Collectively, these defendants and entities, and their subsidiaries and affiliates that manufacture, promote, distribute, and sell opioids, are referred to as "Actavis."

162. 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 the United States. Actavis acquired the rights to Kadian from King Pharmaceuticals, Inc. on December 30, 2008, and began marketing Kadian in 2009.

d. Janssen and Associated Companies

163. Defendant Johnson & Johnson ("J&J") is a New Jersey corporation with its principal place of business in New Brunswick, New Jersey.

164. Defendant Janssen Pharmaceuticals, Inc. is a Pennsylvania corporation with its principal place of business in Titusville, New Jersey, and is a wholly owned subsidiary of J&J.

165. Janssen Pharmaceuticals, Inc. was formerly known as Ortho-McNeil-Janssen Pharmaceuticals, Inc., which was formerly known as Janssen Pharmaceutica, Inc.

166. Defendant Noramco, Inc. is a Delaware company headquartered in Wilmington, Delaware and was a wholly owned subsidiary of J&J until July 2016. Noramco, Inc. is or had

been part of J&J's opium processing. It makes active pharmaceutical ingredients ("APIs") for opioid painkillers.

167. Defendant, Tasmanian Alkaloids Pty. Ltd. ("Tasmanian Alkaloids") is an Australian private company based in Westbury, Australia and incorporated in Tasmania, Australia. Tasmanian Alkaloids Pty. Ltd. was a wholly owned subsidiary of J&J until July 2016 when J&J sold its interests to SK Capital Partners LP, a limited partnership incorporated in Delaware.

168. Johnson & Johnson is the only company that owns over 10% of Janssen Pharmaceuticals stock. J&J controls the sale and development of Janssen Pharmaceuticals drugs and Janssen Pharmaceuticals profits inure to J&J's benefit.

169. J&J, Janssen Pharmaceuticals, Inc., Noramco, Inc., Ortho-McNeil-Janssen Pharmaceuticals, Inc., Tasmanian Alkaloids Pty. Ltd., and Janssen Pharmaceutica, Inc. (collectively, "Janssen") are or have been in the business of manufacturing, selling, promoting, and/or distributing both brand name and generic opioids throughout the United States.

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

171. Janssen made thousands of payments to physicians nationwide, including in Kentucky, ostensibly for activities including participating on speakers' bureaus, providing consulting services, assisting in post-marketing safety surveillance and other services, but, in

fact, these activities were used by Janssen to deceptively promote and maximize the use of opioids.

172. On August 26, 2019, a judge in Oklahoma ruled that Johnson & Johnson had intentionally played down the dangers and oversold the benefits of opioids, and ordered it to pay the state \$572 million in the first trial of a drug manufacturer for the destruction wrought by opioid painkillers.⁶⁸ The judge found that the state had proven that Johnson & Johnson had created a public nuisance by exaggerating the benefits of narcotic painkillers and minimizing their addiction risks. The Oklahoma Court also found that “the public in general are currently experiencing an opioid crisis and epidemic.”⁶⁹

173. According to the Oklahoma Court, Johnson & Johnson’s marketing and promotion activities included, among other things, their sales representatives providing education, literature they funded in medical journals and publications, materials from professional societies/patient advocacy groups, continuing medical education they funded, unbranded marketing materials, and paid speakers.⁷⁰ The key messages in this marketing strategy included promoting the concept that chronic pain was undertreated, and the solution to this problem was increasing opioid use.⁷¹ They used the phrase, “pseudoaddiction,” to describe patients returning to the doctor before a prescription should have run out, not as individuals suffering from addiction but rather as suffering from the undertreatment of their pain, which

⁶⁸ Jan Hoffman, *Johnson & Johnson Ordered to Pay \$572 Million in Landmark Opioid Trial*, THE NEW YORK TIMES (Aug. 26, 2019), available at <https://www.nytimes.com/2019/08/26/health/oklahoma-opioids-johnson-and-johnson.html>. See also Judgment After Non-Jury Trial, Aug. 26, 2019, Case No. CJ-2017-816 (Okla. Cleveland Cty. Dist. Ct.) (“Okla. Judgment”).

⁶⁹ Okla. Judgment, Findings of Fact, ¶1.

⁷⁰ Okla. Judgment, Findings of Fact, ¶19.

⁷¹ Okla. Judgment, Findings of Fact, ¶20.

could best be solved by prescribing those patients more opioids.⁷² Sales representatives did not, however, receive training regarding “pill mill” red flags, such as “pain clinics with patients lined up out the door or patients passed out in the waiting room.”⁷³

174. According to the Oklahoma Court, Johnson & Johnson, through its wholly owned subsidiaries, Tasmanian Alkaloids Limited and Noramco, Inc., supplied opioid manufacturers with active pharmaceutical ingredients (“APIs”) from the 1990s until at least 2016. Tasmanian Alkaloids Limited “cultivated and processed opium poppy plants to manufacture narcotic raw materials that were imported into the U.S. to be processed and made into APIs for manufacturing opioids.” Noramco, Inc. imported the raw materials from Tasmanian Alkaloids Limited, processed these materials into APIs for manufacturing opioids, and sold the APIs to other opioid manufacturers in the United States.⁷⁴

175. According to the Oklahoma Court, drug manufacturers in the United States, including Purdue and Teva, were supplied the following opioid APIs through Johnson & Johnson’s operations: oxycodone, hydrocodone, morphine, codeine, fentanyl, sufentanil, buprenorphine, hydromorphone, and naloxone.⁷⁵ Noramco sold its APIs, including oxycodone, hydrocodone, morphine, codeine, buprenorphine, hydromorphone, and naloxone, through long-term agreements with all 7 of the top U.S. generic manufacturing companies.⁷⁶

⁷² Okla. Judgment, Findings of Fact, ¶22.

⁷³ Okla. Judgment, Findings of Fact, ¶33.

⁷⁴ Okla. Judgment, Findings of Fact, ¶6.

⁷⁵ Okla. Judgment, Findings of Fact, ¶7.

⁷⁶ Okla. Judgment, Findings of Fact, ¶14.

176. According to the Oklahoma Court, in 2015, Johnson & Johnson's operations, comprised of Noramco and Tasmanian Alkaloids, and called "Noramco World Wide Narcotics Franchise," held the distinction of being "the #1 supplier of Narcotic APIs in the United States, the world's largest market."⁷⁷ "Noramco grew to become the No. 1 narcotic API supplier of oxycodone, hydrocodone, codeine and morphine in the United States."⁷⁸

177. Janssen, like many other companies, has a corporate code of conduct, which sets forth the organization's mission, values and principles. Janssen's employees are required to read, understand and follow its Code of Conduct for Health Care Compliance. Johnson & Johnson imposes this code of conduct on Janssen as a pharmaceutical subsidiary of J&J.⁷⁹ Documents posted on J&J's and Janssen's websites confirm J&J's control of the development and marketing of opioids by Janssen. Janssen's website "*Ethical Code for the Conduct of Research and Development*," names only J&J and does not mention Janssen anywhere within the document. The "*Ethical Code for the Conduct of Research and Development*" posted on the Janssen website is J&J's company-wide Ethical Code, which it requires all of its subsidiaries to follow.

178. The "Every Day Health Care Compliance Code of Conduct" posted on Janssen's website is a J&J company-wide document that describes Janssen as one of the "Pharmaceutical Companies of Johnson & Johnson" and as one of the "Johnson & Johnson Pharmaceutical Affiliates." It governs how "[a]ll employees of Johnson & Johnson Pharmaceutical Affiliates," including those of Janssen, "market, sell, promote, research, develop, inform and advertise

⁷⁷ Okla. Judgment, Findings of Fact, ¶8.

⁷⁸ Okla. Judgment, Findings of Fact, ¶15.

⁷⁹ Depomed, Inc. acquired the rights to Nucynta and Nucynta ER from Janssen in 2015.

Johnson & Johnson Pharmaceutical Affiliates' products." All Janssen officers, directors, employees, sales associates must certify that they have "read, understood and will abide by" the code. The code governs all of the forms of marketing at issue in this case. J&J made payments to thousands of physicians nationwide, including in Kentucky, ostensibly for activities including participating on speakers' bureaus, providing consulting services, assisting in post-marketing safety surveillance and other services, but, in fact, these activities were used by J&J to deceptively promote and maximize the use of opioids.

e. Endo and Associated Companies

179. Defendant Endo Health Solutions Inc. is a Delaware corporation with its principal place of business in Malvern, Pennsylvania.

180. Defendant 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.

181. Defendant Par Pharmaceutical, Inc. is a Delaware corporation with its principal place of business located in Chestnut Ridge, New York. Par Pharmaceutical, Inc. is a wholly owned subsidiary of Par Pharmaceutical Companies, Inc. f/k/a Par Pharmaceutical Holdings, Inc.

182. Defendant Par Pharmaceuticals Companies, Inc. is a Delaware corporation with its principal place of business located in Chestnut Ridge, New York (Par Pharmaceutical, Inc. and Par Pharmaceutical Companies, Inc. collectively, "Par Pharmaceutical"). Par Pharmaceutical was acquired by Endo International plc in September 2015 and is an operating company of Endo International plc.

183. According to ARCOS data, from 2006 to 2014, Par Pharmaceutical manufactured and sold 435,584,240 pills of oxycodone and hydrocodone in Kentucky. Among all

manufacturers, Par Pharmaceutical manufactured the third highest number of pills of oxycodone and hydrocodone sold into Kentucky during that eight-year period.

184. Endo Health Solutions Inc. and Endo Pharmaceuticals Inc. (collectively, “Endo”) are or have been in the business of manufacturing, selling, promoting, and/or distributing both brand name and generic opioids throughout the United States.

185. Endo develops, markets, and sells prescription drugs, including the opioids Opana/Opana ER, Percodan, Percocet, generic versions of oxycodone, oxymorphone, hydromorphone and hydrocodone in 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. On June 8, 2017, the FDA requested that Endo remove Opana ER from the market because of a “serious outbreak” of HIV and hepatitis C due to abuse of the drug after the reformulation of Opana from a nasal spray to an injectable.⁸⁰ In response to the FDA’s request, Endo removed Opana ER from the market in July 2017, the first time the agency had ever moved to pull an opioid medication from sale.⁸¹ Endo also manufactures and sells generic opioids such as oxycodone, oxymorphone, hydromorphone, and hydrocodone products in the United States, by itself and through its subsidiary, Qualitest Pharmaceuticals, Inc.

186. Endo made thousands of payments to physicians nationwide, including in Kentucky, ostensibly for activities including participating on speakers’ bureaus, providing

⁸⁰ Press Release, U.S. Food & Drug Administration, FDA Requests Removal of Opana ER for Risks Related to Abuse (June 8, 2017), *available at* <https://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm562401.htm>.

⁸¹ Press Release, Endo International PLC, Endo Provides update on Opana ER (July 6, 2017), *available at* <http://investor.endo.com/news-releases/news-release-details/endo-provides-update-opanar-er>.

consulting services, assisting in post-marketing safety surveillance and other services, but, in fact, these activities were used by Endo to deceptively promote and maximize the use of opioids.

f. Abbott Laboratories

187. Defendant AbbVie, Inc. (“AbbVie”), is a corporation organized under the laws of Delaware, with its principal place of business in North Chicago, Illinois. AbbVie, at times relevant to this Complaint, manufactured, promoted, sold, and distributed branded and generic opioids in the United States and Kentucky.

188. Defendant Abbott Laboratories, Inc. is a corporation organized under the laws of the State of Delaware, with its principal place of business in Chicago, Illinois. Before splitting from AbbVie in 2013, Abbott Laboratories, Inc. manufactured, promoted, sold, and distributed branded and generic opioids in the United States and Kentucky.

189. Defendant Abbott Laboratories is an Illinois corporation with its principal place of business in Abbott Park, Illinois. Defendant Abbott Laboratories, Inc. is a subsidiary of Abbott Laboratories, whose principal place of business is also in Abbott Park, Illinois. Defendants Abbott Laboratories and Abbott Laboratories, Inc. are referred to collectively as “Abbott.”

190. Abbott was primarily engaged in the promotion and distribution of opioids nationally due to the co-promotional agreement with Purdue. Pursuant to that agreement, between 1996 and 2006, Abbott actively promoted, marketed, and distributed Purdue’s opioid products as set forth above.

191. Abbott, as part of the co-promotional agreement, helped turn OxyContin into the largest selling opioid in the nation. Abbott, a much larger company than Purdue, had a sales force entrenched in hospitals and surgical centers, and had existing relationships with anesthesiologists, emergency room doctors, surgeons, and pain management teams. Abbott

devoted at least 300 sales representatives to OxyContin sales – about the same number of people Purdue initially dedicated to the drug – as part of a co-promotional agreement with Purdue.⁸² Winning Abbott’s help was so important to Purdue that it agreed to indemnify the larger company from any legal costs that might arise from the selling of the drug. It was a provision that ended up saving Abbott millions of dollars, and also kept the company out of the headlines as Purdue was forced to pay huge fines and settlements from the illegal marketing of Oxycontin.⁸³

192. Under the co-promotional agreement with Purdue, the more Abbott generated in sales, the higher the reward. Specifically, Abbott received 25% to 30% of all net sales for prescriptions written by doctors its sales force called on. This agreement was in operation from 1996-2002, following which Abbott continued to receive a residual payment of 6% of net sales up through at least 2006.

193. With Abbott’s help, sales of OxyContin went from a mere \$49 million in its first full year on the market to \$1.2 billion in 2002. Over the life of the co-promotional agreement, Purdue paid Abbott nearly half a billion dollars.

194. Abbott and Purdue’s conspiring with Pharmacy Benefit Managers (PBMs) to drive opioid use is well established. As described in an October 28, 2016, article from Psychology Today entitled *America’s Opioid Epidemic*:

Abbott and Purdue actively misled prescribers about the strength and safety of the painkiller [OxyContin]. To undermine the policy of requiring prior authorization, they offered lucrative rebates to middlemen such as Merck Medco [now Express Scripts] and other pharmacy benefits managers on condition that they eased

⁸² “Secret trove reveals bold ‘crusade’ to make OxyContin a blockbuster” by David Armstrong. STAT. September 22, 2016.

⁸³ *Id.*

availability of the drug and lowered co-pays. The records were part of a case brought by the state of West Virginia against both drug makers alleging inappropriate and illegal marketing of the drug as a cause of widespread addiction.... One reason the documents are so troubling is that, in public at least, the drug maker was carefully assuring authorities that it was working with state authorities to curb abuse of OxyContin. Behind the scene, however, as one Purdue official openly acknowledged, the drug maker was “working with Medco (PBM) [now Express Scripts] to try and make parameters [for prescribing] less stringent.”⁸⁴

g. Amneal

195. Defendant Amneal Pharmaceuticals, LLC (“Amneal LLC”) is a Delaware limited liability company with its principal place of in New Jersey.

196. Defendant Amneal Pharmaceuticals, Inc. (“API”) is a Delaware corporation with its principal place of business in New Jersey. API is the managing member of Amneal LLC, and conducts and exercises full control over all activities of Amneal LLC.⁸⁵

197. Impax Laboratories, LLC, formerly known as Impax Laboratories, Inc., is a Delaware limited liability company with its principal place of business in Bridgewater, New Jersey. Upon information and belief, in May 2018, Impax Laboratories, Inc. merged with and into Amneal Pharmaceuticals LLC to form Defendant, Amneal Pharmaceuticals, Inc.

198. Defendant Amneal Pharmaceuticals of New York LLC is a Delaware limited liability company with its principal place of business in Hauppauge, New York.

199. API, Impax Laboratories, LLC, Amneal Pharmaceuticals of New York LLC and Amneal LLC are referred to herein as “Amneal.”

⁸⁴ American Society of Addiction Medicine, *America’s Opioid Epidemic – Court released documents show drug makers blocked efforts to curb prescribing*, Psychology Today, Oct. 28, 2016, <https://www.psychologytoday.com/blog/side-effects/201610/america-s-opioid-epidemic>.

⁸⁵ *Id.*

200. At all relevant times, Amneal has sold prescription drugs including opioids in Kentucky and across the United States.

201. According to ARCOS data, between 2006 and 2014, Amneal sold 81,686,293 pills of oxycodone and hydrocodone in Kentucky. Among all manufacturers, Amneal manufactured the fourth highest number of pills of oxycodone and hydrocodone sold in Kentucky during that eight-year period.

202. Defendant Amneal breached its duties under Kentucky law. As shown by the ARCOS Data, Amneal sold an extraordinary amount of opioids into Kentucky and the areas served by Plaintiffs. Amneal's excessive sales were made possible by, and are evidence of, Amneal's failures to comply with its duties under applicable state law and regulations. Further, Amneal failed to meet its suspicious order monitoring requirements, failed to stop shipment on suspicious orders, and failed to effectively prevent diversion in breach of its duties under Kentucky law. These breaches contributed substantially to the harms borne by Plaintiffs as alleged in the Complaint.

h. Assertio

203. Defendant Assertio Therapeutics, Inc. f/k/a Depomed, Inc. ("Assertio" or "Depomed") is a Delaware corporation with its principal place of business in Lake Forest, Illinois. Assertio describes itself as a specialty pharmaceutical company focused on pain and other central nervous system conditions. Assertio develops, markets, and sells prescriptions drugs in Kentucky and across the United States. Assertio acquired the rights to Nucynta and Nucynta ER for \$1.05 billion from Janssen pursuant to a January 15, 2015, Asset Purchase Agreement. This agreement closed on April 2, 2015.

i. Mallinckrodt Entities

204. Defendant Mallinckrodt plc is an Irish public limited company with its headquarters in Staines-Upon-Thames, Surrey, United Kingdom. Mallinckrodt plc was incorporated in January 2013 for the purpose of holding the pharmaceuticals business of Covidien plc, which was fully transferred to Mallinckrodt plc in June of that year. Mallinckrodt plc also operates under the registered business name Mallinckrodt Pharmaceuticals, with its U.S. headquarters in Hazelwood, Missouri.

205. Defendant Mallinckrodt LLC is a Delaware corporation with its headquarters in Hazelwood, Missouri.

206. Defendant SpecGx LLC is a Delaware limited liability company with its headquarters in Clayton, Missouri and is a wholly-owned subsidiary of Mallinckrodt plc.

207. Mallinckrodt LLC, Mallinckrodt plc, and SpecGx LLC are referred to as “Mallinckrodt.” Mallinckrodt manufactures, markets, sells and distributes pharmaceutical drugs throughout the United States, and to Plaintiffs. Mallinckrodt is the largest U.S. supplier of opioid pain medications and among the top ten generic pharmaceutical manufacturers in the United States, based on prescriptions.

208. According to ARCOS data, SpecGx LLC sold 716,919,264 pills of oxycodone and hydrocodone into Kentucky between 2006 and 2014. Among all manufacturers, SpecGx LLC manufactured the second highest number of pills of oxycodone and hydrocodone sold in Kentucky during that eight-year period.

209. Mallinckrodt manufactures and markets two branded opioids: Exalgo, which is extended-release hydromorphone, sold in 8, 12, 16, and 32 mg dosage strengths, and Roxicodone, which is oxycodone, sold in 15 and 30 mg dosage strengths. In 2009, Mallinckrodt Inc., a subsidiary of Covidien plc, acquired the U.S. rights to Exalgo. The FDA approved Exalgo

for treatment of chronic pain in 2012. Mallinckrodt further expanded its branded opioid portfolio in 2012 by purchasing Roxicodone from Xanodyne Pharmaceuticals. In addition, Mallinckrodt developed Xartemis XR, an extended-release combination of oxycodone and acetaminophen, which the FDA approved in March 2014, and which Mallinckrodt has since discontinued. Mallinckrodt promoted its branded opioid products with its own direct sales force.

210. While it has sought to develop its branded opioid products, Mallinckrodt has long been a leading manufacturer of generic opioids. Mallinckrodt estimated that in 2015 it received approximately 25% of the DEA's entire annual quota for controlled substances that it manufactures. Mallinckrodt also estimated, based on IMS Health⁸⁶ data for the same period, that its generics claimed an approximately 23% market share of DEA Schedules II and III opioid and oral solid dose medications.⁸⁷

211. Mallinckrodt operates a vertically integrated business in the United States: (1) importing raw opioid materials, (2) manufacturing generic opioid products, primarily at its facility in Hobart, New York, and (3) marketing and selling its products to drug distributors, specialty pharmaceutical distributors, retail pharmacy chains, pharmaceutical benefit managers that have mail-order pharmacies, and hospital buying groups.

212. Among the drugs Mallinckrodt manufactures or has manufactured are the following: Schedule II: Exalgo (hydromorphone hydrochloride, extended release), Roxicodone

⁸⁶ "IMS Health was a [provider of] information, services and technology for the healthcare industry, including U.S. physician prescribing data." It has changed its corporate form and is now known as "IQVIA."

⁸⁷ Mallinckrodt plc 2016 Annual Report (Form 10-K), *available at* <http://www.mallinckrodt.com/investors/annual-reports/>.

(oxycodone hydrochloride), Xartemis XR (oxycodone hydrochloride and acetaminophen), Methadose (methadone hydrochloride), Generic (morphine sulfate, extended release, morphine sulfate oral solution, fentanyl transdermal system, oral transmucosal fentanyl citrate, oxycodone and acetaminophen, hydrocodone bitartrate and acetaminophen, hydromorphone hydrochloride, hydromorphone hydrochloride, extended release, oxymorphone hydrochloride, methadone hydrochloride. Schedule III: buprenorphine and naloxone. Unscheduled: naltrexone hydrochloride.

213. Mallinckrodt made thousands of payments to physicians nationwide, including in Kentucky, ostensibly for activities including participating on speakers' bureaus, providing consulting services, assisting in post-marketing safety surveillance and other services, but, in fact, Mallinckrodt used these activities to deceptively promote and maximize the use of opioids

j. KVK Tech

214. Defendant KVK-Tech, Inc. is a privately held Pennsylvania corporation with its principal place of business in Pennsylvania. KVK-Tech, Inc. is a manufacturer of generic prescription opioid, including many Schedule II controlled substances such as oxycodone and hydrocodone.

215. KVK-Tech, Inc. has engaged in the manufacture, promotion, distribution, and sale of the generic prescription opioid drugs sold throughout the country, including into Kentucky.

216. Collectively, the Purdue Individual Co-Conspirators, Actavis, Amneal, Cephalon, Janssen, Assertio, Endo, Abbott, Actavis, Mallinckrodt, and KVK-Tech, Inc. are referred to as "Marketing Defendants."

k. Practice Fusion

217. Defendant Practice Fusion, Inc. (“Practice Fusion”) was a Delaware corporation with headquarters in San Francisco, California.

218. Defendant Allscripts Healthcare Solutions, Inc. (“Allscripts”) is a Delaware corporation, with headquarters in Chicago, Illinois, and, through merger completed February 13, 2018, acquired Practice Fusion, Inc.

219. Defendant Practice Fusion, Inc. was a cloud-based electronic health records (“EHR”) company that provides its cloud-based EHR products to traditionally hard-to-reach small independent physician practices without charge.

220. Practice Fusion and Allscripts are referred to as “Practice Fusion” throughout the Complaint.

221. Beginning in and around 2013, Practice Fusion solicited remuneration from Purdue Pharma in exchange for creating and embedding an alert, known as a clinical decision support (referred to hereafter as the “Pain CDS”), in Practice Fusion’s EHR to prompt doctors to make certain clinical decisions for the purpose of increasing Purdue’s extended-release opioid prescriptions. The Pain CDS suggested that doctors focus on assessing and treating a patient’s pain symptoms and provided the doctor with a list of potential care plan treatment options, including extended-release opioids medications.

222. Practice Fusion understood and has admitted that Purdue Pharma provided remuneration in exchange for the Pain CDS because the Pain CDS could boost sales of Purdue Pharma’s extended-release opioid products.

223. Practice Fusion understood and has admitted that it was unlawful to sell clinical decision support programs based upon anticipated returns on investment that a pharmaceutical company clients like Purdue Pharma could achieve through the programs, and that any clinical

decision support programs must be consistent with any applicable evidence-based medical guidelines and department of Health and Human Services (“HHS”) Centers for Medicare and Medicaid Services (“CMS”) Clinical Quality Measures (“CQM”).

224. Practice Fusion has admitted that it and Purdue Pharma did not pursue a clinical decision support alert to assist doctors in screening patients; instead the parties developed the Pain CDS to increase sales of Purdue Pharma’s extended-release opioid products.

225. Practice Fusion and Purdue Pharma entered into a written statement of work contracting for the Pain CDS effective March 1, 2016, pursuant to which Purdue Pharma paid Practice Fusion \$959,700 for a program directed at chronic pain management treatment with immediate release opioids and chronically used NSAIDs that would support the identification and/or treatment of patients who are recommended to be screened for and receive the treatment specified in what the contract described as “gold standard evidence based clinical guidelines.”

226. The Pain CDS that Practice Fusion and Purdue jointly developed in the next three months violated clinical guidelines current at that time and that have been developed during the time of its use and did not incorporate the recommendations contained in the CDC’s Guidelines for Prescribing Opioids for Chronic Pain issued on March 15, 2016, nor did it implement the recommendations provided by the New England Journal of Medicine (“NEJM”) 2016 article entitled “Opioid Abuse in Chronic Pain-Misconceptions and Mitigation Strategies”.

227. The Pain CDS went live on Practice Fusion’s platform on or about July 6, 2016. It deviated from the various evidence-based guidelines in several material respects, including advocating for the use of Purdue’s extended -release opioid products for patients with less than severe pain; listing those products as an option for patients with pain without regard to whether the pain could be adequately treated by non-opioid products; listing Purdue’s extended-release

opioid products as an option for patients who had not previously received opioid therapy; and suggesting Purdue's extended-release opioid products as a treatment option for patients whose pain was not chronic, but who presented with separate complaints of acute pain within three months.

228. In so doing, at a time when evidence-based guidelines issued by the CDC and by scientific journals such as the NEJM were advocating for *limited* use of Purdue's extended-release opioid products, Practice Fusion solicited payment from Purdue to use its EHR platform to cause the healthcare professionals who used that platform to *increase* prescriptions of such products in situations that violated those Guidelines. In sum, the Pain CDS on Practice Fusion's platform was not consistent with the guidelines such as the CDC Guidelines; the Pain CDS was inconsistent with applicable CQM; and the Pain CDS was funded by Purdue Pharma's marketing department and Purdue Pharma's drug marketers were involved in its design.

229. On November, 6, 2017, Practice Fusion and Purdue Pharma employees publicly announced at a national American Medical Informatics association ("AMIA") Annual Symposium held in Washington, D.C. that they had begun to study the effectiveness of the CDS Pain Program on Practice Fusion's platform. The researchers tested pain alerts for roughly 13 million patients per year. They concluded that such reminders "may have a sustained influence on the rate of opioid prescribing."

230. The CDS Pain Program that went live on July 2016 continued until the spring of 2019, more than a year after Defendant Allscripts Healthcare Solutions, Inc.'s acquisition of Practice Fusion. The rigged alerts popped up on doctors' computers more than 230 million times between July 2006 and the spring of 2019 when criminal charges were filed. The healthcare

providers who received them prescribed extended-release opioids at a higher rate than those who did not receive them.

231. On information and belief, at the time of Practice Fusion's merger with Allscripts and for some time before the merger, Allscripts was aware of Practice Fusion's arrangement with Purdue Pharma described herein and the investigation of the illegality of Practice Fusion's conduct under that arrangement by the U.S. Attorney for the District of Vermont, but took no steps to stop Practice Fusion's conduct until the U.S. Attorney charged Practice Fusion with unlawful criminal conduct in the spring of 2019.

232. On January 27, 2020, Practice Fusion paid a total of \$145 million to resolve criminal and civil investigations that asserted that the arrangement described above and thirteen others like it constituted illegal kickback schemes under the Anti-Kickback Statute, 42 U.S.C. sections 1320(a)-7(b)(1) and that it had conspired with Purdue Pharma to violate Section 371 of that statute. Practice Fusion admitted only to its opioids agreement with Purdue Pharma. It paid a total of \$118.6 million to the federal government and to the states to resolve allegations that it accepted kickbacks from Purdue Pharma and other pharmaceutical companies and also caused its users to submit false claims for federal incentive payments by misrepresenting the capabilities of its EHR software.

2. Distributor Defendants

233. The Distributor Defendants are defined below. At all relevant times, the Distributor Defendants have distributed, supplied, sold, and placed into the stream of commerce prescription opioids, without fulfilling the fundamental duty of wholesale drug distributors to detect and warn of diversion of dangerous drugs for non-medical purposes. The Distributor Defendants, who are wholesale distributors that engaged in the chain of distribution or resale of Schedule II controlled substances, universally failed to comply with Kentucky law regulating that activity. Plaintiffs allege the unlawful conduct by the Distributor Defendants is a substantial cause for the volume of prescription opioids plaguing Plaintiffs' communities.

a. **AmerisourceBergen Drug Corporation**

234. Defendant AmerisourceBergen Drug Corporation ("AmerisourceBergen") is a Delaware corporation with its principal place of business in Chesterbrook, Pennsylvania. AmerisourceBergen is a wholesaler of pharmaceutical drugs that distributes opioids throughout the country, including to Kentucky.

235. AmerisourceBergen is the eleventh largest company by revenue in the United States, with annual revenue of \$147 billion in 2016.

236. According to its 2016 Annual Report, AmerisourceBergen is "one of the largest global pharmaceutical sourcing and distribution services companies, helping both healthcare providers and pharmaceutical and biotech manufacturers improve patient access to products and enhance patient care."⁸⁸

⁸⁸ AmerisourceBergen, 2016 Summary Annual Report, *available at* <http://investor.amerisourcebergen.com/static-files/37daf1ed-4d41-4547-bb87-86d501087dbb> (last accessed August 1, 2018).

237. AmerisourceBergen, at all relevant times, operated as a licensed distributor wholesaler in Kentucky, licensed by the Kentucky Board of Pharmacy.

238. According to ARCOS data, between 2006 and 2014, AmerisourceBergen distributed 584,198,415 pills of hydrocodone and oxycodone into Kentucky during this eight-year period, making AmerisourceBergen the top distributor of these opioid pills during that eight-year period.

b. Anda, Inc.

239. Defendant Anda, Inc., (“Anda”) through its various DEA registrant subsidiaries and affiliated entities, including but not limited to, Anda Pharmaceuticals, Inc., is the fourth largest distributor of generic pharmaceuticals in the United States. Anda is a Florida corporation with its principal place of business in Weston, Florida. In October 2016, Defendant Teva Ltd. acquired Anda from Allergan plc (i.e. Defendant Actavis), for \$500 million in cash. At all times relevant to this Complaint, Anda distributed prescription opioids throughout the United States, including in Kentucky and within the communities served by Plaintiffs.

c. Cardinal

240. Defendant Cardinal Health, Inc. (“Cardinal”) is an Ohio Corporation with its principal place of business in Dublin, Ohio. In 2016, Cardinal generated revenues of \$121.5 billion.

241. Cardinal is a global distributor of pharmaceutical drugs and medical products. It is one of the largest distributors of opioids in the United States. It has annual resources of over \$120 billion. Additionally, in December 2013, Cardinal formed a ten-year agreement with CVS Caremark to form the largest generic drug sourcing operation in the United States. Cardinal has, at all relevant times, had distribution centers throughout the United States, including Kentucky, and has distributed opioids nationwide.

242. Cardinal Health at all relevant times, operated as a licensed distributor wholesaler in Kentucky, licensed by the Kentucky Board of Pharmacy.

d. H.D. Smith, LLC

243. Defendant H. D. Smith, LLC f/k/a H. D. Smith Wholesale Drug Co. (“H. D. Smith”) through its various DEA registered subsidiaries and affiliated entities, is a wholesaler of pharmaceutical drugs that distributes opioids throughout the United States, including Kentucky and the communities served by Plaintiffs. H. D. Smith is a privately held independent pharmaceuticals distributor of wholesale brand, generic and specialty pharmaceuticals and is a Delaware corporation with its principal place of business in Illinois. H. D. Smith Wholesale Drug Co. has been restructured and is currently doing business as H. D. Smith, LLC. H.D. Smith LLC’s sole member is H. D. Smith Holdings, LLC, and its sole member is H. D. Smith Holding Company, a Delaware corporation with its principal place of business in Illinois. H. D. Smith is the largest independent wholesaler in the United States. In January 2018, Defendant AmerisourceBergen acquired H. D. Smith. At all relevant times, H. D. Smith distributed prescription opioids throughout the United States including in Kentucky.

e. Henry Schein

244. Henry Schein, Inc. (“Henry Schein”) describes its business as providing a products and services to integrated health systems, designed specifically for and focused exclusively on, the non-acute care space. Henry Schein is incorporated in Delaware, with its principal place of business located in Melville, New York.

245. Henry Schein distributes, among other things, branded and generic pharmaceuticals to customers that include dental practitioners, dental laboratories, animal health practices and clinics, and office-based medical practitioners, ambulatory surgery centers, and other institutions.

246. At all relevant times, Henry Schein was in the business of distributing, and redistributing, pharmaceutical products to consumers within Kentucky.

247. In 2015, Henry Schein reported that its sales reached a record \$10.4 billion and that it had grown at a compound annual rate of approximately 16 percent since becoming a public company in 1995. Overall, it is the world's largest provider of health care products and services to office-based dental, animal health, and medical practitioners.

f. Smith Drug Company

248. Defendant Smith Drug Company is a South Carolina business entity with its principal place of business in South Carolina.

249. At all times relevant to this Complaint, Smith Drug Company was in the business of distributing and redistributing prescription opioids throughout the United States, including in Kentucky.

250. Based on ARCOS data, opioids sold and distributed by Smith Drug Company represent a substantial market share in Kentucky during the relevant time period. Between 2006 and 2014, Smith Drug company was one of the top five distributors of hydrocodone and oxycodone in thirty-eight (38) Kentucky counties, distributing 117,073,140 pills of hydrocodone and oxycodone in just those Kentucky counties during that eight-year period.

251. Cardinal, Anda, H. D. Smith, Henry Schein, AmerisourceBergen, and Smith Drug Company are collectively referred to as the "Distributor Defendants."

3. National Retail Pharmacies

a. CVS

252. Defendant CVS Health Corporation is a Delaware corporation with its principal place of business in Rhode Island.

253. Defendant CVS Pharmacy, Inc. is a Rhode Island corporation with its principal place of business in Rhode Island.

254. Defendant Kentucky CVS Pharmacy, L.L.C. is Kentucky limited liability company with its principal place of business in Rhode Island.

255. CVS Health Corporation, CVS Pharmacy Inc., Kentucky CVS Pharmacy, L.L.C. are collectively referred to as “CVS.” CVS distributed prescription opioids throughout the United States, including in Kentucky.

256. As a vertically integrated seller of opioids, CVS knew or should have known that an excessive volume of pills was being sold into Kentucky.

257. According to ARCOS data, from 2006 to 2014, CVS was a top five distributor of oxycodone and hydrocodone pills in twenty Kentucky counties, distributing approximately 36,763,200 pills into Kentucky in just those counties during that eight-year period. Kentucky CVS Pharmacy, L.L.C. was also was one of the top five pharmacies selling oxycodone and hydrocodone pills in twenty-five Kentucky counties. In just those counties, Kentucky CVS Pharmacy, L.L.C. sold approximately 73,251,195 pills into Kentucky during that eight year period.

258. Discovery will reveal that CVS knew or should have known that its pharmacies in Kentucky were (a) filling multiple prescriptions to the same patient using the same doctor (b) filling multiple prescriptions by the same patient using different doctors (c) filling prescriptions of unusual size and frequency for the same patient (d) filling prescriptions of unusual size and frequency from out-of-state patients; (e) filling prescriptions of unusual size and frequency paid for in cash (f) filling prescriptions of unusual size and frequency from the same prescribing physician (g) filling prescriptions of unusual size and frequency from out-of-state physicians;

and (h) filing prescriptions for patients and doctors in combinations that were indicative of diversion and abuse. Upon information and belief, the volumes of opioids distributed to and dispensed by these pharmacies were disproportionate to non-controlled drugs and other products sold by these pharmacies, and disproportionate to the sales of opioids in similarly sized pharmacy markets.

259. At all relevant times, and as the parent company of Defendants CVS Pharmacy, Inc., and Kentucky CVS Pharmacy, L.L.C., Defendant CVS Health Corporation established national policies and procedures governing the distribution and sales of controlled substances throughout the United States that it directed and intended that those policies and procedures would be implemented on a nationwide basis including in, specifically, Kentucky. At all times relevant to this Complaint, CVS was responsible for directing and implementing policies and procedures governing the distribution and sales of controlled substances by its subsidiaries throughout the United States, including in Kentucky and Plaintiffs' communities specifically.

260. CVS Pharmacy, Inc. had complete access to, and full visibility of, all opioid distribution data related to CVS pharmacies in and around Kentucky.

261. CVS Pharmacy, Inc. had complete access to, and full visibility of, all prescription opioid dispensing data related to CVS pharmacies in and around Kentucky.

262. CVS Pharmacy, Inc. had complete access to information revealing the customers which filled (or sought to fill) prescriptions for opioids in CVS pharmacies in and around Kentucky.

263. CVS Pharmacy, Inc. had complete access to information revealing the opioid and non-opioid prescriptions dispensed by CVS pharmacies in Kentucky, including those which were being paid for in cash. CVS Pharmacy, Inc. had complete access to information revealing the

geographic location of out-of-state prescriptions for opioids that were being filled in and around Kentucky.

b. The Kroger Co.

264. Defendant The Kroger Co. is an Ohio corporation with headquarters in Cincinnati, Ohio.

265. Defendant, Kroger Limited Partnership I, an Ohio corporation with its principal place of business located in Cincinnati, Ohio.

266. Defendant, Kroger Limited Partnership II, is an Ohio limited partnership with its principal place of business located in Columbus, Ohio.

267. The Kroger Co., Kroger Limited Partnership I, and Kroger Limited Partnership II are collectively referred to as “Kroger.” Kroger operates 2,268 pharmacies in the United States, including in Kentucky. At all times relevant to this Complaint, Kroger distributed prescription opioids throughout the United States, including in Kentucky.

268. As a vertically integrated dispenser of prescription opioids, Kroger knew or should have known that an excessive volume of pills was being sold into Kentucky.

269. Discovery will reveal that Kroger knew or should have known that its pharmacies in Kentucky were (a) filling multiple prescriptions to the same patient using the same doctor (b) filling multiple prescriptions by the same patient using different doctors (c) filling prescriptions of unusual size and frequency for the same patient (d) filling prescriptions of unusual size and frequency from out-of-state patients; (e) filling prescriptions of unusual size and frequency paid for in cash (f) filling prescriptions of unusual size and frequency from the same prescribing physician (g) filling prescriptions of unusual size and frequency from out-of-state physicians; and (h) filing prescriptions for patients and doctors in combinations that were indicative of diversion and abuse. Upon information and belief, the volumes of opioids distributed to and

dispensed by these pharmacies were disproportionate to non-controlled drugs and other products sold by these pharmacies, and disproportionate to the sales of opioids in similarly sized pharmacy markets.

270. At all relevant times, and as the parent company, Defendant The Kroger Co. established national policies and procedures governing the distribution and dispensing of controlled substances throughout the United States that it directed and intended that those policies and procedures would be implemented on a nationwide basis including, specifically, Kentucky. At all times relevant to this Complaint, Defendant The Kroger Co. was responsible for directing and implementing policies and procedures governing the distribution and dispensing of controlled substances by its subsidiaries throughout the United States, including in Kentucky and Plaintiffs' Community specifically.

271. Kroger had complete access to, and full visibility of, all prescription opioid distribution data related Kroger pharmacies in and around Kentucky.

272. Kroger had complete access to, and full visibility of, all prescription opioid dispensing data related to Kroger pharmacies in and around Kentucky.

273. Kroger had complete access to information revealing the customers which filled (or sought to fill) prescriptions for opioids in Kroger pharmacies in and around Kentucky.

274. Kroger had complete access to information revealing the opioid and non-opioid prescriptions dispensed by Kroger pharmacies in Kentucky, including those which were being paid for in cash. Kroger had complete access to information revealing the geographic location of out-of-state prescriptions for opioids that were being filled in and around Kentucky.

c. Rite-Aid of Maryland, Inc.

275. Defendant Rite Aid of Kentucky, Inc., d/b/a Rite Aid Mid-Atlantic Customer Support Center, Inc. (“Rite Aid”), is a Maryland corporation with its principal office located in Camp Hill, Pennsylvania. At all times relevant to this Complaint, Rite Aid distributed prescription opioids throughout the United States, including in Kentucky.

d. Walgreens

276. Defendant Walgreen Co. (“Walgreen Co.”) is an Illinois corporation with its principal place of business in Deerfield, Illinois. Walgreen Co. conducted business as a licensed wholesale distributor. At all times relevant to this Complaint, Walgreen Co. distributed opioids throughout the United States, including into Kentucky.

277. Defendant Walgreen Eastern Co., Inc. (“WEC”) is a New York corporation with its principal place of business in Deerfield, Illinois. WEC conducted business as a licensed wholesale distributor. At all times relevant to this Complaint, WEC distributed opioids throughout the United States, including into Kentucky.

278. Defendant Walgreens Boots Alliance, Inc. (“WBA”) is a Delaware corporation with its principal place of business in Illinois. WBA acted by and through its own subsidiaries and affiliated entities to distribute opioids throughout the country, including in Kentucky.

279. Walgreens Co., WBA, and WEC are collectively referred to herein as “Walgreens.” At all times relevant to this Complaint, Walgreens distributed prescription opioids throughout the United States, including in Kentucky.

280. According to ARCOS data, Walgreen Co. was the fourth largest distributors of pills of oxycodone and hydrocodone in Kentucky between 2006 and 2014. During this eight-year period, Walgreens distributed 276,846,260 pills of oxycodone and hydrocodone into Kentucky.

Walgreens pharmacies were also top opioid sellers in Kentucky, with two Walgreens pharmacies in Louisville ranking in the top five sellers of oxycodone and hydrocodone.

281. As a vertically integrated dispenser of prescription opioids, Walgreens knew or should have known that an excessive volume of pills were being distributed in Kentucky.

282. Discovery will reveal that Walgreens knew or should have known that its pharmacies in Kentucky were (a) filling multiple prescriptions to the same patient using the same doctor (b) filling multiple prescriptions by the same patient using different doctors (c) filling prescriptions of unusual size and frequency for the same patient (d) filling prescriptions of unusual size and frequency from out-of-state patients; (e) filling prescriptions of unusual size and frequency paid for in cash (f) filling prescriptions of unusual size and frequency from the same prescribing physician (g) filling prescriptions of unusual size and frequency from out-of-state physicians; and (h) filing prescriptions for patients and doctors in combinations that were indicative of diversion and abuse. Upon information and belief, the volumes of opioids distributed to and dispensed by these pharmacies were disproportionate to non-controlled drugs and other products sold by these pharmacies, and disproportionate to the sales of opioids in similarly sized pharmacy markets.

283. At all relevant times, Walgreens established national policies and procedures governing the distribution of controlled substances throughout the United States that it directed and intended that those policies and procedures would be implemented on a nationwide basis including, specifically, Kentucky. At all times relevant to this Complaint, Walgreens was responsible for directing and implementing policies and procedures governing the distribution of controlled substances by its subsidiaries throughout the United States, including in Kentucky and Plaintiffs' Community specifically.

284. Walgreens had complete access to, and full visibility of opioid distribution data related to its pharmacies in and around Kentucky.

285. Walgreens had complete access to, and full visibility of, all prescription opioid dispensing data related to Walgreens pharmacies in and around Kentucky.

286. Walgreens had complete access to information revealing the customers which filled (or sought to fill) prescriptions for opioids in Walgreens pharmacies in and around Kentucky.

287. Walgreens had complete access to information revealing the opioid and non-opioid prescriptions dispensed by Walgreens pharmacies in Kentucky, including those which were being paid for in cash. Walgreens had complete access to information revealing the geographic location of out-of-state prescriptions for opioids that were being filled in and around Kentucky.

e. Wal-Mart Inc.

288. Defendant Wal-Mart Inc., formerly known as Wal-Mart Stores, Inc., is a Delaware corporation with its principal place of business in Arkansas.

289. Defendant Wal-Mart Stores East, LP is a Delaware limited partnership with its principal place of business in Arkansas.

290. Wal-Mart, Inc. and Wal-Mart Stores East, LP are collectively referred to as “Wal-Mart.” At all times relevant to this Complaint, Walmart distributed prescription opioids throughout the United States, including in Kentucky.

291. According to ARCOS data, between 2006 and 2014 Walmart was the fifth largest seller of oxycodone and hydrocodone pills in Kentucky. Walmart distributed 185,434,100 pills of oxycodone and hydrocodone in Kentucky, including in Plaintiffs’ communities during that

eight-year period. Walmart's noncompliant sales were made possible by, and are evidence of, Walmart's failures to comply with its duties under state and federal controlled substance laws.

292. From 1996 to 2010, Walmart utilized employees at its distribution centers to review orders for controlled substances, speak to pharmacies about the orders, and escalate any order needing further review. However, Walmart had no written criteria regarding how to identify orders that needed further review. Walmart simply relies on the experience of hourly associates reviewing hundreds of orders each day to recall what an unusual order would be for one of Walmart's more than 4000 pharmacies. Under this system, few, if any orders were ever identified by distribution center employees as needing further review or followed up on.

293. Walmart's policies during this time period failed to identify suspicious orders before shipment or anytime, and, as a consequence, Walmart routinely shipped suspicious orders. Walmart failed to use available reports and information to monitor for suspicious orders. Walmart further did not have a process to monitor or keep track of any order that was flagged.

294. Walmart conducted very little due diligence during the relevant time period. Even once Walmart put policy in place requiring flagged orders to be reviewed, Walmart failed to follow its own policy and the review of these orders failed to occur.

295. Though Walmart had access to significant information about red flags due to its vertical integration with its stores, Walmart failed to use available information from indicating red flags in order to more effectively prevent diversion.

296. As a National Pharmacy, Walmart knew or should have known that its pharmacies in Illinois were (a) filling multiple prescriptions to the same patient using the same doctor (b) filling multiple prescriptions by the same patient using different doctors (c) filling orders of unusual size and frequency for the same patient (d) filling orders of unusual size and

frequency from out-of-state patients; (e) filling orders of unusual size and frequency paid for in cash (f) filling orders of unusual size and frequency from the same prescribing physician (g) filling orders of unusual size and frequency from out-of-state physicians.

297. Because of its vertically integrated structure, Walmart has access to complete information regarding red flags of diversion across its pharmacies in and around Illinois, including Plaintiffs' Community, but Walmart failed to utilize this information to effectively prevent diversion.

298. Collectively, Defendants CVS, Kroger, Rite Aid, Walgreens, and Walmart are referred to as "National Retail Pharmacies."

299. Defendants include the above referenced entities as well as their predecessors, successors, affiliates, subsidiaries, partnerships and divisions to the extent that they are engaged in the manufacture, promotion, distribution, sale and/or dispensing of opioids.

300. The Distributor Defendants and the National Retail Pharmacies are collectively referred to as the "Supply Chain Defendants."

4. Defendants' Agents and Affiliated Persons

301. All of the actions described in this Complaint are part of, and in furtherance of, the unlawful conduct alleged herein, and were authorized, ordered, and/or done by Defendants' officers, agents, employees, or other representatives while actively engaged in the management of Defendants' affairs within the course and scope of their duties and employment, and/or with Defendants' actual, apparent, and/or ostensible authority.

302. The true names and capacities, whether individual, corporate, associate, or otherwise of certain vendors, distributors and/or their alter egos, sued herein as DOES 1 through 100 inclusive, are presently unknown to Plaintiffs, who therefore sues these Defendants by fictitious names. Plaintiffs will seek leave of this Court to amend this Complaint to show their

true names and capacities when they become ascertained. Each of the Doe Defendants has taken part in and participated with, and/or aided and abetted, some or all of the other Defendants in some or all of the matters referred to herein, and therefore are liable for the same.

IV. FACTUAL BACKGROUND

A. The History of Opioids

303. The synthetic opioids manufactured and distributed by Defendants are related to the opium poppy, which has been used to relieve pain for centuries.

304. The opium poppy was a well-known symbol which signified both sleep and death in Roman Civilization. The Romans used opium not only as a medicine but also as a poison.⁸⁹

305. During the Civil War, opioids, then known as “tinctures of laudanum,” gained popularity among doctors and pharmacists for their ability to reduce anxiety and relieve pain on the battlefield. They were also used in a wide variety of commercial products ranging from pain elixirs to cough suppressants to beverages.

306. Kentucky law imposes a hierarchy of restrictions on prescribing and dispensing drugs based on their medicinal value, likelihood of addiction or abuse, and safety. Opioids generally have been categorized as Schedule II or Schedule III drugs. Schedule II drugs have a high potential for abuse, have a currently accepted medical use, and may lead to severe psychological or physical dependence; Schedule III drugs are deemed to have a lower potential for abuse, but their abuse may lead to moderate or low physical dependence or high psychological dependence. *See* KRS § 218A.060; KRS § 218A.080.

307. The strength of various opioids is defined by medical professionals in terms of morphine milligram equivalents (“MME”). Opioids provide varying levels of MMEs. For

⁸⁹ Martin Booth, *Opium: A History*, at 20 (Simon & Schuster Ltd. 1996).

example, just 33 mg of oxycodone provides 50 MME. According to the CDC, doses at or above 50 MME/day double the risk of overdose compared to 20 MME/day. Thus, at OxyContin's twice-daily dosing, the 50 MME/day threshold is nearly reached by a prescription of 15 mg twice daily. One 160 mg tablet of OxyContin, which Purdue took off the market in 2001, delivered 240 MME.

308. The effects of opioids vary by duration. Long-acting opioids, such as Purdue's OxyContin and MS Contin, Janssen's Nucynta ER and Duragesic, Endo's Opana ER, and Actavis's Kadian, are designed to be taken once or twice daily and are purported to provide continuous opioid therapy for, in general, 12 hours. Short-acting opioids, such as Cephalon's Actiq and Fentora, are designed to be taken in addition to long-acting opioids to address "episodic pain" (also referred to as "breakthrough pain") and provide fast-acting, supplemental opioid therapy lasting approximately 4 to 6 hours. Still other short-term opioids, such as Subsys (a product of nonparty and co-conspirator, Insys Therapeutics, Inc. ("Insys")), are designed to be taken in addition to long-acting opioids to specifically address breakthrough cancer pain, excruciating pain suffered by some patients with end-stage cancer. The Marketing Defendants and Purdue promoted the idea that non-cancer related pain should be treated by taking long-acting opioids continuously and supplementing them by also taking short-acting, rapid-onset opioids for episodic or "breakthrough" pain.

309. Patients develop tolerance to the analgesic effect of opioids relatively quickly. As tolerance increases, a patient typically requires progressively higher doses in order to obtain the same perceived level of pain reduction. The same is true of the euphoric effects of opioids—the "high." However, opioids depress respiration, and at very high doses can and often do arrest

respiration altogether. At higher doses, the effects of withdrawal are more severe. Long-term opioid use can also cause hyperalgesia, a heightened sensitivity to pain.

310. Discontinuing opioids after more than just a few weeks of therapy will cause most patients to experience withdrawal symptoms. These withdrawal symptoms include: severe anxiety, nausea, vomiting, headaches, agitation, insomnia, tremors, hallucinations, delirium, pain, and other serious symptoms, which may persist for months after a complete withdrawal from opioids, depending on how long the opioids were used.

311. Opioids provide effective treatment for short-term, post-surgical and trauma-related pain, and for palliative end-of-life care. They are approved by the FDA for use in the management of moderate to severe pain when use of an opioid analgesic is appropriate for more than a few days. Defendants, however, have manufactured, promoted, marketed, and distributed opioids for the management of chronic pain by misleading consumers and medical providers, such as hospitals, through misrepresentations or omissions regarding the appropriate uses, risks, and safety of opioids.

312. As one doctor put it, the widespread, long-term use of opioids “was an experiment on the population of the United States. It wasn’t randomized, it wasn’t controlled, and no data was collected until they started gathering death statistics.”

B. The Opioid Epidemic

313. Opioids have become widely used. In 2010, enough prescription opioids were sold to medicate every adult in the United States with a dose of 5 milligrams of hydrocodone

every 4 hours for 1 month.⁹⁰ Marketing Defendants and Purdue manufacture, market, sell, and distribute branded and/or generic prescription opioid pain medications. Some of the relevant brand-name drugs include OxyContin, Butrans, Hysingla ER, Actiq, Fentora, Opana/Opana ER, Percodan, Percocet, Zydene, Nucynta/Nucynta ER, Duragesic, Exalgo, and Xartemis XR. Marketing Defendants and Purdue used misrepresentations regarding the risks and benefits of opioids to enable the widespread prescribing of opioids for common, chronic pain conditions like low back pain, arthritis, and headaches.

314. Despite the enormous number of prescriptions, recent studies have concluded that treatment with opioids is not superior to treatment with non-opioid medications for improving pain-related function.⁹¹ Even for patients presenting to the emergency room with acute extremity pain, there is no significant or clinically important difference in pain reduction at 2 hours among single-dose treatment with ibuprofen and acetaminophen or with three different opioid and acetaminophen combination analgesics.⁹²

315. In 2011, the CDC declared prescription painkiller overdoses at epidemic levels. The News Release noted:

⁹⁰ Katherine M. Keyes, et al., *Understanding the Rural-Urban Differences in Nonmedical Prescription Opioid Use and Abuse in the United States*, 104 Am. J. Pub. Health e52-e59 (2014), available at <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3935688/>.

⁹¹ Erin E. Krebs, M.D., et al., *Effect of Opioid vs Nonopioid Medications on Pain-Related Function in Patients with Chronic Back Pain or Hip or Knee Osteoarthritis Pain*, 319 JAMA 872-882 (2018), doi: 10.1001/jama.2018.0899, available at <https://jamanetwork.com/journals/jama/article-abstract/2673971?redirect=true>.

⁹² Andrew K. Chang, M.D., et al., *Effect of a Single Dose of Oral Opioid and Nonopioid Analgesics on Acute Extremity Pain in the Emergency Department*, 318 JAMA 1661-1667 (2017), doi: 10.1001/jama.2017.16190, available at <https://jamanetwork.com/journals/jama/article-abstract/2661581?widget=personalizedcontent&previousarticle=2673971&redirect=true>.

- a. The death toll from overdoses of prescription painkillers has more than tripled in the past decade.
- b. More than 40 people die every day from overdoses involving narcotic pain relievers like hydrocodone (Vicodin), methadone, oxycodone (OxyContin), and oxymorphone (Opana).
- c. Overdoses involving prescription painkillers are at epidemic levels and now kill more Americans than heroin and cocaine combined.
- d. The increased use of prescription painkillers for nonmedical reasons, along with growing sales, has contributed to a large number of overdoses and deaths. In 2010, 1 in every 20 people in the United States age 12 and older—a total of 12 million people—reported using prescription painkillers non-medically according to the National Survey on Drug Use and Health. Based on the data from the Drug Enforcement Administration, sales of these drugs to pharmacies and health care providers have increased by more than 300 percent since 1999.
- e. Prescription drug abuse is a silent epidemic that is stealing thousands of lives and tearing apart communities and families across America.
- f. Almost 5,500 people start to misuse prescription painkillers every day.⁹³

316. The CDC has also identified addiction to prescription pain medication as the strongest risk factor for heroin addiction. People who are dependent on prescription opioid painkillers – which, at the molecular level and in their effect, closely resemble heroin - are forty times more likely to be addicted to heroin.⁹⁴ According to a recent study, among young urban heroin users, 86% used opioid pain relievers prior to using heroin.⁹⁵

⁹³ See Prescription Painkiller Overdoses at Epidemic Levels, *supra* n. 28.

⁹⁴ See Centers for Disease Control and Prevention, *Today's Heroin Epidemic*, available at <https://www.cdc.gov/vitalsigns/heroin/index.html> (last accessed August 1, 2018).

⁹⁵ Nat'l Inst. on Drug Abuse, *Prescription Opioids and Heroin* (Jan. 2018), available at <https://d14rmgtrwzf5a.cloudfront.net/sites/default/files/19774-prescription-opioids-and-heroin.pdf>.

317. The synthetic opioid fentanyl has been a driving force behind the nation's opioid epidemic, killing tens of thousands of Americans in overdoses. The drug is so powerful that it is now being used to execute prisoners on death row.⁹⁶

318. In a November 2016 report, the DEA declared opioid prescription drugs, heroin, and fentanyl as the most significant drug-related threats to the United States.⁹⁷

319. The U.S. opioid epidemic is continuing, and drug overdose deaths nearly tripled during 1999–2014. Among the 47,055 drug overdose deaths that occurred in 2014 in the United States, 28,647 (60.9%) involved an opioid.⁹⁸

320. The rate of death from opioid overdose has quadrupled during the past 15 years in the United States. Nonfatal opioid overdoses that require medical care in a hospital or emergency department have increased by a factor of six in the past 15 years.⁹⁹

321. The National Institute on Drug Abuse identifies misuse and dependence on opioids as “a serious national crisis that affects public health as well as social and economic

⁹⁶ Mitch Smith, *Fentanyl Used to Execute Nebraska Inmate*, in *First for U.S.*, (Aug. 14, 2018), available at <https://www.nytimes.com/2018/08/14/us/carey-dean-moore-nebraska-execution-fentanyl.html>.

⁹⁷ Rudd *et al.*, Centers for Disease Control and Prevention, *Increases in Drug and Opioid-Involved Overdose Deaths—United States, 2010-2015* (Dec. 30, 2016), Morbidity & Mortality Wkly. Rep. 2016; 65; 1445-1452, doi: <http://dx.doi.org/10.15585/mmwr.mm655051e1>, available at <https://www.cdc.gov/mmwr/volumes/65/wr/mm655051e1.htm>.

⁹⁸ See Rudd *et al.*, Centers for Disease Control and Prevention, *Increases in Drug and Opioid-Involved Overdose Deaths—United States, 2010-2015* (Dec. 30, 2016), Morbidity & Mortality Wkly. Rep. 2016; 65; 1445-1452, DOI: <http://dx.doi.org/10.15585/mmwr.mm655051e1>, available at <https://www.cdc.gov/mmwr/volumes/65/wr/mm655051e1.htm>.

⁹⁹ See Nora D. Volkow, M.D. & A. Thomas McLellan, M.D., *Opioid Abuse in Chronic Pain – Misconceptions and Mitigation Strategies*, 374 N Engl J Med 1253-1263 (2016), DOI: 10.1056/NEJMra1507771, <http://www.nejm.org/doi/full/10.1056/NEJMra1507771>, (“Volkow & McLellan”).

welfare.”¹⁰⁰ The economic burden of prescription opioid misuse alone is \$78.5 billion a year, including the costs of healthcare, lost productivity, addiction treatment, and criminal justice expenditures.¹⁰¹

322. In 2016, the President of the United States officially declared an opioid and heroin epidemic.¹⁰²

C. Congressional Response to the Opioid Crisis

323. Congressional interest in the opioid crisis has been intense. Multiple committees in both the House and Senate have conducted dozens of hearings exploring the issue from almost every angle, including effects on the health care system, people and their communities, law enforcement, workplaces, schools, and the Native American community. Congressional efforts culminated in the passage of the “Substance Use-Disorder Prevention that Promotes Opioid Recovery and Treatment for Patients and Communities Act,” or the “SUPPORT for Patients and Communities Act.” This Bill passed the House by a vote of 396-14 on June 22, 2018, passed the Senate by a vote of 99-1 on September 17, 2018, and was signed into law by the President on October 24, 2018. Among other provisions, the Bill made it easier to intercept drugs being shipped into the country, authorized new funding for more comprehensive treatment, sped up research on non-addictive painkillers, and provided for broader coverage for substance abuse

¹⁰⁰ *Id.*

¹⁰¹ *Id.* (citing at note 2, Florence CS, et al., *The Economic Burden of Prescription Opioid Overdose, Abuse, and Dependence in the United States*, 2013 (Oct. 2016), 54 Med. Care 901-906 (2016), DOI: 10.1097/MLR.0000000000000625, available at <https://www.ncbi.nlm.nih.gov/pubmed/27623005>).

¹⁰² See Proclamation No. 9499, 81 Fed. Reg. 65173 (Sept. 16, 2016) (proclaiming “Prescription Opioid and Heroin Epidemic Awareness Week”), available at <https://www.gpo.gov/fdsys/pkg/FR-2016-09-22/pdf/2016-22960.pdf>.

under Medicare and Medicaid regulations that have occasionally stood in the way of treatment. Congressional interest in the issue is ongoing.

V. THE MARKETING DEFENDANTS' AND PURDUE'S FALSE, DECEPTIVE, AND UNFAIR MARKETING OF OPIOIDS

324. The opioid epidemic did not happen by accident.

325. Before the 1990s, generally accepted standards of medical practice dictated that opioids should only be used short-term for acute pain, pain relating to recovery from surgery, or for cancer or palliative (end-of-life) care. Due to the lack of evidence that opioids improved patients' ability to overcome pain and function, coupled with evidence of greater pain complaints as patients developed tolerance to opioids over time and the serious risk of addiction and other side effects, the use of opioids for chronic pain was discouraged or prohibited. As a result, doctors generally did not prescribe opioids for chronic pain.

326. Each Marketing Defendant and Purdue has conducted a marketing scheme designed to persuade doctors and patients that opioids can and should be used for chronic pain, resulting in opioid treatment for a far broader group of patients who are much more likely to become addicted and suffer other adverse effects from the long-term use of opioids. In connection with this scheme, each Marketing Defendant and Purdue spent, and continues to spend, millions of dollars on promotional activities and materials that falsely deny, trivialize, or materially understate the risks of opioids while overstating the benefits of using them for chronic pain.

327. The Marketing Defendants and Purdue have disseminated these common messages to reverse the generally accepted medical understanding of opioids and risks of opioid use. They disseminated these messages directly, through their sales representatives, in speaker

groups led by physicians that the Marketing Defendants recruited for their support of their marketing messages, and through unbranded marketing and industry-funded Front Groups.

328. The Marketing Defendants' and Purdue's efforts have been wildly successful. Opioids are now the most prescribed class of drugs. Globally, opioid sales generated \$11 billion in revenue for drug companies in 2010 alone; sales in the United States have exceeded \$8 billion in revenue annually since 2009.¹⁰³ In an open letter to the nation's physicians in August 2016, the then U.S. 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 legitimate pain."¹⁰⁴ This epidemic has resulted in a flood of opioids available for illicit use or sale (the supply), and a population of patients physically and psychologically dependent on them (the demand). And when those patients can no longer afford or obtain opioids from licensed dispensaries, they often turn to the street to buy prescription opioids or even non-prescription opioids, like heroin.

329. The Marketing Defendants and Purdue promoted, and profited from, their misrepresentations about the risks and benefits of opioids for chronic pain even though they knew that their marketing was false and misleading. The history, research, as well as clinical experience over the last 20 years of opioids, established that opioids were highly addictive and responsible for a long list of very serious adverse outcomes. The FDA and other regulators warned Marketing Defendants and Purdue of these risks. The Marketing Defendants and Purdue had access to scientific studies, detailed prescription data, and reports of adverse events,

¹⁰³ See Katherine Eban, *Oxycontin: Purdue Pharma's Painful Medicine*, FORTUNE (Nov. 9, 2011), available at <http://fortune.com/2011/11/09/oxycontin-purdue-pharmas-painful-medicine/>; David Crow, *Drugmakers Hooked on \$10bn Opioid Habit*, FINANCIAL TIMES (Aug. 10, 2016).

¹⁰⁴ Letter from Vivek H. Murthy, M.D., U.S. Surgeon General, *supra* n. 48.

including reports of addiction, hospitalization, and deaths – all of which made clear the harms from long-term opioid use and that patients were suffering from addiction, overdoses, and death in alarming numbers. More recently, the FDA and CDC issued pronouncements based on existing medical evidence that conclusively expose the known falsity of these Defendants' misrepresentations.

330. The Marketing Defendants and Purdue intentionally continued their conduct, as alleged herein, with knowledge that such conduct was creating the opioid nuisance and causing the harms and damages alleged herein.

331. As alleged throughout this Complaint, Defendants' conduct created a public health crisis and a public nuisance. The harm and endangerment to the public health, safety, and the environment created by this public nuisance is ongoing and has not been abated.

332. The public nuisance— *i.e.*, the opioid epidemic—created, perpetuated, and maintained by Defendants can be abated and further recurrence of such harm can be ameliorated by (a) educating prescribers (especially primary care physicians and the most prolific prescribers of opioids) and patients regarding the true risks and benefits of opioids, including the risk of addiction, in order to prevent the next cycle of addiction; (b) providing addiction treatment to patients who are already addicted to opioids; and (c) making naloxone widely available so that overdoses are less frequently fatal.

333. Defendants have the ability to act to abate the public nuisance, and the law recognizes that they must do so. It is the manufacturer of a drug that has primary responsibility to ensure the safety, efficacy, and appropriateness of a drug's labeling, marketing, and promotion. All companies in the supply chain of a controlled substance are primarily responsible for ensuring that such drugs are only distributed and dispensed to appropriate patients and not

diverted. These responsibilities to ensure that their products and practices meet state controlled substances and consumer protection laws and regulations, exist independent of any FDA or DEA regulation. As registered manufacturers and distributors of controlled substances, Defendants are placed in a position of special trust and responsibility, and are uniquely positioned, based on their knowledge of prescribers and orders, to act as a first line of defense.

334. The Marketing Defendants and Purdue spread their false and deceptive statements by marketing their branded opioids directly to doctors and patients throughout the United States. The Marketing Defendants and Purdue also deployed seemingly unbiased and independent third parties that they controlled to spread their false and deceptive statements about the risks and benefits of opioids for the treatment of chronic pain throughout Kentucky.

335. Across the pharmaceutical industry, “core message” development is funded and overseen on a national basis by the drug manufacturer’s corporate headquarters. This comprehensive approach ensures that the Marketing Defendants and Purdue’s messages are accurately and consistently delivered across marketing channels – including detailing visits, speaker events, and advertising – and in each sales territory. The Marketing Defendants and Purdue consider this high level of coordination and uniformity crucial to successfully marketing their drugs.

336. The Marketing Defendants and Purdue 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. The Marketing Defendants and Purdue’s sales representatives and physician speakers were required to stick to prescribed talking points, sales

messages, and slide decks, and supervisors rode along with them periodically to both check on their performance and compliance.

A. The Marketing Defendants' and Purdue's False and Deceptive Statements About Opioids

337. The Marketing Defendants' and Purdue's misrepresentations fall into the following ten categories:

- a. The risk of addiction from chronic opioid therapy is low;
- b. To the extent there is a risk of addiction, it can be easily identified and managed;
- c. Signs of addictive behavior are "pseudoaddiction," requiring more opioids;
- d. Blaming persons dependent on opioids as "abusers" of opioids;
- e. Opioid withdrawal can be avoided by tapering;
- f. Opioid doses can be increased without limit or greater risks;
- g. Long-term opioid use improves functioning;
- h. Alternative forms of pain relief pose greater risks than opioids;
- i. A version of OxyContin marketed by Purdue was effective in providing 12-hour pain relief; and
- j. New formulations of certain opioids successfully deter abuse.

338. Each of these propositions was false. The Marketing Defendants and Purdue knew this, but they nonetheless set out to convince physicians, patients, and the public at large of the truth of each of these propositions in order to expand the market for their opioids.

339. The categories of misrepresentations are offered to organize the numerous statements the Marketing Defendants and Purdue made and to explain their role in the overall marketing effort, not as a checklist for assessing each Marketing Defendant's liability. While each Marketing Defendant and Purdue deceptively promoted their opioids specifically, and,

together with other Marketing Defendants and Purdue, opioids generally, not every Marketing Defendant propagated (or needed to propagate) each misrepresentation. Each Marketing Defendant's and Purdue's conduct, and each misrepresentation, contributed to an overall narrative that aimed to—and did—mislead doctors, patients, and payors about the risks and benefits of opioids. While this Complaint endeavors to document examples of each Marketing Defendant's and Purdue's misrepresentations and the manner in which they were disseminated, they are just that—examples. The Complaint is not, especially prior to discovery, an exhaustive catalog of the nature and manner of each deceptive statement by each Marketing Defendant and Purdue.

1. **Falsehood #1: The Risk of Addiction from Chronic Opioid Therapy is Low**

340. Central to the Marketing Defendants' and Purdue's promotional scheme was the misrepresentation that opioids are rarely addictive when taken for chronic pain. Through their marketing efforts, the Marketing Defendants and Purdue advanced the idea that the risk of addiction is low when opioids are taken as prescribed by "legitimate" pain patients. That, in turn, directly led to the expected and intended result that doctors prescribed more opioids to more patients—thereby enriching the Marketing Defendants and Purdue and substantially contributing to the opioid epidemic.

341. Each of the Marketing Defendants and Purdue claimed that the potential for addiction from its opioids was relatively small or non-existent, even though there was no scientific evidence to support those claims. None of them have acknowledged, retracted, or corrected their false statements.

342. In fact, studies have shown that a substantial percentage of long-term users of opioids experience addiction. Addiction can result from the use of any opioid, "even at

recommended dose,”¹⁰⁵ and the risk substantially increases with more than three months of use.¹⁰⁶ As the CDC Guideline states, “[o]pioid pain medication use presents serious risks, including overdose and opioid use disorder” (a diagnostic term for addiction).¹⁰⁷

a. **Purdue and Abbott’s Misrepresentations Regarding Addiction Risk**

36. When it launched OxyContin, Purdue knew it would need data to overcome decades of wariness regarding opioid use. It needed some sort of research to back up its messaging. But Purdue had not conducted any studies about abuse potential or addiction risk as part of its application for FDA approval for OxyContin. Purdue (and, later, the other Defendants) found this “research” in the form of a one-paragraph letter to the editor published in the New England Journal of Medicine (“NEJM”) in 1980.

37. This letter, by Dr. Hershel Jick and Jane Porter, declared the incidence of addiction “rare” for patients treated with opioids.¹⁰⁸ They had analyzed a database of hospitalized patients who were given opioids in a controlled setting to ease suffering from acute pain. Porter and Jick considered a patient not addicted if there was no sign of addiction noted in patients’ records.

¹⁰⁵ FDA announces safety labeling changes and post market study requirements for extended-release and long-acting opioid analgesics, FDA (Sept. 10, 2013). *See also* FDA announces enhanced warnings for immediate-release opioid pain medications related to risks of misuse, abuse, addiction, overdose and death, FDA (Mar. 22, 2016).

¹⁰⁶ Dowell, CDC Guideline, *supra* n. 24, at 27.

¹⁰⁷ *Id.* at 2.

¹⁰⁸ Jane Porter and Herschel Jick, MD, *Addiction Rare in Patients Treated with Narcotics*, 302(2) N Engl J Med. 123 (Jan. 10, 1980), available at <http://www.nejm.org/doi/pdf/10.1056/NEJM198001103020221>.

ADDICTION RARE IN PATIENTS TREATED WITH NARCOTICS

To the Editor: Recently, we examined our current files to determine the incidence of narcotic addiction in 39,946 hospitalized medical patients¹ who were monitored consecutively. Although there were 11,882 patients who received at least one narcotic preparation, there were only four cases of reasonably well documented addiction in patients who had no history of addiction. The addiction was considered major in only one instance. The drugs implicated were meperidine in two patients,² Percodan in one, and hydromorphone in one. We conclude that despite widespread use of narcotic drugs in hospitals, the development of addiction is rare in medical patients with no history of addiction.

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1. Jick H, Miettinen OS, Shapiro S, Lewis GP, Siskind Y, Slone D. Comprehensive drug surveillance. JAMA. 1970; 213:1455-60.

2. Miller RR, Jick H. Clinical effects of meperidine in hospitalized medical patients. J Clin Pharmacol. 1978; 18:180-8.

38. As Dr. Jick explained to a journalist years later, he submitted the statistics to NEJM as a letter because the data were not robust enough to be published as a study.¹⁰⁹

39. Purdue nonetheless began repeatedly citing this letter in promotional and educational materials as evidence of the low risk of addiction, while failing to disclose that its source was a letter to the editor, not a peer-reviewed paper.¹¹⁰ Citation of the letter, which was largely ignored for more than a decade, significantly increased after the introduction of OxyContin. While first Purdue and then other Marketing Defendants used it to assert that their opioids were not addictive, “that’s not in any shape or form what we suggested in our letter,” according to Dr. Jick.

¹⁰⁹ Barry Meier, *Pain Killer: A “Wonder” Drug’s Trail Of Addiction And Death*, 174 (Rodale 2003) (herein after “Pain Killer”).

¹¹⁰ J. Porter & H. Jick, *Addiction Rare in Patients Treated with Narcotics*, 302(2) New. Eng. J. Med. 123 (1980).

40. Purdue specifically used the Porter and Jick Letter in its 1998 promotional video “I got my life back,” in which Dr. Alan Spanos states “In fact, the rate of addiction amongst pain patients who are treated by doctors is *much less than 1%*.”¹¹¹ Purdue trained its sales representatives to tell prescribers that less than 1% of patients who took OxyContin became addicted. (In 1999, a Purdue-funded study of patients who used OxyContin for headaches found that the addiction rate was 13%).¹¹²

41. Other Defendants relied on and disseminated the same false and deceptive messaging. The enormous impact of Defendants’ misleading amplification of this letter was well documented in another letter published in the NEJM on June 1, 2017, describing the way the one-paragraph 1980 letter had been irresponsibly cited and, in some cases, “grossly misrepresented.” In particular, the authors of this letter explained:

[W]e found that a five-sentence letter published in the *Journal* in 1980 was heavily and uncritically cited as evidence that addiction was rare with long-term opioid therapy. We believe that this citation pattern contributed to the North American opioid crisis by helping to shape a narrative that allayed prescribers’ concerns about the risk of addiction associated with long-term opioid therapy.¹¹³

¹¹¹ Our Amazing World, *Purdue Pharma OxyContin Commercial*, available at <https://www.youtube.com/watch?v=Er78Dj5hyeI>, (last accessed August 1, 2018) (emphasis added).

¹¹² Patrick R. Keefe, *The Family that Built an Empire of Pain*, *The New Yorker* (Oct. 30, 2017), available at <https://www.newyorker.com/magazine/2017/10/30/the-family-that-built-an-empire-of-pain> (“*Empire of Pain*”).

¹¹³ Pamela T.M. Leung, B.Sc. Pharm., Erin M. Macdonald, M.Sc., Matthew B. Stanbrook, M.D., Ph.D., Irfan Al Dhalla, M.D., David N. Juurlink, M.D., Ph.D., *A 1980 Letter on the Risk of Opioid Addiction*, 376 N Engl J Med 2194-95 (June 1, 2017), available at <http://www.nejm.org/doi/full/10.1056/NEJMc1700150#t=article>.

42. “It’s difficult to overstate the role of this letter,” said Dr. David Juurlink of the University of Toronto, who led the analysis. “It was the key bit of literature that helped the opiate manufacturers convince front-line doctors that addiction is not a concern.”¹¹⁴

43. Alongside its use of the Porter and Jick Letter, Purdue also crafted its own materials and spread its deceptive message through numerous additional channels. In its 1996 press release announcing the release of OxyContin, for example, Purdue declared, “The fear of addiction is exaggerated.”¹¹⁵

44. Abbott sales staff were instructed about the euphoria patients were receiving on the shorter-acting painkiller Vicodin; they should tell physicians that “OxyContin has fewer such effects.” Abbott’s “King of Pain” taught his staff of “Royal Crusaders” that OxyContin would “minimize[e] the risk of dependence” and “lower[] euphoria,” when, in fact, he had little knowledge of pharmacology and no basis for these statements.

45. In an internal memo, Abbott told representatives to highlight the “less abuse/addiction potential” of the drug, which could be taken just twice a day because of its time-release formulation.¹¹⁶

46. Abbott’s sales representatives were also given a graphic to show doctors that depicted levels of its pain-killing ingredient in the bloodstream holding steady, but it looked

¹¹⁴ Marilyn Marchione, *Painful words: How a 1980 letter fueled the opioid epidemic*, STAT (May 31, 2017), available at <https://www.statnews.com/2017/05/31/opioid-epidemic-nejm-letter/>.

¹¹⁵ Press Release, OxyContin, *New Hope for Millions of Americans Suffering from Persistent Pain: Long-Acting OxyContin Tablets Now Available to Relieve Pain* (May 31, 1996) available at <http://documents.latimes.com/oxycontin-press-release-1996/>.

¹¹⁶ “Secret trove reveals bold ‘crusade’ to make OxyContin a blockbuster” by David Armstrong. STAT. Sept. 22, 2016.

“flatter” than the levels actually were, according to the court records. The use of a similar graph was cited in the federal case against Purdue as a key part of evidence that it falsely marketed OxyContin as having less euphoric effects and abuse potential than shorter-acting opioids.¹¹⁷

47. A “coaching sheet” prepared for Abbott sales personnel advised discussing the potential abuse of OxyContin only if a doctor brought it up, and to tell physicians that “street users” were misusing the drug not “true pain patients.”¹¹⁸

48. The more Abbott generated in sales, the higher the reward for the company, as well. Under the agreement with Purdue, Abbott received 25 percent of all net sales, up to \$10 million, for prescriptions written by doctors its sales reps called on, and 30 percent of sales above \$10 million, according to court records. Purdue deducted an unspecified amount for costs related to items such as shipping and distribution.¹¹⁹

49. Abbott refused to provide West Virginia’s lawyers figures showing its earnings from OxyContin, according to the court records, but documents obtained by the state in its lawsuit “show millions of dollars in earnings to Abbott.”¹²⁰

50. In an attached letter from an Abbott executive to Purdue’s vice president of marketing, Abbott pledged to take the relationship between the companies to “new heights with our positioning of OxyContin as a key component of Abbott Pain Management.”¹²¹

¹¹⁷ *Id.*

¹¹⁸ *Id.*

¹¹⁹ *Id.*

¹²⁰ *Id.*

¹²¹ *Id.*

51. The sales forces of Abbott and Purdue worked in tandem. They held regular strategy sessions, alternating meeting locations between Purdue's headquarters and Abbott's corporate offices in Illinois, according to the court records.¹²²

52. At a hearing before the House of Representatives' Subcommittee on Oversight and Investigations of the Committee on Energy and Commerce in August 2001, Purdue emphasized "legitimate" treatment, dismissing cases of overdose and death as something that would not befall "legitimate" patients: "Virtually all of these reports involve people who are abusing the medication, not patients with legitimate medical needs under the treatment of a healthcare professional."¹²³

53. Purdue spun this baseless "legitimate use" distinction out even further in a patient brochure about OxyContin, called *A Guide to Your New Pain Medicine and How to Become a Partner Against Pain*. In response to the question "Aren't opioid pain medications like OxyContin Tablets 'addicting'?" Purdue claimed that there was no need to worry about addiction if taking opioids for legitimate, "medical" purposes:

Drug addiction means using a drug to get "high" rather than to relieve pain. You are taking opioid pain medication for medical purposes. The medical purposes are clear and the effects are beneficial, not harmful.

¹²² *Id.*

¹²³ *Oxycontin: Its Use and Abuse: Hearing Before the House Subcommittee on Oversight and Investigations of the Comm. on Energy and Commerce*, 107th Cong. 1 (Aug. 28, 2001) (statement of Michael Friedman, Executive Vice President, Chief Operating Officer, Purdue Pharma, L.P.), available at <https://www.gpo.gov/fdsys/pkg/CHRG-107hhrg75754/html/CHRG-107hhrg75754.htm>.

54. Sales representatives marketed OxyContin as a product “to start with and to stay with.”¹²⁴ Sales representatives also received training in overcoming doctors’ concerns about addiction with talking points they knew to be untrue about the drug’s abuse potential. One of Purdue’s early training memos compared doctor visits to “firing at a target,” declaring that “[a]s you prepare to fire your ‘message,’ you need to know where to aim and what you want to hit!”¹²⁵ According to the memo, the target is physician resistance based on concern about addiction: “The physician wants pain relief for these patients without addicting them to an opioid.”¹²⁶

55. Purdue, through its unbranded website *Partners Against Pain*,¹²⁷ stated the following: “Current Myth: Opioid addiction (psychological dependence) is an important clinical problem in patients with moderate to severe pain treated with opioids. Fact: Fears about psychological dependence are exaggerated when treating appropriate pain patients with opioids.”

56. Former sales representative Steven May, who worked for Purdue from 1999 to 2005, explained to a journalist how he and his coworkers were trained to overcome doctors’ objections to prescribing opioids. The most common objection he heard about prescribing

¹²⁴ Keefe, *Empire Of Pain*, *supra* n. 112.

¹²⁵ *Pain Killer*, *supra* n. 109, at 102.

¹²⁶ *Id.*

¹²⁷ *Partners Against Pain* consists of both a website, styled as an “advocacy community” for better pain care, and a set of medical education resources distributed to prescribers by sales representatives. It has existed since at least the early 2000s and has been a vehicle for Purdue to downplay the risks of addiction from long-term opioid use. One early pamphlet, for example, answered concerns about OxyContin’s addictiveness by claiming: “Drug addiction means using a drug to get ‘high’ rather than to relieve pain. You are taking opioid pain medication for medical purposes. The medical purposes are clear and the effects are beneficial, not harmful.”

OxyContin was that “it’s just too addictive.”¹²⁸ May and his coworkers were trained to “refocus” doctors on “legitimate” pain patients, and to represent that “legitimate” patients would not become addicted. In addition, they were trained to say that the 12-hour dosing made the extended-release opioids less “habit-forming” than painkillers that need to be taken every four hours.

57. According to interviews with prescribers and former Purdue sales representatives, Purdue has continued to distort or omit the risk of addiction while failing to correct its earlier misrepresentations, leaving many doctors with the false impression that pain patients will only rarely become addicted to opioids.

58. With regard to addiction, Purdue’s label for OxyContin has not sufficiently disclosed the true risks to, and experience of, its patients. Until 2014, the OxyContin label stated in a black-box warning that opioids have “abuse potential” and that the “risk of abuse is increased in patients with a personal or family history of substance abuse.”

59. However, the FDA made clear to Purdue as early as 2001 that the disclosures in its OxyContin label were insufficient.

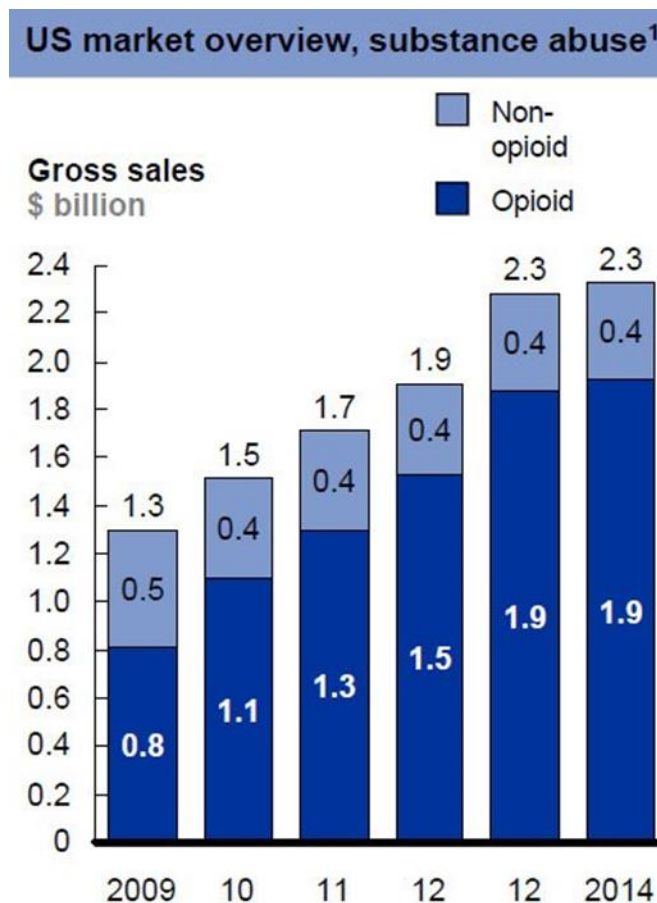
60. In 2001, Purdue revised the indication and warnings for OxyContin.

61. In the end, Purdue narrowed the recommended use of OxyContin to situations when “a continuous, around-the-clock analgesic is needed for an extended period of time” and added a warning that “[t]aking broken, chewed, or crushed OxyContin tablets” could lead to a “potentially fatal dose.” However, Purdue did not, until 2014, change the label to indicate that

¹²⁸ David Remnick, *How OxyContin Was Sold to the Masses* (Steven May interview with Patrick Radden Keefe), *The New Yorker* (Oct. 27, 2017), available at <https://www.newyorker.com/podcast/the-new-yorker-radio-hour/how-oxycontin-was-sold-to-the-masses>.

OxyContin should not be the first therapy, or even the first opioid, used, and did not disclose the incidence or risk of overdose and death even when OxyContin was not abused. Purdue announced the label changes in a letter to health care providers.

62. Purdue's awareness of the addictive properties of their opioid products is exemplified by their cynical attempts to profit from addiction treatment. In 2007, Co-Conspirator Richard Sackler filed an application for a patent for a purported treatment for opioid addiction. In September 2014, Co-Conspirator Kathe Sackler dialed in to a confidential call about Project Tango -- a secret plan for Purdue to expand into the business of selling drugs to treat opioid addiction. In their internal documents, Ms. Sackler and staff wrote down what Purdue publicly denied for decades: that addictive opioids and opioid addiction are "naturally linked." They determined that Purdue should expand across "the pain and addiction spectrum," to become "an end-to-end pain provider." Purdue illustrated the end-to-end business model with a picture of a dark hole labeled "Pain treatment" that a patient could fall into — and "Opioid addiction treatment" waiting at the bottom. Ms. Sackler and the *Project Tango* team reviewed their findings that the "market" of people addicted to opioids, measured coldly in billions of dollars, had doubled from 2009 to 2014:



Purdue's measure of the opioid addiction "market"

63. Co-Conspirator Kathe Sackler and the staff found that the catastrophe provided an excellent compound annual growth rate ("CAGR"): "Opioid addiction (other than heroin) has grown by ~20% CAGR from 2000 to 2010." Ms. Kathe Sackler and the staff revealed in their internal documents that Purdue's tactic of blaming addiction on untrustworthy patients was a lie. Instead, the truth is that opioid addiction can happen to anyone who is prescribed opioids.

- *“This can happen to any-one – from a 50 year old woman with chronic lower back pain to a 18 year old boy with a sports injury, from the very wealthy to the very poor”*

Purdue’s “Project Tango” patient and clinical rationale

64. Ms. Kathe Sackler and the staff concluded that millions of people who became addicted to opioids were the Sackler Co-Conspirators’ next business opportunity. Staff wrote: “It is an attractive market. Large unmet need for vulnerable, underserved and stigmatized patient population suffering from substance abuse, dependence and addiction.” The team identified eight ways that Purdue’s experience getting patients *on* opioids could now be used to sell treatment for opioid addiction.

65. In June 2017, the Sackler Co-Conspirators met to discuss a revised version of *Project Tango* - another try at profiting from the opioid crisis. This time, they considered a scheme to sell the overdose antidote NARCAN. The need for NARCAN to reverse overdoses was rising so fast that the Sackler Co-Conspirators calculated it could provide a growing source of revenue, tripling from 2016 to 2018.

b. Endo’s Misrepresentations Regarding Addiction Risk

66. Endo also falsely represented that addiction is rare in patients who are prescribed opioids.

67. Until April 2012, Endo’s website for Opana, www.opana.com, stated that “[m]ost healthcare providers who treat patients with pain agree that patients treated with prolonged opioid medicines usually do not become addicted.”

68. In consideration of a reasonable opportunity for further investigation and discovery, Plaintiffs allege that Endo improperly instructed its sales representatives to diminish and distort the risk of addiction associated with Opana ER.

69. One of the Front Groups with which Endo worked most closely was the American Pain Foundation (“APF”), described more fully below.

70. APF conveyed through its National Initiative on Pain Control (“NIPC”) and its website www.Painknowledge.com, which claimed that “[p]eople who take opioids as prescribed usually do not become addicted.”

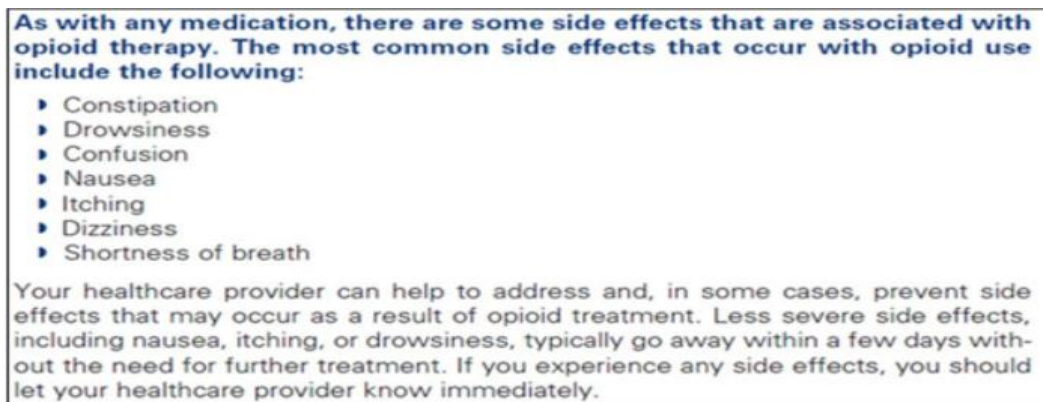
71. Another Endo website, www.PainAction.com, stated: “Did you know? Most chronic pain patients do not become addicted to the opioid medications that are prescribed for them.”

72. A brochure available on www.Painknowledge.com titled “*Pain: Opioid Facts*,” an Endo- sponsored NIPC, stated that “people who have no history of drug abuse, including tobacco, and use their opioid medication as directed will probably not become addicted.” In numerous patient education pamphlets, Endo repeated this deceptive message.

73. In a patient education pamphlet titled “*Understanding Your Pain: Taking Oral Opioid Analgesics*,” Endo answers the hypothetical patient question — “What should I know about opioids and addiction?” — by focusing on explaining what addiction is (“a chronic brain disease”) and is not (“Taking opioids for pain relief”). It goes on to explain that “[a]ddicts take opioids for other reasons, such as unbearable emotional problems. Taking opioids as prescribed

for pain relief is not addiction.” This publication is still available online and was edited by KOL Dr. Russell Portenoy.¹²⁹

74. In addition, a 2009 patient education publication, *Pain: Opioid Therapy*, funded by Endo and posted on www.Painknowledge.com, omitted addiction from the “common risks” of opioids, as shown below:



c. Janssen’s Misrepresentations Regarding Addiction Risk

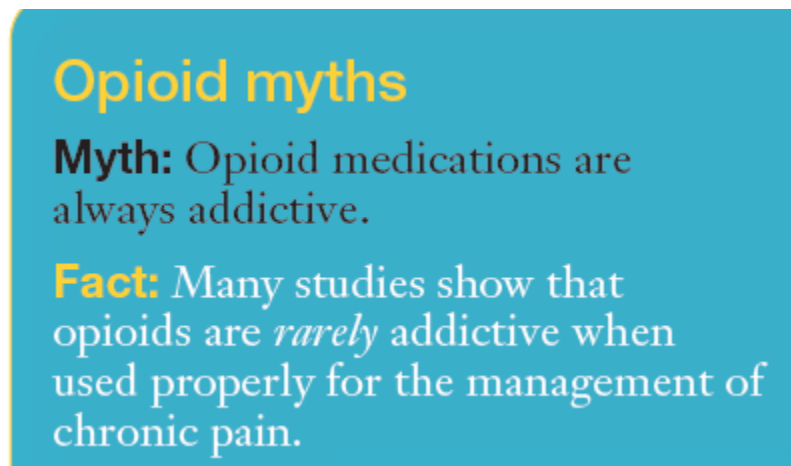
75. Janssen likewise misrepresented the addiction risk of opioids on its websites and print materials. One website, *Let’s Talk Pain*, states, among other things, that “the stigma of drug addiction and abuse” associated with the use of opioids stemmed from a “lack of understanding addiction.”

76. The *Let’s Talk Pain* website also perpetuated the concept of pseudoaddiction, associating patient behaviors such as “drug seeking,” “clock watching,” and “even illicit drug use or deception” with undertreated pain which can be resolved with “effective pain management.”

¹²⁹ Margo McCaffery, RN MS, FAAN & Chris Pasero, RN, MS FAAN, *Understanding Your Pain, Taking Oral Opioid Analgesics*, available at http://www.thblack.com/links/rsd/understand_pain_opioid_analgesics.pdf (last accessed October 26, 2018)

77. A Janssen unbranded website, www.PrescribeResponsibly.com, states that concerns about opioid addiction are “overestimated” and that “true addiction occurs only in a small percentage of patients.”¹³⁰

78. Janssen reviewed, edited, approved, and distributed a patient education guide entitled *Finding Relief: Pain Management for Older Adults*, which, as seen below, described as “myth” 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” (emphasis in original). Until recently, this guide was still available online.



79. Janssen’s website for Duragesic included a section addressing “Your Right to Pain Relief” and a hypothetical patient’s fear that “I’m afraid I’ll become a drug addict.” The website’s response: “Addiction is relatively rare when patients take opioids appropriately.”

d. Cephalon’s Misrepresentations Regarding Addiction Risk

80. Cephalon sponsored and facilitated the development of a guidebook, *Opioid Medications and REMS: A Patient’s Guide*, which included claims that “patients without a

¹³⁰ Keith Candiotti, M.D., *Use of Opioid Analgesics in Pain Management*, Prescribe Responsibly, available at <http://www.prescriberesponsibly.com/articles/opioid-pain-management> (last modified July 2, 2015).

history of abuse or a family history of abuse do not commonly become addicted to opioids.” Similarly, Cephalon sponsored APF’s *Treatment Options: A Guide for People Living with Pain* (2007), which taught that addiction is rare and limited to extreme cases of unauthorized dose escalations, obtaining opioids from multiple sources, or theft.

81. For example, a 2003 Cephalon-sponsored CME presentation titled *Pharmacologic Management of Breakthrough or Incident Pain*, posted on Medscape in February 2003, teaches:

[C]hronic pain is often undertreated, particularly in the non-cancer patient population. . . . The continued stigmatization of opioids and their prescription, coupled with often unfounded and self-imposed physician fear of dealing with the highly regulated distribution system for opioid analgesics, remains a barrier to effective pain management and must be addressed. Clinicians intimately involved with the treatment of patients with chronic pain recognize that the majority of suffering patients lack interest in substance abuse. In fact, patient fears of developing substance abuse behaviors such as addiction often lead to under treatment of pain. The concern about patients with chronic pain becoming addicted to opioids during long-term opioid therapy may stem from confusion between physical dependence (tolerance) and psychological dependence (addiction) that manifests as drug abuse.¹³¹

e. Actavis’s Misrepresentations Regarding Addiction Risk

82. Through its “Learn More about customized pain control with Kadian” material, Actavis claimed that it is possible to become addicted to morphine-based drugs like Kadian, but that it is “less likely” to happen in those who “have never had an addiction problem.” The piece goes on to advise that a need for a “dose adjustment” is the result of tolerance, and “not addiction.”

¹³¹ Michael J. Brennan, et al., *Pharmacologic Management of Breakthrough or Incident Pain*, Medscape (Feb. 26, 2003), available at <http://www.medscape.org/viewarticle/449803>, (last accessed July 27, 2017).

83. Training for Actavis sales representatives deceptively minimized the risk of addiction by: (i) attributing addiction to “predisposing factors” like family history of addiction or psychiatric disorders; (ii) repeatedly emphasizing the difference between substance dependence and substance abuse; and (iii) using the term pseudoaddiction, which, as described below, dismisses evidence of addiction as the undertreatment of pain and, dangerously, counsels doctors to respond to its signs with more opioids.

84. Actavis conducted a market study on takeaways from prescribers’ interactions with Kadian sales representatives. The doctors had a strong recollection of the sales representatives’ discussion of the low-abuse potential. Actavis’ sales representatives’ misstatements on the low- abuse potential was considered an important factor to doctors, and was most likely repeated and reinforced to their patients. Additionally, doctors reviewed visual aids that the Kadian sales representatives use during the visits, and Actavis noted that doctors associate Kadian with less abuse and no highs, in comparison to other opioids. Numerous marketing surveys of doctors in 2010 and 2012, for example, confirmed Actavis’s messaging about Kadian’s purported low addiction potential, and that it had less abuse potential than other similar opioids.

85. A guide for prescribers under Actavis’s copyright deceptively represented that Kadian is more difficult to abuse and less addictive than other opioids. The guide includes the following statements: 1) “unique pharmaceutical formulation of KADIAN may offer some protection from extraction of morphine sulfate for intravenous use by illicit users,” and 2) KADIAN may be less likely to be abused by health care providers and illicit users” because of “Slow onset of action,” “Lower peak plasma morphine levels than equivalent doses of other formulations of morphine,” “Long duration of action,” and “Minimal fluctuations in peak to

trough plasma levels of morphine at steady state.” These statements convey both that (1) Kadian does not cause euphoria and therefore is less addictive and that (2) Kadian is less prone to tampering and abuse, even though Kadian was not approved by the FDA as abuse deterrent, and, upon information and belief, Actavis had no studies to suggest it was.

f. Mallinckrodt’s Misrepresentations Regarding Addiction Risk

86. As described below, Mallinckrodt promoted its branded opioids Exalgo and Xartemis XR, and opioids generally, in a campaign that consistently mischaracterized the risk of addiction. Mallinckrodt did so through its website and sales force, as well as through unbranded communications distributed through the “C.A.R.E.S. Alliance” it created and led.

87. Mallinckrodt in 2010 created the C.A.R.E.S. (Collaborating and Acting Responsibly to Ensure Safety) Alliance, which it describes as “a coalition of national patient safety, provider and drug diversion organizations that are focused on reducing opioid pain medication abuse and increasing responsible prescribing habits.” The “C.A.R.E.S. Alliance” itself is a service mark of Mallinckrodt LLC (and was previously a service mark of Mallinckrodt, Inc.) copyrighted and registered as a trademark by Covidien, its former parent company. Materials distributed by the C.A.R.E.S. Alliance, however, include unbranded publications that do not disclose a link to Mallinckrodt.

88. By 2012, Mallinckrodt, through the C.A.R.E.S. Alliance, was promoting a book titled *Defeat Chronic Pain Now!* This book is still available online.¹³² The false claims and misrepresentations in this book include the following statements:

¹³² Available at https://books.google.com/books?id=VcSQGYKXWdYC&printsec=frontcover&source=gbs_ViewAPI#v=snippet&q=only%20rarely%20does%20opioid%20medication&f=false

- a. “Only rarely does opioid medication cause a true addiction when prescribed appropriately to a chronic pain patient who does not have a prior history of addiction.”
- b. “It is currently recommended that every chronic pain patient suffering from moderate to severe pain be viewed as a potential candidate for opioid therapy.”
- c. “When chronic pain patients take opioids to treat their pain, they rarely develop a true addiction and drug craving.”
- d. “Only a minority of chronic pain patients who are taking long-term opioids develop tolerance.”
- e. “The bottom line: Only rarely does opioid medication cause a true addiction when prescribed appropriately to a chronic pain patient who does not have a prior history of addiction.”
- f. “Here are the facts. It is very uncommon for a person with chronic pain to become ‘addicted’ to narcotics IF (1) he doesn’t have a prior history of any addiction and (2) he only takes the medication to treat pain.”
- g. “Studies have shown that many chronic pain patients can experience significant pain relief with tolerable side effects from opioid narcotic medication when taken daily and no addiction.”

89. In a 2013 *Mallinckrodt Pharmaceuticals Policy Statement Regarding the Treatment of Pain and Control of Opioid Abuse*, which is still available online, Mallinckrodt stated that, “[s]adly, even today, pain frequently remains undiagnosed and either untreated or undertreated” and cites to a report that concludes that “the majority of people with pain use their prescription drugs properly, are not a source of misuse, and should not be stigmatized or denied access because of the misdeeds or carelessness of others.”

90. Marketing Defendants’ and Purdue’s suggestions that the opioid epidemic is the result of bad patients who manipulate doctors to obtain opioids illicitly helped further their marketing scheme is at odds with the facts. While there are certainly patients who unlawfully obtain opioids, they are a small minority. For example, patients who “doctor-shop”—i.e., visit multiple prescribers to obtain opioid prescriptions—are responsible for roughly 2% of opioid

prescriptions. The epidemic of opioid addiction and abuse is overwhelmingly a problem of false marketing (and unconstrained distribution) of the drugs, not problem patients.

2. Falsehood #2: To the Extent There is a Risk of Addiction, It Can Be Easily Identified and Managed

91. While continuing to maintain that most patients can safely take opioids long-term for chronic pain without becoming addicted, the Marketing Defendants and Purdue assert that to the extent that *some* patients are at risk of opioid addiction, doctors can effectively identify and manage that risk by using screening tools or questionnaires. In materials they produced, sponsored, or controlled, Defendants instructed patients and prescribers that screening tools can identify patients predisposed to addiction, thus making doctors feel more comfortable prescribing opioids to their patients and patients more comfortable starting opioid therapy for chronic pain. These tools, they say, identify those with higher addiction risks (stemming from personal or family histories of substance use, mental illness, trauma, or abuse) so that doctors can then more closely monitor those patients.

92. Purdue shared its *Partners Against Pain* “Pain Management Kit,” which contains several screening tools and catalogues of Purdue materials.

93. Janssen, on its website www.PrescribeResponsibly.com, states that the risk of opioid addiction “can usually be managed” through tools such as opioid agreements between patients and doctors.¹³³ The website, which directly provides screening tools to prescribers for

¹³³ Howard A. Heit, MD, FACP, FASAM and Douglas L. Gourlay, MD, MSc, FRCPC, FASAM, *What a Prescriber Should Know Before Writing the First Prescription*, Prescribe Responsibly, available at <https://web.archive.org/web/20171003105720/> (“What a Prescriber Should Know Before Writing the First Prescription”).

risk assessments,¹³⁴ includes a “[f]our question screener” to purportedly help physicians identify and address possible opioid misuse.¹³⁵

94. Purdue and Cephalon sponsored the APF’s *Treatment Options: A Guide for People Living with Pain* (2007), which also falsely reassured patients that opioid agreements between doctors and patients can “ensure that you take the opioid as prescribed” and counseled patients that opioids “give [pain patients] a quality of life we deserve.”

95. Purdue sponsored a 2011 webinar taught by Dr. Lynn Webster, entitled *Managing Patient’s Opioid Use: Balancing the Need and Risk*. This publication misleadingly taught prescribers that screening tools, urine tests, and patient agreements have the effect of preventing “overuse of prescriptions” and “overdose deaths.”

96. Purdue sponsored a similar 2011 CME program titled *Managing Patient’s Opioid Use: Balancing the Need and Risk*. This presentation deceptively instructed prescribers that screening tools, patient agreements, and urine tests prevented “overuse of prescriptions” and “overdose deaths.”

97. Purdue also funded a 2012 CME program called *Chronic Pain Management and Opioid Use: Easing Fears, Managing Risks, and Improving Outcomes*. The presentation deceptively instructed doctors that, through the use of screening tools, more frequent refills, and other techniques, even high-risk patients showing signs of addiction could be treated with opioids.

¹³⁴ Risk Assessment Resources, *PRESCRIBE RESPONSIBLY*, available at <http://www.prescriberesponsibly.com/risk-assessment-resources> (last accessed August 1, 2018).

¹³⁵ *Id.*

98. Endo paid for a 2007 supplement available for continuing education credit in the *Journal of Family Practice* written by a doctor who became a member of Endo's speaker's bureau in 2010. This publication, entitled *Pain Management Dilemmas in Primary Care: Use of Opioids*, (i) recommended screening patients using tools like (a) the *Opioid Risk Tool* (ORT) created by Dr. Webster and linked to Janssen or (b) the *Screening and Opioid Assessment for Patients with Pain*, and (ii) taught that patients at high risk of addiction could safely receive chronic opioid therapy using a "maximally structured approach" involving toxicology screens and pill counts. The ORT was linked to Endo-supported websites, as well.

99. There are three fundamental flaws in the Marketing Defendants' and Purdue's representations that doctors can consistently identify and manage the risk of addiction. First, there is no reliable scientific evidence that doctors can depend on the screening tools currently available to materially limit the risk of addiction. Second, there is no reliable scientific evidence that high-risk patients identified through screening can take opioids long-term without triggering addiction, even with enhanced monitoring. Third, there is no reliable scientific evidence that patients who are not identified through such screening can take opioids long-term without significant danger of addiction.

100. The CDC Guideline confirmed the falsity of marketing Defendants' and Purdue's claims about the utility of patient screening and management strategies in managing addiction risk. The Guideline notes that there are no studies assessing the effectiveness of risk mitigation strategies — such as screening tools or patient contracts — "for improving outcomes related to overdose, addiction, abuse, or misuse." The CDC Guideline recognized that available risk screening tools "show insufficient accuracy for classification of patients as at low or high risk for

[opioid] abuse or misuse” and counseled that doctors “should not overestimate the ability of these tools to rule out risks from long-term opioid therapy.”¹³⁶

3. Falsehood #3: Signs of Addictive Behavior are “Pseudoaddiction” Requiring More Opioids

101. The Marketing Defendants and Purdue instructed patients and prescribers that signs of addiction are actually indications of untreated pain, such that the appropriate response is to prescribe even more opioids. Dr. David Haddox, who later became a Senior Medical Director for Purdue, published a study in 1989 coining the term “pseudoaddiction,” which he characterized as “the iatrogenic syndrome of abnormal behavior developing as a direct consequence of inadequate pain management.”¹³⁷ In other words, people on prescription opioids who exhibited classic signs of addiction—for example, asking for more and higher doses of opioids, self-escalating their doses, or claiming to have lost prescriptions in order to get more opioids—were not addicted, but rather simply suffering from under-treatment of their pain.

102. In the materials and outreach they produced, sponsored, or controlled, the Marketing Defendants and Purdue made each of these misrepresentations and omissions, and have never acknowledged, retracted, or corrected them.

103. Cephalon, Endo, and Purdue sponsored the Federation of State Medical Boards’ (“FSMB”) *Responsible Opioid Prescribing* (2007) written by Dr. Scott Fishman and discussed in more detail below, which taught that behaviors such as “requesting drugs by name,” “demanding

¹³⁶ Dowell, CDC Guideline, *supra* n. 24, at 28.

¹³⁷ David E. Weissman and J. David Haddox, *Opioid pseudoaddiction—an iatrogenic syndrome*, 36(3) *Pain* 363-66 (Mar. 1989) available at <https://www.ncbi.nlm.nih.gov/pubmed/2710565> (“Iatrogenic” describes a condition induced by medical treatment).

or manipulative behavior,” seeing more than one doctor to obtain opioids, and hoarding, which are signs of genuine addiction, are all really signs of “pseudoaddiction.”

104. Purdue posted an unbranded pamphlet entitled *Clinical Issues in Opioid Prescribing* on its unbranded website, *PartnersAgainstPain.com*, in 2005, and circulated this pamphlet through at least 2007 and on its website through at least 2013. The pamphlet listed conduct including “illicit drug use and deception” that it claimed was not evidence of true addiction but “pseudoaddiction” caused by untreated pain:

A term which has been used to describe patient behaviors that may occur when pain is undertreated. Patients with unrelieved pain may become focused on obtaining medications, may ‘clock watch,’ and may otherwise seem inappropriately ‘drug-seeking.’ Even such behaviors as illicit drug use and deception can occur in the patient’s efforts to obtain relief. Pseudoaddiction can be distinguished from true addiction in that the behaviors resolve when the pain is effectively treated.

105. Purdue again urged doctors to prescribe higher doses, stating that opioids “are frequently underdosed - or even withheld due to a widespread lack of information ... about their use among healthcare professionals.”

106. Purdue’s *Pain Management Kit* is another example of publication used by Purdue’s sales force that endorses pseudoaddiction by claiming that “pain-relief seeking behavior can be mistaken for drug-seeking behavior.” In consideration of a reasonable opportunity for further investigation and discovery, Plaintiffs allege that the kit was in use from roughly 2011 through at least June 2016.

107. A Purdue presentation for doctors titled *Medication Therapy Management* recited what had been the consensus view for decades: “Many medical students are taught that if opioids are prescribed in high doses or for a prolonged time, the patient will become an addict.” Purdue then assured doctors that this traditional concern about addiction was wrong — that patients

instead suffer from “pseudoaddiction” because “opioids are frequently prescribed in doses that are inadequate.” Doctors on Purdue’s payroll admitted in writing that pseudoaddiction was used to describe “behaviors that are clearly characterized as drug abuse” and put Purdue at risk of “ignoring” addiction and “sanctioning abuse.” Purdue, nevertheless, urged doctors to respond to signs of addiction by prescribing higher doses of Purdue’s drugs.

108. Purdue publications touting the concept of “pseudoaddiction” were regularly provided to the Purdue Individual Co-Conspirators by Purdue staff. Staff also regularly reported on the distribution of such materials to the Purdue Individuals.

109. Endo also sponsored a NIPC CME program in 2009 titled *Chronic Opioid Therapy: Understanding Risk While Maximizing Analgesia*, which promoted pseudoaddiction and listed “[d]ifferentiation among states of physical dependence, tolerance, pseudoaddiction, and addiction” as an element to be considered in awarding grants to CME providers.

110. Endo itself has repudiated the concept of pseudoaddiction. In finding that “[t]he pseudoaddiction concept has never been empirically validated and in fact has been abandoned by some of its proponents,” the New York Attorney General, in a 2016 settlement with Endo, reported that “Endo’s Vice President for Pharmacovigilance and Risk Management testified to [the NY AG] that he was not aware of any research validating the ‘pseudoaddiction’ concept” and acknowledged the difficulty in distinguishing “between addiction and ‘pseudoaddiction.’”¹³⁸ Endo thereafter agreed not to “use the term ‘pseudoaddiction’ in any training or marketing” in New York.

¹³⁸ Attorney General of the State of New York, In the Matter of Endo Health Solutions Inc. & Endo Pharmaceuticals Inc., Assurance No.:15-228, Assurance of Discontinuance Under Executive Law Section 63. Subdivision 15 at 7, *available at* https://www.ag.ny.gov/pdfs/Endo_AOD_030116-Fully_Executed.pdf.

111. The FAQs section of *www.pain-topics.org*, a now-defunct website to which Mallinckrodt provided funding, also contained misleading information about pseudoaddiction. Specifically, the website advised providers to “keep in mind” that signs of potential drug diversion, rather than signaling “actual” addiction, “may represent pseudoaddiction,” which the website described as behavior that occurs in patients when pain is “undertreated” and includes patients becoming “very focused on obtaining opioid medications and may be erroneously perceived as ‘drug seeking.’”

112. Janssen sponsored, funded, and edited a website called *Let’s Talk Pain*, which in 2009 stated “pseudoaddiction . . . refers to patient behaviors that may occur when pain is undertreated Pseudoaddiction is different from true addiction because such behaviors can be resolved with effective pain management.” This website was accessible online until at least May 2012. Janssen also currently runs a website, *www.Prescriberresponsibly.com*, which claims that concerns about opioid addiction are “overestimated,” and describes pseudoaddiction as “a syndrome that causes patients to seek additional medications due to inadequate pharmacotherapy being prescribed. Typically, when the pain is treated appropriately the inappropriate behavior ceases.”¹³⁹

113. Marketing Defendants and Purdue also promoted the concept of pseudoaddiction through Dr. Russell Portenoy, a leading KOL for the Defendants. In doing so, he popularized the concept and falsely claimed that pseudoaddiction is substantiated by scientific evidence.

114. The CDC Guideline for prescribing opioids for chronic pain, a “systematic review of the best available evidence” by a panel excluding experts with conflicts of interest, rejects the concept of pseudoaddiction. The Guideline nowhere recommends opioid doses be increased if a

¹³⁹ *What a Prescriber Should Know Before Writing the First Prescription*, *supra* n. 133.

patient is not experiencing pain relief. To the contrary, 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.”¹⁴⁰

115. Dr. Lynn Webster, a KOL discussed below, admitted that pseudoaddiction “is already something we are debunking as a concept” and became “too much of an excuse to give patients more medication. It led us down a path that caused harm.”

4. Falsehood #4: Blaming Addicted Patients as “Untrustworthy” “Abusers”

116. A recurring strategy employed by the Purdue Individual Co-Conspirators, over a period of decades, was to blame any negative consequences from opioid use on moral failings of a minority of users, who would be labeled as “abusers” or “untrustworthy” people.

117. In 2001, Co-Conspirator Richard Sackler wrote down his solution to the overwhelming evidence of overdose and death: blame and stigmatize people who become addicted to opioids. Richard Sackler wrote in a confidential email: “we have to hammer on the abusers in every way possible. They are the culprits and the problem. They are reckless criminals.” The Sackler Co-Conspirators chose to stigmatize people who were hurt by opioids, calling them “junkies” and “criminals.”

118. In December 2011, Co-Conspirator John Stewart gave a speech titled Providing Relief, Preventing Abuse in Connecticut, which deceptively blamed the addiction, overdose, and death on “abuse.” A Purdue pamphlet titled “*Responsible Opioid Prescribing*” told doctors that

¹⁴⁰ Dowell, CDC Guideline, *supra* n. 24, at 13.

only “a small minority of people seeking treatment may not be reliable or trustworthy” and not suitable for addictive opioid drugs.

119. Purdue managers praised sales representatives for pitching doctors on the idea that prescribing to “trustworthy” patients was safe. A sales rep reported that one doctor: “let me know that she will Rx OxyContin when the pts [patients] has chronic pain and are trustworthy.” The rep added that he would “Follow up with Dr and ask what pts does she consider ‘trustworthy?’” A Purdue district manager responded: “Great follow up question on what patients does he consider trustworthy.”

120. Purdue managers praised sales representatives for pitching doctors on the idea that prescribing to “trustworthy” patients was safe. Co-Conspirator Richard Sackler, in a 2007 patent application he filed for a purported treatment for opioid addiction, referred to addicts as “junkies.” In the application, he asks for a monopoly on the treatment of addicts. He received the patent in January 2018.

5. Falsehood #5: Opioid Withdrawal Can Be Avoided by Tapering

121. In an effort to underplay the risk and impact of addiction, the Marketing Defendants and Purdue falsely claimed that, while patients become physically dependent on opioids, physical dependence is not the same as addiction and can be easily addressed, if and when pain relief is no longer desired, by gradually tapering a patient’s dose to avoid the adverse effects of withdrawal. Defendants failed to disclose the extremely difficult and painful effects that patients can experience when they are removed from opioids—adverse effects that also make it less likely that patients will be able to stop using the drugs. Defendants also failed to disclose how difficult it is for patients to stop using opioids after they have used them for a prolonged period.

122. A non-credit educational program sponsored by Endo, *Persistent Pain in the Older Adult*, claimed that withdrawal symptoms, which make it difficult for patients to stop using opioids, could be avoided by simply tapering a patient's opioid dose over ten days.

123. However, this claim is at odds with the experience of patients addicted to opioids. Most patients who have been taking opioids regularly will, upon stopping treatment, experience withdrawal, characterized by intense physical and psychological effects, including anxiety, nausea, headaches, and delirium, among others. This painful and arduous struggle to terminate use can leave many patients unwilling or unable to give up opioids and heightens the risk of addiction.

124. Purdue sponsored APF's *A Policymaker's Guide to Understanding Pain & Its Management*, which taught that "Symptoms of physical dependence can often be ameliorated by gradually decreasing the dose of medication during discontinuation," but the guide did not disclose the significant hardships that often accompany cessation of use.

125. To this day, the Marketing Defendants and Purdue have not corrected or retracted their misrepresentations regarding tapering as a solution to opioid withdrawal.

6. Falsehood #6: Opioid Doses Can Be Increased Without Limit or Greater Risk

126. In materials they produced, sponsored or controlled, Marketing Defendants and Purdue instructed prescribers that they could safely increase a patient's dose to achieve pain relief. Each of the Marketing Defendants' and Purdue's claims was deceptive in that they omitted warnings of increased adverse effects that occur at higher doses that were confirmed by scientific evidence.

127. These misrepresentations were integral to the Marketing Defendants' and Purdue's promotion of prescription opioids. As discussed above, patients develop a tolerance to

opioids' analgesic effects, so that achieving long-term pain relief requires constantly increasing the dose. Patients who take larger doses, and who escalate to larger doses faster, are much more likely to remain on opioids for a longer period of time, resulting in increased revenue.

128. In addition, sales representatives aggressively pushed doctors to prescribe stronger doses of opioids. For example, one Purdue sales representative wrote about how his regional manager would drill the sales team on their upselling tactics:

It went something like this. "Doctor, what is the highest dose of OxyContin you have ever prescribed?" "20mg Q12h." "Doctor, if the patient tells you their pain score is still high you can increase the dose 100% to 40mg Q12h, will you do that?" "Okay." "Doctor, what if that patient then came back and said their pain score was still high, did you know that you could increase the OxyContin dose to 80mg Q12h, would you do that?" "I don't know, maybe." "Doctor, but you do agree that you would at least Rx the 40mg dose, right?" "Yes."

The next week the representative would see that same doctor and go through the same discussion with the goal of selling higher and higher doses of OxyContin. Stronger doses were more expensive and increased the likelihood of addiction.

129. These misrepresentations were particularly dangerous. Opioid doses at or above 50 MME (morphine milligram equivalents)/day double the risk of overdose compared to 20 MME/day, and 50 MME is equal to just 33 mg of oxycodone. The recommendation of 320 mg every twelve hours is ten times that.

130. In its 2010 Risk Evaluation and Mitigation Strategy ("REMS") for OxyContin, however, Purdue does not address the increased risk of respiratory depression and death from increasing dose, and instead advises prescribers that "dose adjustments may be made every 1-2 days"; "it is most appropriate to increase the q12h dose"; the "total daily dose can usually be

increased by 25% to 50%”; and if “significant adverse reactions occur, treat them aggressively until they are under control, then resume upward titration.”¹⁴¹

131. Purdue, for years, used a marketing theme dubbed “Individualize the Dose,” which was a euphemism for “Increase the Dose,” as a means of propounding the false notion that increasing doses of painkillers was in patients’ best interests. Staff regularly reported to the Sackler Co-Conspirators that Purdue’s sales representatives were continuing the *Individualize the Dose* campaign.

132. Endo sponsored a website, www.Painknowledge.com, which claimed that opioids may be increased until “you are on the right dose of medication for your pain,” at which point further dose increases would not be required.

133. Endo also published on its website a patient education pamphlet entitled *Understanding Your Pain: Taking Oral Opioid Analgesics*. 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.”

134. Marketing Defendants and Purdue were aware of the greater dangers high dose opioids posed. In 2013, the FDA acknowledged “that the available data do suggest a relationship between increasing opioid dose and risk of certain adverse events” and that studies “appear to credibly suggest a positive association between high-dose opioid use and the risk of overdose and/or overdose mortality.” A study of the Veterans Health Administration from 2004 to 2008 found the rate of overdose deaths is directly related to maximum daily dose.

¹⁴¹ Purdue Pharma, L.P., *OxyContin Risk Evaluation and Mitigation Strategy*, Purdue Pharma L.P., available at <https://web.archive.org/web/2/https://www.fda.gov/downloads/Drugs/DrugSafet%20y/Postmarke%20DrugSafetyInformationforPatientsandProviders/UCM220990.pdf>, (last modified Nov. 2010).

7. **Falsehood #7: Long-Term Opioid Use Improves Functioning**

135. Despite the lack of evidence of improved function and the existence of evidence to the contrary, the Marketing Defendants and Purdue consistently promoted opioids for patients' function and quality of life because they viewed these claims as a critical part of their marketing strategies. In recalibrating the risk-benefit analysis for opioids, increasing the perceived benefits of treatment was necessary to overcome its risks.

136. Janssen, for example, promoted Duragesic as improving patients' functioning and work productivity through an ad campaign that included the following statements: "[w]ork, uninterrupted," "[l]ife, uninterrupted," "[g]ame, uninterrupted," "[c]hronic pain relief that supports functionality," and "[i]mprove[s] . . . physical and social functioning."

137. Purdue noted the need to compete with this messaging, despite the lack of data supporting improvement in quality of life with OxyContin treatment:

Janssen has been stressing decreased side effects, especially constipation, as well as patient quality of life, as supported by patient rating compared to sustained release morphine. . . . We do not have such data to support OxyContin promotion In addition, Janssen has been using the "life uninterrupted" message in promotion of Duragesic for non-cancer pain, stressing that Duragesic "helps patients think less about their pain." This is a competitive advantage based on our inability to make any quality of life claims.¹⁴²

138. Despite its acknowledgment that "[w]e do not have such data to support OxyContin promotion," Purdue ran a full-page ad for OxyContin in the Journal of the American Medical Association, proclaiming, "There Can Be Life With Relief," and showing a man happily fly-fishing alongside his grandson, implying that OxyContin would help users' function. This ad earned a warning letter from the FDA, which admonished, "It is particularly disturbing that your

¹⁴² *Pain Killer*, *supra* n. 109, at 281.

November ad would tout ‘Life With Relief’ yet fail to warn that patients can die from taking OxyContin.”¹⁴³

139. Purdue sponsored 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. But the article cited as support for this in fact stated the contrary, noting the absence of long-term studies and concluding, “[f]or functional outcomes, the other analgesics were significantly more effective than were opioids.”

140. A series of medical journal advertisements for OxyContin in 2012 presented “Pain Vignettes”—case studies featuring patients with pain conditions persisting over several months—that implied functional improvement. For example, one advertisement described a “writer with osteoarthritis of the hands” and implied that OxyContin would help him work more effectively.

141. Similarly, since at least May of 2011, Endo has distributed and made available on its website, www.opana.com, a pamphlet promoting Opana ER with photographs depicting patients with physically demanding jobs like those of a construction worker or chef, misleadingly implying that the drug would provide long-term pain relief and functional improvement.

142. As noted above, 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.” This guide features a man playing golf on the cover and lists examples of expected functional improvement from opioids, like sleeping through

¹⁴³ Chris Adams, *FDA Orders Purdue Pharma To Pull Its OxyContin Ads*, WALL STREET JOURNAL (Jan. 23, 2003, 12:01am), available at <https://www.wsj.com/articles/SB1043259665976915824>.

the night, returning to work, recreation, sex, walking, and climbing stairs. It assures patients that, “[u]sed properly, opioid medications can make it possible for people with chronic pain to ‘return to normal.’” Similarly, *Responsible Opioid Prescribing* (2007), sponsored and distributed by Teva, Endo, and Purdue, taught that relief of pain by opioids, by itself, improved patients’ function. The book remains for sale online.

143. In addition, Janssen’s *Let’s Talk Pain* website featured a video interview, which was edited by Janssen personnel, claiming that opioids were what allowed a patient to “continue to function,” falsely implying that her experience would be representative.

144. Endo’s NIPC website, www.Painknowledge.com, claimed 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.” In addition to “improved function,” the website touted improved quality of life as a benefit of opioid therapy. The grant request that Endo approved for this project specifically indicated NIPC’s intent to make claims of functional improvement.

145. 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.

146. Mallinckrodt’s website, in a section on responsible use of opioids, claims that “[t]he effective pain management offered by our medicines helps enable patients to stay in the

workplace, enjoy interactions with family and friends, and remain an active member of society.”¹⁴⁴

147. The Marketing Defendants’ and Purdue’s claims that long-term use of opioids improves patient function and quality of life are unsupported by clinical evidence. There are no controlled studies of the use of opioids beyond 16 weeks, and there is no evidence that opioids improve patients’ pain and function long term. The FDA, for years, has made clear through warning letters to manufacturers the lack of evidence for claims that the use of opioids for chronic pain improves patients’ function and quality of life.¹⁴⁵ Based upon a review of the existing scientific evidence, the CDC Guideline concluded that “there is no good evidence that opioids improve pain or function with long-term use.”¹⁴⁶

148. Consistent with the CDC’s findings, substantial evidence exists demonstrating that opioid drugs are ineffective for the treatment of chronic pain and worsen patients’ health. For example, a 2006 study-of-studies found that opioids as a class did not demonstrate improvement in functional outcomes over other non-addicting treatments. The few longer-term

¹⁴⁴ Mallinckrodt Pharmaceuticals, Responsible Use, *available at* <http://www.mallinckrodt.com/corporate-responsibility/responsible-use>, (last accessed July 16, 2018).

¹⁴⁵ The FDA has warned other drug makers that claims of improved function and quality of life were misleading. See Warning Letter from Thomas Abrams, Dir., FDA Div. of Mktg., Adver., & Commc’ns, to Doug Boothe, CEO, Actavis Elizabeth LLC (Feb. 18, 2010), (rejecting claims that Actavis’ opioid, Kadian, had an “overall positive impact on a patient’s work, physical and mental functioning, daily activities, or enjoyment of life.”); Warning Letter from Thomas Abrams, Dir., FDA Div. of Mktg., Adver., & Commc’ns, to Brian A. Markison, Chairman, President and Chief Executive Officer, King Pharmaceuticals, Inc. (March 24, 2008), (finding the claim that “patients who are treated with [Avinza (morphine sulfate ER)] 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.”). The FDA’s warning letters were available to Defendants on the FDA website.

¹⁴⁶ Dowell, CDC Guideline, *supra* n. 24, at 20.

studies of opioid use had “consistently poor results,” and “several studies have showed that Opioids for chronic pain may actually worsen pain and functioning . . .”¹⁴⁷ along with general health, mental health, and social function. Over time, even high doses of potent opioids often fail to control pain, and patients exposed to such doses are unable to function normally.

149. On the contrary, the available evidence indicates opioids may worsen patients’ health and pain. Increased duration of opioid use is strongly associated with increased prevalence of mental health disorders (depression, anxiety, post-traumatic stress disorder, and substance abuse), increased psychological distress, and greater health care utilization. The CDC Guideline concluded that “[w]hile benefits for pain relief, function and quality of life with long-term opioid use for chronic pain are uncertain, risks associated with long-term opioid use are clearer and significant.”¹⁴⁸ According to the CDC, “for the vast majority of patients, the known, serious, and too-often-fatal risks far outweigh the unproven and transient benefits [of opioids for chronic pain].”¹⁴⁹

150. Assessing existing evidence, the CDC Guideline found that there is “insufficient evidence to determine the long-term benefits of opioid therapy for chronic pain.”¹⁵⁰ 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-

¹⁴⁷ Thomas Frieden and Debra Houry, *Reducing the Risks of Relief – The CDC Opioid-Prescribing Guideline*, at 1503, 374 New Eng. J. Med., 4/21/16, at 1503. (April 21, 2016).

¹⁴⁸ Dowell, CDC Guideline, *supra* n. 24, at 2, 18.

¹⁴⁹ Thomas Frieden & Debra Houry, *Reducing the Risks of Relief – The CDC Opioid-Prescribing Guideline*, at 1503, 374 New Eng. J. Med. 1501-1504 (Apr. 21, 2016), doi: 10.1056/NEJMp1515917, available at <http://www.nejm.org/doi/full/10.1056/NEJMp1515917>.

¹⁵⁰ Dowell, CDC Guideline, *supra* n. 24, at 10.

controlled randomized trials $\leq$ 6 weeks in duration)”¹⁵¹ and that other treatments were more or equally beneficial and less harmful than long-term opioid use. The FDA, too, has recognized the lack of evidence to support 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.”¹⁵² As a result, the CDC recommends that opioids not be used in the first instance and for treatment of chronic pain; rather, opioids should be used only after prescribers have exhausted alternative treatments. Nevertheless, upon information and belief, Marketing Defendants and Purdue touted the purported benefits of long-term opioid use, while falsely and misleadingly suggesting that these benefits were supported by scientific evidence.

151. As one pain specialist observed, “opioids may work acceptably well for a while, but over the long term, function generally declines, as does general health, mental health, and social functioning. Over time, even high doses of potent opioids often fail to control pain, and these patients are unable to function normally.”¹⁵³ In fact, research such as a 2008 study in the journal *Spine* has shown that pain sufferers prescribed opioids long-term suffered addiction that made them more likely to be disabled and unable to work.¹⁵⁴ Another study demonstrated that injured workers who received a prescription opioid for more than seven days during the first six

¹⁵¹ Dowell, CDC Guideline, *supra* n. 24, at 9.

¹⁵² Letter from Janet Woodcock, M.D., Dir., Ctr. For Drug Eval. & Res., to Andrew Kolodny, M.D., Pres. *Physicians for Responsible Opioid Prescribing*, Re Docket No. FDA-2012-P-0818 (Sept. 10, 2013), at 10.

¹⁵³ Andrea Rubinstein, *Are We Making Pain Patients Worse?*, Sonoma Med. (Fall 2009), available at <http://www.nbcms.org/en-us/about-us/sonoma-county-medical-association/magazine/sonoma-medicine-are-we-making-pain-patients-worse.aspx?pageid=144&tabid=747>.

¹⁵⁴ Jeffrey Dersh, *et al.*, *Prescription opioid dependence is associated with poorer outcomes in disabling spinal disorders*, 33(20) *Spine* 2219-27 (Sept. 15, 2008), available at <https://www.ncbi.nlm.nih.gov/pubmed/18725868>.

weeks after the injury were 2.2 times more likely to remain on work disability a year later than workers with similar injuries who received no opioids at all.¹⁵⁵ Yet, Marketing Defendants and Purdue have not acknowledged, retracted, or corrected their false statements.

8. **Falsehood #8: Alternative Forms of Pain Relief Pose Greater Risks Than Opioids**

152. In materials they produced, sponsored or controlled, the Marketing Defendants and Purdue omitted known risks of chronic opioid therapy and emphasized or exaggerated risks of competing products so that prescribers and patients would favor opioids over other therapies such as over-the-counter acetaminophen or over-the-counter or prescription non-steroidal anti-inflammatory drugs (“NSAIDs”).

153. For example, in addition to failing to disclose the risks of addiction, overdose, and death in promotional materials, the Marketing Defendants and Purdue routinely ignored the risks of hyperalgesia, a “known serious risk associated with chronic opioid analgesic therapy in which the patient becomes more sensitive to certain painful stimuli over time,”¹⁵⁶ hormonal dysfunction,¹⁵⁷ decline in immune function; mental clouding, confusion, and dizziness, increased falls and fractures in the elderly;¹⁵⁸ NAS (when an infant exposed to opioids prenatally suffers

¹⁵⁵ Franklin, GM, *et al.*, *Early opioid prescription and subsequent disability among workers with back injuries: the Disability Risk Identification Study Cohort*, 33 Spine 199, 201-202 (Jan. 15, 2008) doi: 10.1097/BRS.0b013e318160455c, available at <https://www.ncbi.nlm.nih.gov/pubmed/18197107>.

¹⁵⁶ Letter from Janet Woodcock, M.D., Dir., Ctr. For Drug Eval. & Res., to Andrew Kolodny, M.D., Pres. *Physicians for Responsible Opioid Prescribing*, Re Docket No. FDA-2012-P-0818 (Sept. 10, 2013).

¹⁵⁷ H.W. Daniell, Hypogonadism in men consuming sustained-action oral opioids, 3(5) J. Pain 377-84 (2001), available at <https://www.ncbi.nlm.nih.gov/pubmed/14622741>.

¹⁵⁸ See Bernhard M. Kuschel, *et al.*, *The risk of fall injury in relation to commonly prescribed medications among older people – a Swedish case-control study*, 25 Eur. J. Pub. H. 527-32

withdrawal after birth), and potentially fatal interactions with alcohol or with benzodiazepines, which are used to treat anxiety and may be co-prescribed with opioids, particularly to veterans suffering from pain.¹⁵⁹

154. The APF's *Treatment Options: A Guide for People Living with Pain*, sponsored by Purdue and Teva, warned that risks of NSAIDs increase if "taken for more than a period of months," with no corresponding warning about opioids. The publication falsely attributed 10,000 to 20,000 deaths annually to NSAID overdose, when the figure is actually closer to 3,200.¹⁶⁰

155. Janssen sponsored *Finding Relief: Pain Management for Older Adults* (2009) that listed dose limitations as "disadvantages" of other pain medicines but omitted any discussion of risks from increased doses of opioids. *Finding Relief* described the advantages and disadvantages of NSAIDs on one page, and the "myths/facts" of opioids on the facing page. The disadvantages of NSAIDs are described as involving "stomach upset or bleeding," "kidney or liver damage if taken at high doses or for a long time," "adverse reactions in people with asthma," and "can increase the risk of heart attack and stroke." The only adverse effects of opioids listed are "upset stomach or sleepiness," which the brochure claims will go away, and constipation.

156. Endo's NIPC website, www.Painknowledge.org, contained a flyer called "Pain: Opioid Therapy." This publication listed opioids' adverse effects but with significant omissions,

(July 31, 2014), doi: 10.1093/eurpub/cku120, available at <https://www.ncbi.nlm.nih.gov/pubmed/25085470>.

¹⁵⁹ Karen H. Seal, et al., *Association of Mental Health Disorders With Prescription Opioids and High- Risk Opioids in US Veterans of Iraq and Afghanistan*, 307(9) J. Am. Med. Ass'n 940-47, (March 7, 2012) doi:10.1001/jama.2012.234, available at <https://jamanetwork.com/journals/jama/fullarticle/1105046>.

¹⁶⁰ Robert E. Tarone, et al., *Nonselective Nonaspirin Nonsteroidal Anti-Inflammatory Drugs and Gastrointestinal Bleeding: Relative and Absolute Risk Estimates from Recent Epidemiologic Studies*, 11 Am. J. of Therapeutics 17-25 (2004), available at <https://www.ncbi.nlm.nih.gov/pubmed/14704592>.

including hyperalgesia, immune and hormone dysfunction, cognitive impairment, tolerance, dependence, addiction, and death.

157. In April 2007, Endo sponsored an article aimed at prescribers, published in *Pain Medicine News*, titled “Case Challenges in Pain Management: Opioid Therapy for Chronic Pain.”¹⁶¹ The article asserted:

Opioids represent a highly effective but controversial and often misunderstood class of analgesic medications for controlling both chronic and acute pain. The phenomenon of tolerance to opioids – the gradual waning of relief at a given dose – and fears of abuse, diversion, and misuse of these medications by patients have led many clinicians to be wary of prescribing these drugs, and/or to restrict dosages to levels that may be insufficient to provide meaningful relief.¹⁶²

158. To help allay these concerns, Endo emphasized the risks of NSAIDs as an alternative to opioids. The article included a case study that focused on the danger of extended use of NSAIDs, including that the subject was hospitalized with a massive upper gastrointestinal bleed believed to have resulted from his protracted NSAID use. In contrast, the article did not provide the same detail concerning the serious side effects associated with opioids.

159. Additionally, Purdue acting with Endo sponsored *Overview of Management Options*, a CME issued by the AMA in 2003, 2007, 2010, and 2013. The 2013 version remains available for CME credit. The CME taught that NSAIDs and other drugs, but not opioids, are unsafe at high doses.

¹⁶¹ Charles E. Argoff, *Case Challenges in Pain Management: Opioid Therapy for Chronic Pain*, *Pain Med. News*, available at http://www.painmedicineneeds.com/download/BtoB_Opana_WM.pdf.

¹⁶² *Id.*

160. As a result of the Marketing Defendants' and Purdue's deceptive promotion of opioids over safer and more effective drugs, opioid prescriptions increased even as the percentage of patients visiting a doctor for pain remained constant. A study of 7.8 million doctor visits between 2000 and 2010 found that opioid prescriptions increased from 11.3% to 19.6% of visits, as NSAID and acetaminophen prescriptions fell from 38% to 29%, driven primarily by the decline in NSAID prescribing.¹⁶³

9. Falsehood #9: OxyContin Provides Twelve Hours of Pain Relief

161. Purdue also dangerously misled doctors and patients about OxyContin's duration and onset of action, making the knowingly false claim that OxyContin would provide 12 hours of pain relief for most patients. As laid out below, Purdue made this claim for two reasons. First, it provided the basis for both Purdue's patent and its market niche, allowing it to both protect and differentiate itself from competitors. Second, it allowed Purdue to imply or state outright that OxyContin had a more even, stable release mechanism that avoided peaks and valleys and therefore the rush that fostered addiction and attracted abusers.

162. Purdue promotes OxyContin as an extended-release opioid, but the oxycodone does not enter the body on a linear rate. OxyContin works by releasing a greater proportion of oxycodone into the body upon administration, and the release gradually tapers, as illustrated in the following chart, which was apparently adapted from Purdue's own sales materials.

¹⁶³ M. Daubresse, *et al.*, *Ambulatory Diagnosis and Treatment of Nonmalignant Pain in the United States, 2000-2010*, 51(10) Med. Care, 870-878 (2013) available at <https://insights.ovid.com/pubmed?pmid=24025657> ("For back pain alone, the percentage of patients prescribed opioids increased from 19% to 29% between 1999 and 2010, even as the use of NSAIDs or acetaminophen declined from 39.9% to 24.5% of these visits; and referrals to physical therapy remained steady."). See also, J. Mafi, *et al.*, *Worsening Trends in the Management and Treatment of Back Pain*, 173(17) J. of the Am Med. Ass'n Internal Med. 1573, 1573 (2013) available at <https://www.ncbi.nlm.nih.gov/pubmed/23896698>.

OxyContin PI Figure, Linear y-axis

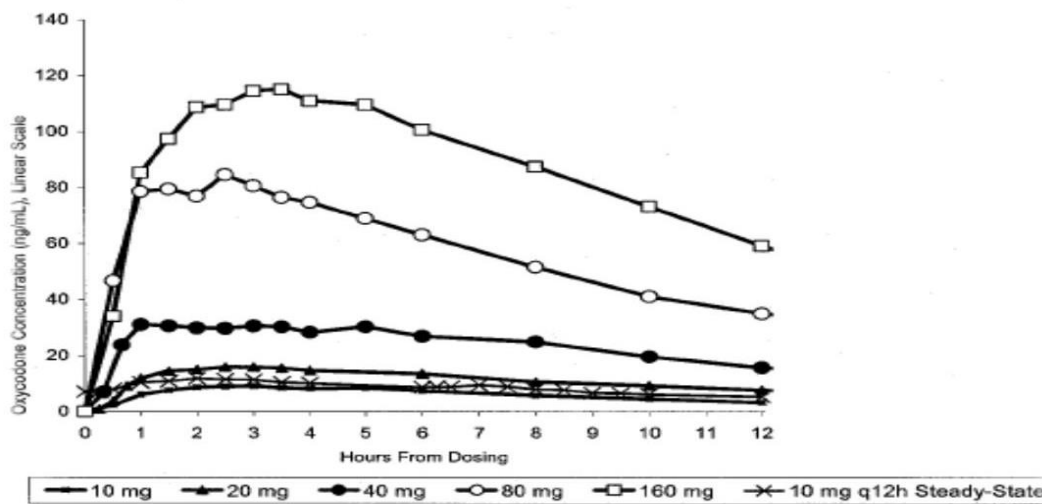


Figure 1

163. The reduced release of the drug over time means that the OxyContin no longer provides the same level of pain relief; as a result, in many patients, OxyContin does not last for the twelve hours for which Purdue promoted it — a fact that Purdue had known at all times relevant to this action.

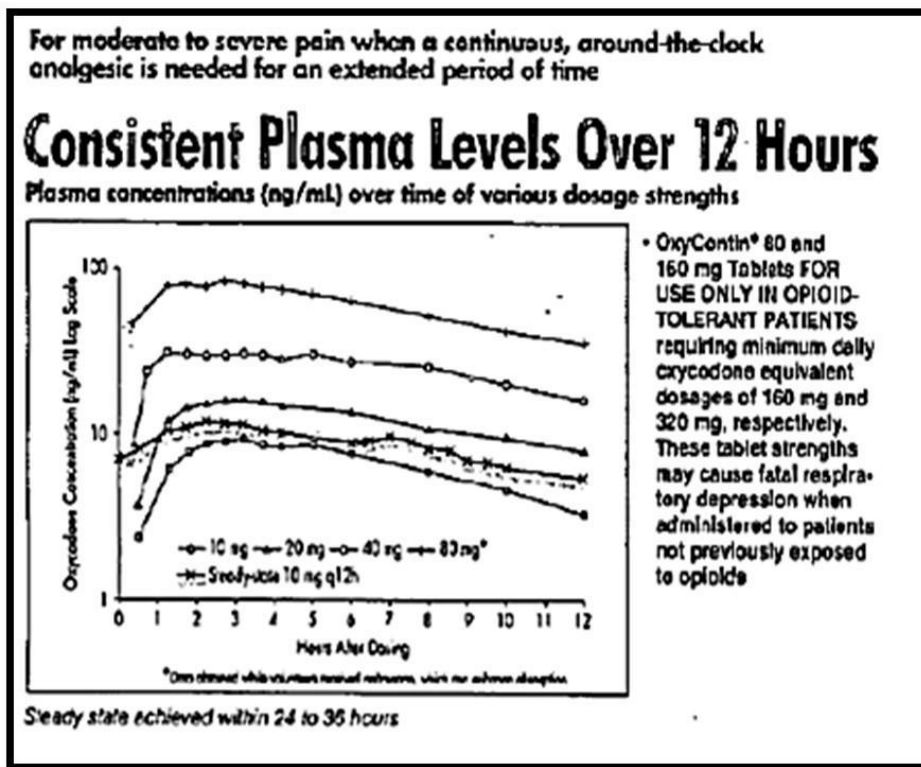
164. OxyContin tablets provide an initial absorption of approximately 40% of the active medicine. This has a two-fold effect. First, the initial rush of nearly half of the powerful opioid triggers a powerful psychological response. OxyContin thus behaves more like an immediate release opioid, which Purdue itself once claimed was more addicting in its original 1995 FDA-approved drug label. Second, the initial burst of oxycodone means that there is less of the drug at the end of the dosing period, which results in the drug's not lasting for a full twelve hours and precipitates withdrawal symptoms in patients, a phenomenon known as "end of dose" failure. (The FDA found in 2008 that a "substantial number" of chronic pain patients will experience end-of-dose failure with OxyContin.)

165. End-of-dose failure renders OxyContin even more dangerous because patients begin to experience withdrawal symptoms, followed by a euphoric rush with their next dose—a cycle that fuels a craving for OxyContin. For this reason, Dr. Theodore Cicero, a neuropharmacologist at the Washington University School of Medicine in St. Louis, has called OxyContin’s 12-hour dosing “the perfect recipe for addiction.”¹⁶⁴ Many patients will exacerbate this cycle by taking their next dose ahead of schedule or resorting to a rescue dose of another opioid, increasing the overall quantity of opioids they are taking.

166. It was Purdue’s decision to submit OxyContin for approval with 12-hour dosing. While the OxyContin label indicates that “[t]here are no well-controlled clinical studies evaluating the safety and efficacy with dosing more frequently than every 12 hours,” that is because Purdue has conducted no such studies.

167. Purdue nevertheless has falsely promoted OxyContin as if it were effective for a full twelve hours. Its advertising in 2000 included claims that OxyContin provides “Consistent Plasma Levels Over 12 Hours.” That claim was accompanied by a chart, mirroring the chart on the previous page. However, this version of the chart deceptively minimized the rate of end-of-dose failure by depicting 10 mg in a way that it appeared to be half of 100 mg in the table’s y-axis. That chart, shown below, depicts the same information as the chart above, but does so in a way that makes the absorption rate appear more consistent:

¹⁶⁴ Harriet Ryan, *et al.*, ‘*You Want a Description of Hell?*’ *OxyContin’s 12-Hour Problem*, LOS ANGELES TIMES (May 5, 2016), available at <http://www.latimes.com/projects/oxycontin-part1/> (“*You Want a Description of Hell?*”).



168. Purdue's 12-hour messaging was key to its competitive advantage over short-acting opioids that required patients to wake in the middle of the night to take their pills. Purdue advertisements also emphasized "Q12h" dosing. These include an advertisement in the February 2005 *Journal of Pain* and 2006 *Clinical Journal of Pain* featuring an OxyContin logo with two pill cups, reinforcing the twice-a-day message. A Purdue memo to the OxyContin launch team stated that "OxyContin's positioning statement is 'all of the analgesic efficacy of immediate-release oxycodone, with convenient q12h dosing,'" and further that "[t]he convenience of q12h dosing was emphasized as the most important benefit."¹⁶⁵

169. Purdue executives therefore maintained the messaging of twelve-hour dosing even when many reports surfaced that OxyContin did not last twelve hours. Instead of

¹⁶⁵ Purdue Meeting Memo, *OxyContin launch*, LOS ANGELES TIMES (May 5, 2016), available at <http://documents.latimes.com/oxycontin-launch-1995/>.

acknowledging a need for more frequent dosing, Purdue instructed its representatives to push higher-strength pills, even though higher dosing carries its own risks, as noted above. Higher Dosing also means that patients will experience higher highs and lower lows, increasing their craving for their next pill. Nationwide, based on an analysis by the LOS ANGELES TIMES, more than 52% of patients taking OxyContin longer than three months are on doses greater than 60 milligrams per day—which converts to the 90 MED (morphine equivalent dose) that the CDC Guideline urges prescribers to “avoid” or “carefully justify.”¹⁶⁶

170. The information that OxyContin did not provide pain relief for a full twelve hours was known to Purdue, and Purdue’s competitors, but was not disclosed to prescribers. Purdue’s knowledge of some pain specialists’ tendency to prescribe OxyContin three times per day instead of two is apparent from MEDWATCH Adverse Event reports for OxyContin.

171. Even Purdue’s competitor, Endo, was aware of the problem; Endo attempted to position its Opana ER drug as offering “durable” pain relief, which Endo understood to suggest a contrast to OxyContin. Opana ER advisory board meetings featured pain specialists’ citing lack of 12-hour dosing as a disadvantage of OxyContin. Endo even ran advertisements for Opana ER referring to “real” 12-hour dosing.

172. For example, in a 1996 sales strategy memo from a Purdue regional manager, the manager emphasized that representatives should “convinc[e] the physician that there is no need” for prescribing OxyContin in shorter intervals than the recommended 12-hour interval, and

¹⁶⁶ Dowell, CDC Guideline, *supra* n. 24, at 16.

instead the solution is prescribing higher doses.”¹⁶⁷ One sales manager instructed her team that anything shorter than 12-hour dosing “needs to be nipped in the bud. NOW!!”¹⁶⁸

173. Purdue’s failure to disclose the prevalence of end-of-dose failure meant that prescribers were misinformed about the advantages of OxyContin in a manner that preserved Purdue’s competitive advantage and profits, at the expense of patients, who were placed at greater risk of overdose, addiction, and other adverse effects.

10. Falsehood #10: New Formulations of Certain Opioids Successfully Deter Abuse

174. Rather than take the widespread abuse of and addiction to opioids as reason to cease their untruthful marketing efforts, Marketing Defendants Purdue and Endo seized them as an opportunity to compete. These companies developed and oversold “abuse-deterrent formulations” (“ADF”) opioids as a solution to opioid abuse and as a reason that doctors could continue to safely prescribe their opioids, as well as an advantage of these expensive branded drugs over other opioids. These Defendants’ false and misleading marketing of the benefits of their ADF opioids preserved and expanded their sales and falsely reassured prescribers thereby prolonging the opioid epidemic. Other Marketing Defendants, including Actavis and Mallinckrodt, also promoted their branded opioids as formulated to be less addictive or less subject to abuse than other opioids.

175. The CDC Guideline confirms that “[n]o studies” support the notion that “abuse-deterrent technologies [are] a risk mitigation strategy for deterring or preventing abuse,” noting

¹⁶⁷ Southern Region Memo to Mr. B. Gergely, *Sales manager on 12-hour dosing*, LOS ANGELES TIMES (May 5, 2016), available at <http://documents.latimes.com/sales-manager-on12-hour-dosing-1996/>.

¹⁶⁸ *You Want a Description of Hell?*, *supra* n. 164.

that the technologies “do not prevent opioid abuse through oral intake, the most common route of opioid abuse, and can still be abused by non-oral routes.” Tom Frieden, the former Director of the CDC, reported that his staff could not find “any evidence showing the updated opioids [ADF opioids] actually reduce rates of addiction, overdoses, or death.”

a. **Purdue’s Deceptive Marketing of Reformulated OxyContin and Hysingla ER**

176. Reformulated ADF OxyContin was approved by the FDA in April 2010. It was not until 2013 that the FDA, in response to a citizen petition filed by Purdue, permitted reference to the abuse-deterrent properties in its label. When Hysingla ER (extended-release hydrocodone) launched in 2014, the product included similar abuse-deterrent properties and limitations. But in the beginning, the FDA made clear the limited claims that could be made about ADF, noting that no evidence supported claims that ADF prevented tampering, oral abuse, or overall rates of abuse.

177. Purdue introduced reformulated ADF OxyContin shortly before generic versions of OxyContin were to become available. By so doing, Purdue anticipated and countered a threat to its market share and the price it could charge for OxyContin. Purdue nonetheless touted its introduction of ADF opioids as evidence of its good corporate citizenship and commitment to address the opioid crisis.

178. Internal documents reveal that Purdue knew, and in fact discussed, the fact that the “crush-proof” ADF reformulation would not prevent the vast majority of opioid abuse, which comes from swallowing pills, and that they introduced the product solely for purposes of extending their patent. In 2008, Purdue’s then CEO, wrote to Defendant Richard Sackler that reformulating OxyContin “will not stop patients from the simple act of taking too many pills.”

179. Despite its self-proclaimed good intention, Purdue merely continued its generally deceptive tactics with respect to ADF. Purdue sales representatives regularly overstated and misstated the evidence for and impact of the abuse-deterrent features of these opioids. Specifically, Purdue sales representatives:

- a. claimed that Purdue's ADF opioids prevent tampering and that its ADFs could not be crushed or snorted;
- b. claimed that Purdue's ADF opioids reduce opioid abuse and diversion;
- c. asserted or suggested that its ADF opioids are non-addictive or less addictive;
- d. asserted or suggested that Purdue's ADF opioids are safer than other opioids, could not be abused or tampered with, and were not sought out for diversion; and
- e. failed to disclose that Purdue's ADF opioids do not impact oral abuse or misuse.

180. If pressed, Purdue acknowledged that perhaps some "extreme" patients might still abuse the drug but claimed the ADF features protect the majority of patients. These misrepresentations and omissions are misleading and contrary to Purdue's ADF labels, Purdue's own information, and publicly available data.

181. Purdue knew or should have known that reformulated OxyContin is not more tamper-resistant than the original OxyContin and is still regularly tampered with.

182. In 2009, the FDA noted in permitting ADF labeling that "the tamper-resistant properties will have no effect on abuse by the oral route (the most common mode of abuse)." In the 2012 medical office review of Purdue's application to include an abuse-deterrence claim in its label for OxyContin, the FDA noted that the overwhelming majority of deaths linked to

OxyContin were associated with oral consumption, and that only 2% of deaths were associated with recent injection and only 0.2% with snorting the drug.

183. The FDA's Director of the Division of Epidemiology stated in September 2015 that no data that she had seen suggested the reformulation of OxyContin "actually made a reduction in abuse," between continued oral abuse, shifts to injection of other drugs (including heroin), and defeat of the ADF mechanism. Even Purdue's own funded research shows that half of OxyContin abusers continued to do so orally after the reformulation rather than shift to other drugs.

184. A 2013 article presented by Purdue employees based on review of data from poison control centers, concluded that ADF OxyContin can reduce abuse, but ignored important negative findings. The article revealed that abuse merely shifted to other drugs and that, when the actual incidence of harmful exposures was calculated, there were more harmful exposures to opioids after the reformulation of OxyContin. In short, the article deceptively emphasized the advantages and ignored the disadvantages of ADF OxyContin.

185. Websites and message boards used by drug abusers, such as www.bluelight.org and www.reddit.com, report a variety of ways to tamper with OxyContin and Hysingla ER, including through grinding, microwaving then freezing, or drinking soda or fruit juice in which a tablet is dissolved. Purdue has been aware of these methods of abuse for more than a decade.

186. One-third of the patients in a 2015 study defeated the ADF mechanism and were able to continue inhaling or injecting the drug. To the extent that the abuse of Purdue's ADF opioids was reduced, there was no meaningful reduction in opioid abuse overall, as many users simply shifted to other opioids such as heroin.

187. In 2015, claiming a need to further assess its data, Purdue abruptly withdrew a supplemental new drug application related to reformulated OxyContin one day before FDA staff was to release its assessment of the application. The staff review preceded an FDA advisory committee meeting related to new studies by Purdue “evaluating the misuse and/or abuse of reformulated OxyContin” and whether those studies “have demonstrated that the reformulated product has a meaningful impact on abuse.”¹⁶⁹ In consideration of a reasonable opportunity for further investigation and discovery, Plaintiffs allege that Purdue never presented the data to the FDA because the data would not have supported claims that OxyContin’s ADF properties reduced abuse or misuse.

188. Despite its own evidence of abuse, and the lack of evidence regarding the benefit of Purdue’s ADF opioids in reducing abuse, Dr. J. David Haddox, the Vice President of Health Policy for Purdue, falsely claimed in 2016 that the evidence does not show that Purdue’s ADF opioids are being abused in large numbers. Purdue’s recent advertisements in national newspapers also continues to claim its ADF opioids as evidence of its efforts to reduce opioid abuse, continuing to mislead prescribers, patients, payors, and the public about the efficacy of its actions.

b. Endo’s Deceptive Marketing of Reformulated Opana ER

189. Opana ER was particularly likely to be tampered with and abused. That is because Opana ER has lower “bioavailability” than other opioids, meaning that the active pharmaceutical ingredient (the “API” or opioid) does not absorb into the bloodstream as rapidly as other opioids when taken orally. Additionally, when swallowed whole, the extended-release mechanism

¹⁶⁹ Meeting Notice, Joint Meeting of the Drug Safety and Risk Management Advisory Committee and the Anesthetic and Analgesic Drug Products Advisory Committee; Notice of Meeting, May 25, 2015, 80 FR 30686.

remains intact, so that only 10% of Opana ER's API is released into the patient's bloodstream relative to injection; when it is taken intranasally, that rate increases to 43%. The larger gap between bioavailability when consumed orally versus snorting or injection, the greater the incentive for users to manipulate the drug's means of administration.

190. In December 2011, Endo obtained approval for a new formulation of Opana ER that added a hard coating that the company claimed made it crush-resistant.

191. Even prior to its approval, the FDA advised Endo that it could not market the new Opana ER as abuse-deterrent.

192. Nonetheless, in August of 2012, Endo submitted a citizen petition asking the FDA for permission to change its label to indicate that Opana ER was abuse-resistant, both in that it was less able to be crushed and snorted and that it was resistant to injection by syringe. Borrowing a page from Purdue's playbook, Endo announced it would withdraw original Opana ER from the market and sought a determination that its decision was made for safety reasons (its lack of abuse-deterrence), which would prevent generic copies of original Opana ER.

193. Endo then sued the FDA, seeking to force expedited consideration of its citizen petition. The court filings confirmed Endo's true motives: in a declaration submitted with its lawsuit, Endo's chief operating officer indicated that a generic version of Opana ER would decrease the company's revenue by up to \$135 million per year. Endo also claimed that if the FDA did not block generic competition, \$125 million, the amount Endo spent on developing the reformulated drug to "promote the public welfare" would be lost.¹⁷⁰ The FDA responded that:

¹⁷⁰ Pl's Opp. to Defs.' and Intervenor's Mots. to Dismiss and Pl's Reply in Supp. of Mot. for Prelim. Inj. ("Endo Br."), *Endo Pharmaceuticals Inc. v. U.S. Food and Drug Administration, et al.*, No. 1:12-cv-01936, Doc. 23 at 20 (D.D.C. Dec.14, 2012).

“Endo’s true interest in expedited FDA consideration stems from business concerns rather than protection of the public health.”¹⁷¹

194. Despite Endo’s purported concern with public safety, not only did Endo continue to distribute original, admittedly unsafe Opana ER for nine months after the reformulated version became available, it declined to recall original Opana ER despite its dangers. In fact, Endo claimed in September 2012 to be “proud” that “almost all remaining inventory” of the original Opana ER had “been utilized.”¹⁷²

195. In its citizen petition, Endo asserted that redesigned Opana ER had “safety advantages.” Endo even relied on its rejected assertion that Opana was less crushable to argue that it developed Opana ER for patient safety reasons and that the new formulation would help, for example, “where children unintentionally chew the tablets prior to an accidental ingestion.”¹⁷³

196. However, in a 2013 decision rejecting the petition, the FDA found that “study data show that the reformulated version’s extended-release features can be compromised when subjected to ... cutting, grinding, or chewing.” The FDA also determined that “reformulated Opana ER” could also be “readily prepared for injections and more easily injected[.]” In fact, the FDA warned that preliminary data—including in Endo’s own studies—suggested that a higher percentage of reformulated Opana ER abuse is via injection than was the case with the original formulation.

¹⁷¹ Defs.’ Resp. to the Court’s November 30, 2012 Order, *Endo Pharmaceuticals Inc. v. U.S. Food and Drug Administration, et al.*, No. 1:12-cv-01936, Doc. 9 at 6 (D.D.C. Dec. 3, 2012).

¹⁷² *Id.*; Endo News Release, Sept. 6, 2012 (Ex. L to Rurka Decl.), *Endo Pharmaceuticals Inc. v. U.S. Food and Drug Administration, et al.*, No. 1:12-cv-01936, Doc. 18-4 (D.D.C. Dec. 9, 2012).

¹⁷³ Citizens Petition, FDA Docket 2012-8-0895, at 2.

197. In 2009, only 3% of Opana ER abuse was by intravenous means. Since the reformulation, injection of Opana ER has increased by more than 500%. Endo's own data, presented in 2014, found that between October 2012 and March 2014, 64% of abusers of Opana ER did so by injection, compared with 36% for the old formulation.¹⁷⁴ The transition into injection of Opana ER made the drug even less safe than the original formulation. Injection carries risks of HIV, hepatitis C, and, in reformulated Opana ER's specific case, the blood-clotting disorder thrombotic thrombocytopenic purpura (TTP), which can cause kidney failure.

198. Publicly, Endo sought to minimize the problem. On a 2013 call with investors, when asked about an outbreak of TTP in Ohio from injecting Opana ER, Endo sought to limit its import by assigning it to "a very, very distinct area of the country."

199. Despite its knowledge that Opana ER was widely abused and injected, Endo marketed the drug as tamper-resistant and abuse-deterrent. In consideration of a reasonable opportunity for further investigation and discovery, Plaintiffs allege that based on the company's detailing elsewhere, Endo sales representatives informed doctors that Opana ER was abuse-deterrent, could not be tampered with, and was safe. In addition, sales representatives did not disclose evidence that Opana was easier to abuse intravenously and, if pressed by prescribers, claimed that while outlier patients might find a way to abuse the drug, most would be protected.

200. A review of national surveys of prescribers regarding their "take-aways" from pharmaceutical detailing confirms that prescribers remember being told Opana ER was tamper-resistant. Endo also tracked messages that doctors took from its in-person marketing. Among the

¹⁷⁴ Theresa Cassidy, *et al.*, *The Changing Abuse Ecology: Implications for Evaluating the Abuse Pattern of Extended-Release Oxymorphone and Abuse-Deterrent Opioid Formulations*, Inflexxion (Sept. 7, 2014)), available at <https://www.inflexxion.com/changing-abuse-ecology-extended-release-oxymorphone/>.

advantages of Opana ER, according to participating doctors, was its “low abuse potential.” For example, a June 14, 2012 Endo press release announced “the completion of the company’s transition of its Opana ER franchise to the new formulation designed to be crush resistant.”

201. The press release further stated that: “We firmly believe that the new formulation of Opana ER, coupled with our long-term commitment to awareness and education around appropriate use of opioids will benefit patients, physicians and payers. The press release described the old formulation of Opana as subject to abuse and misuse, but failed to disclose the absence of evidence that reformulated Opana was any better. In September 2012, another Endo press release stressed that reformulated Opana ER employed “INTAC Technology” and continued to describe the drug as “designed to be crush-resistant.”

202. Similarly, journal advertisements that appeared in April 2013 stated Opana ER was “designed to be crush resistant.” A January 2013 article in *Pain Medicine News*, based in part on an Endo press release, described Opana ER as “crush-resistant.” This article was posted on the *Pain Medicine News* website, which was accessible to patients and prescribers.

203. In 2015, the Indiana Department of Public Health determined that an HIV outbreak in Southeastern Indiana was linked to injection of Opana, the first documented HIV outbreak in the United States associated with injection of a prescription painkiller.

204. In March 2017, because Opana ER could be “readily prepared for injection” and was linked to outbreaks of HIV and TTP, an FDA advisory committee recommended that Opana be withdrawn from the market. The FDA adopted this recommendation on June 8, 2017.¹⁷⁵ Endo

¹⁷⁵ FDA requests removal of Opana ER, *supra* n. 80.

announced on July 6, 2017 that it would agree to stop marketing and selling Opana ER.¹⁷⁶ However, by this point, the damage had been done. Even then, Endo continued to insist, falsely, that it “has taken significant steps over the years to combat misuse and abuse.”

**c. Other Marketing Defendants’ and Purdue’s
Misrepresentations Regarding Abuse Deterrence**

205. A guide for prescribers under Actavis’s copyright deceptively represents that Kadian is more difficult to abuse and less addictive than other opioids. The guide declares that “unique pharmaceutical formulation of KADIAN may offer some protection from extraction of morphine sulfate for intravenous use by illicit users,” and “KADIAN may be less likely to be abused by health care providers and illicit users” because of its “[s]low onset of action.” Kadian, however, was not approved by the FDA as abuse deterrent, and, upon information and belief, Actavis had no studies to suggest it was.

206. Mallinckrodt promoted both Exalgo (extended-release hydromorphone) and Xartemis XR (oxycodone and acetaminophen) as specifically formulated to reduce abuse. For example, Mallinckrodt’s promotional materials stated that “the physical properties of EXALGO may make it difficult to extract the active ingredient using common forms of physical and chemical tampering, including chewing, crushing and dissolving.”¹⁷⁷ One member of the FDA’s Controlled Substance Staff, however, noted in 2010 that hydromorphone has “a high abuse potential comparable to oxycodone” and further stated that “we predict that Exalgo will have high levels of abuse and diversion.”

¹⁷⁶ Endo Provides Update on Opana ER, (July 6, 2017), *supra* n. 81.

¹⁷⁷ Mallinckrodt Press Release, Medtronic, *FDA Approves Mallinckrodt’s EXALGO® (hydromorphone HCl) Extended-Release Tablets 32 mg (CII) for Opioid-Tolerant Patients with Moderate-to-Severe Chronic Pain* (Aug. 27, 2012), available at <http://newsroom.medtronic.com/phoenix.zhtml?c=251324&p=irol-newsArticle&ID=2004159>

207. With respect to Xartemis XR, Mallinckrodt's promotional materials stated that "XARTEMIS XR has technology that requires abusers to exert additional effort to extract the active ingredient from the large quantity of inactive and deterrent ingredients."¹⁷⁸ In anticipation of Xartemis XR's approval, Mallinckrodt added 150-200 sales representatives to promote it, and CEO Mark Trudeau said the drug could generate "hundreds of millions in revenue."¹⁷⁹

208. While Marketing Defendants and Purdue promoted patented technology as the solution to opioid abuse and addiction, none of their "technology" addresses the most common form of abuse—oral ingestion—and their statements regarding abuse-deterrent formulations give the misleading impression that these reformulated opioids can be prescribed safely.

209. In sum, each of the nine categories of misrepresentations discussed above regarding the use of opioids to treat chronic pain was either not supported by or was contrary to the scientific evidence. In addition, the Defendants' misrepresentations and omissions as set in this Complaint are misleading and contrary to the Marketing Defendants' and Purdue's products' labels.

B. The Marketing Defendants and Purdue Directly Targeted Hospitals

210. From the beginning, hospitals were directly targeted by the Marketing Defendants. Internal documents from the 1995 "OxyContin Launch" orchestrated by Defendants Purdue and Abbott (1) identified "hospital pharmacists" as among their "audience," (2) identified "hospitals" among their "institutional targets," (3) identified an objective of "[f]ormulary

¹⁷⁸ Mallinckrodt, *Responsible Use of Opioid Pain Medications* (Mar. 7, 2014).

¹⁷⁹ Samantha Liss, *Mallinckrodt banks on new painkillers for sales*, ST. LOUIS BUSINESS JOURNAL (Dec. 30, 2013), available at <http://argentscapital.com/mallinckrodt-banks-on-new-painkillers-for-sales/>.

acceptance in 75% of hospitals for first twelve months,” and (4) identified an objective of developing a “successful distribution program” to “hospitals.”

211. In 1996, Purdue made a deal with Defendant Abbott under which Abbott’s sales force would promote Purdue’s lead opioid, OxyContin, in hospitals. Abbott’s co-promotion of OxyContin was, in the words of Abbott’s counsel, by terms of its contract, dedicated to “hospitals, surgical centers and hospital-based surgeons.” Promoting the use of OxyContin for “postoperative pain” and “support[ing] the Abbott agreement” were paramount objectives identified in Purdue’s internal documents. “Abbott and Purdue consciously targeted hospitals. [Purdue] representatives will work with their Abbott counterparts to make calls on all Pharmacy and Therapeutic (P&T) communities.” “[S]ales force will provide the *appropriate* clinical data necessary to continue to add OxyContin Tablets to hospital formularies.”¹⁸⁰

212. Initial plans called for marketing to “[a]ll 1,200 cancer centers,” “[a]ll 1,200 major teaching institutions,” and “[a]ll 2,500 community hospitals with $\geq$ 100 beds.” The hospital marketing plan further entailed the following actions:

- a. The Purdue Frederick sales force should call on all hospital P&T committees to gain hospital formulary acceptance during the first three months of launch. This effort would entail contacting directors of pharmacies in an effort to gain formulary acceptance of OxyContin.
- b. Educate MD’s/RN’s/RPH’s regarding the advantages of OxyContin over other Step 2 opioids for cancer patients. The promotional effort should focus on the ease of use and the reduced administration time. If available,

¹⁸⁰ 2002 Purdue Budget Plan, *available at* <https://khn.org/news/purdue-and-the-oxycontin-files/> (last visited Aug. 20, 2018) (emphasis added).

clinical outcomes studies, showing improved quality of life and cost effectiveness, should be used to convince the house staff to use OxyContin as their opioid of choice.

- c. Educational lectures should be held through the Speakers' Bureau program during grand rounds, tumor boards, etc. The Purdue Frederick Speakers' Bureau should educate the house staff about the benefits of OxyContin, while presenting clinical study data.
- d. Educational symposia should be conducted through the use of satellite teleconferencing to various cancer centers and major teaching institutions across the country, offering CME credits to MD's/RN's/RPH's and focus on the implementation of the AHCPR Clinical Practice Guideline for the Management of Cancer Pain and the results of clinical trials with OxyContin.
- e. Target the top 100 MS CONTIN/Duragesic hospitals and offer them a special pain management day where our OxyContin clinical investigators will train the staff on the use of OxyContin.

213. Defendant Abbott, in a 1997 document, indicated that prescriptions written by "Abbott MD's" comprised 25% of all OxyContin prescriptions. In addition, Purdue's budget records reveal details of the payments to Abbott for its OxyContin work, which were termed "commissions." From 1996 through 2002, Abbott was paid \$374 million in commissions, according to those documents. Total sales of the drug during that time were nearly \$5 billion. From 2003 to 2006, OxyContin sales were nearly \$6 billion. From 1996 to 2005, inclusive, Abbott's "commissions" exceeded \$500 million.

214. The importance of targeting hospital emergency rooms was illustrated by a study that demonstrated that patients who receive an opiate prescription within 7 days of surgery are 44% more likely to still be using the medication one year after surgery than patients who do not receive an opioid prescription.”¹⁸¹

C. The Marketing Defendants and Purdue Disseminated Their Misleading Messages About Opioids Through Multiple Direct and Indirect Channels

215. The Marketing Defendants and Purdue utilized various channels to carry out their marketing scheme of targeting the medical community and patients with deceptive information about opioids: (1) direct, targeted communications with prescribers by sales representatives or “detailers;” (2) “Front Groups” with the appearance of independence from the Marketing Defendants and Purdue; (3) so-called KOLs, that is, doctors who were paid by the Marketing Defendants and Purdue to promote their pro-opioid message; (4) disseminating their misleading messages through reputable organizations; (5) CME programs controlled and/or funded by the Marketing Defendants and Purdue; (6) branded advertising; (7) unbranded advertising; (8) publications; and (9) speakers bureaus and programs.

1. The Marketing Defendants and Purdue Used “Detailers” To Directly Disseminate Their Misrepresentations to Prescribers

216. The Marketing Defendants’ and Purdue’s sales representatives executed carefully crafted marketing tactics, developed at the highest rungs of their corporate ladders, to reach targeted doctors and hospitals with centrally orchestrated messages. The Marketing Defendants’ and Purdue’s sales representatives also distributed third-party marketing material to their target audience that was deceptive. The Marketing Defendants’ and Purdue’s direct contact with

¹⁸¹ Cheryl Genord et al., *Opioid exit plan: A pharmacist’s role in managing acute postoperative pain*, Journal of the American Pharmacists Association (Jan. 2017), at 593, available at [https://www.japha.org/article/S1544-3191\(17\)30016-X/fulltext](https://www.japha.org/article/S1544-3191(17)30016-X/fulltext) (“Opioid Exit Plan”).

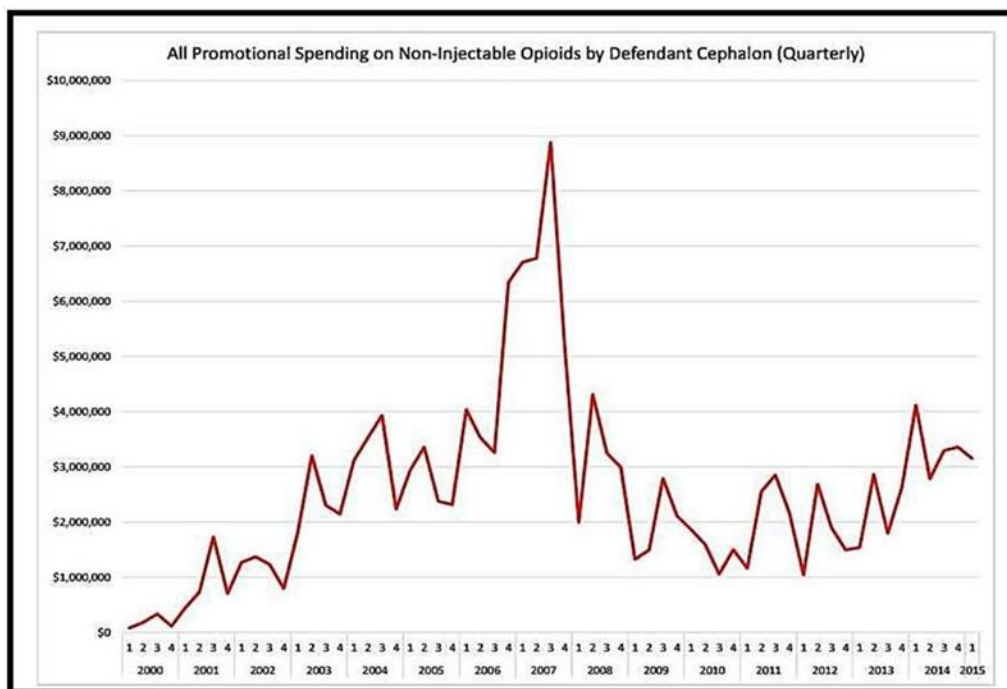
prescribers was, by far, their most important means of disseminating the False Narrative and increasing opioid prescriptions, and, accordingly, their sales.

217. Each Marketing Defendant and Purdue promoted opioids through sales representatives (also called “detailers”) and, in consideration of a reasonable opportunity for further investigation and discovery, Plaintiffs allege that small group speaker programs were designed to reach out to individual prescribers. By establishing close relationships with doctors, the Marketing Defendants and Purdue were able to disseminate their misrepresentations in targeted, one-on-one settings that allowed them to promote their opioids and to allay individual prescribers’ concerns about prescribing opioids for chronic pain.

218. In accordance with common industry practice, the Marketing Defendants purchased and closely analyzed prescription sales data from IMS Health (now IQVIA), a healthcare data collection, management, and analytics corporation. This data allowed them to precisely track the rates of initial and renewal prescribing by individual doctors, which allowed them to target and tailor their appeals. Sales representatives visited hundreds of thousands of doctors and disseminated the misinformation and materials described above.

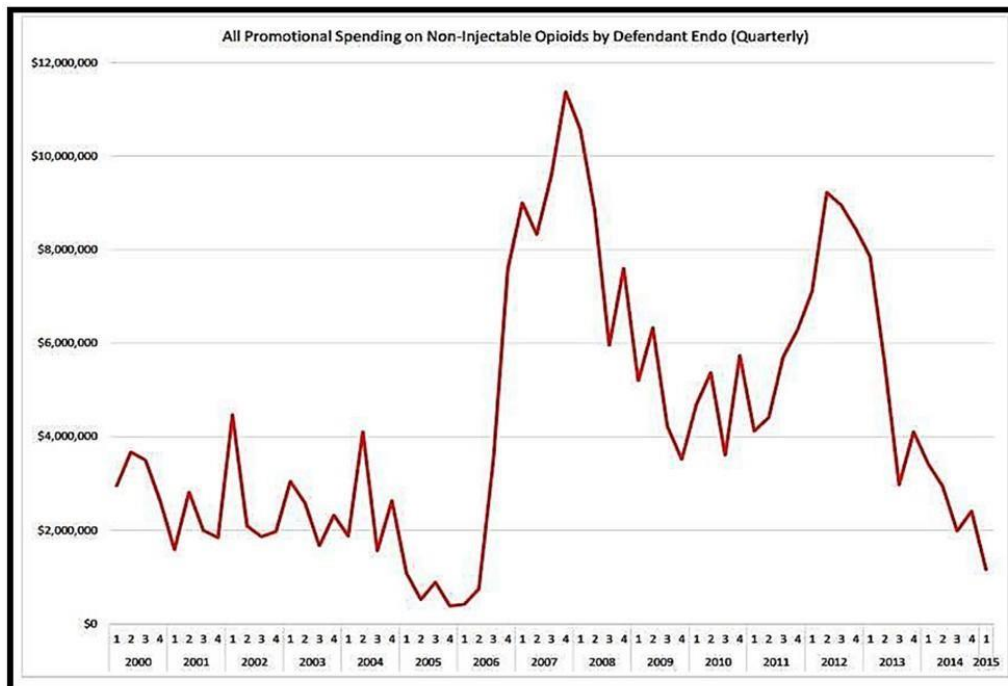
219. Marketing Defendants and Purdue devoted and continue to devote massive resources to direct sales contacts with doctors. In 2014 alone, Marketing Defendants and Purdue spent \$166 million on detailing branded opioids to doctors. This amount is twice as much as Marketing Defendants and Purdue spent on detailing in 2000. The amount includes \$108 million spent by Purdue, \$34 million by Janssen, \$13 million by Teva, and \$10 million by Endo.

220. Cephalon’s quarterly spending steadily climbed from below \$1 million in 2000 to more than \$3 million in 2014 (and more than \$13 million for the year), with a peak, coinciding with the launch of Fentora, of more than \$27 million in 2007, as shown below:

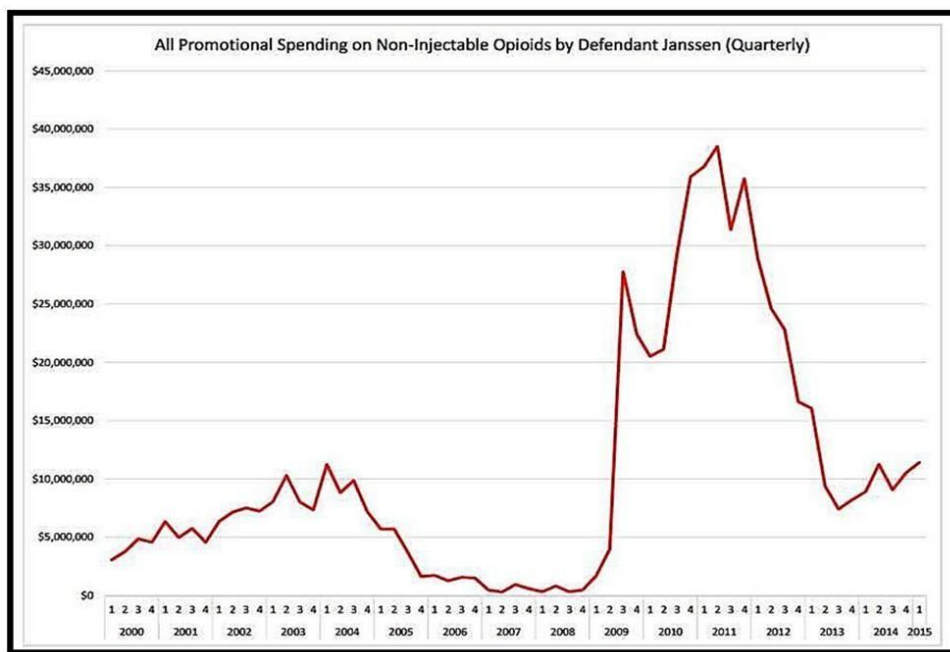


221. For its opioid, Actiq, Cephalon also engaged in direct marketing in direct contravention of the FDA's strict instructions that Actiq be prescribed only to terminal cancer patients and by oncologists and pain management doctors experienced in treating cancer pain.

222. Endo's quarterly spending went from the \$2 million to \$4 million range in 2000-2004 to more than \$10 million following the launch of Opana ER in mid-2006 (and more than \$38 million for the year in 2007) and more than \$8 million coinciding with the launch of a reformulated version in 2012 (and nearly \$34 million for the year), as shown below:



223. Janssen's quarterly spending dramatically rose from less than \$5 million in 2000 to more than \$30 million in 2011, coinciding with the launch of Nucynta ER (with yearly spending at \$142 million for 2011), as shown below:



224. Abbott, which was tasked with marketing Purdue's products to hospitals, heavily incentivized its staff to push OxyContin, offering \$20,000 cash prizes and luxury vacations to top performers. Abbott's almost religious zeal to sell the drug is evident in the wide use of terminology from the Middle Ages Crusades: Sales reps were called "royal crusaders" and "knights" in internal documents, and they were supervised by the "Royal Court of OxyContin" – executives referred to in memos as the "Wizard of OxyContin," "Supreme Sovereign of Pain Management," and the "Empress of Analgesia." The head of pain care sales, Jerry Eichhorn, was the "King of Pain," and signed memos simply as "King."



225. At Purdue, aggressive and frequent visits to prescribers was always its most important marketing technique. The Sackler Co-Conspirators set targets for each representative to visit over 7 prescribers per day, and closely monitored actual data. Some doctors were visited multiple times per week. The pressure on sales representatives, and on prescribers, was relentless, and was dictated by the Sackler Co-Conspirators.

226. Each of these in-person sales visits cost Purdue money — on average more than \$200 per visit. But Purdue made that money back many times over, because it convinced doctors to prescribe its addictive drugs. When Purdue identified a doctor as a profitable target, Purdue visited the doctor frequently: often weekly, sometimes almost every day. Purdue salespeople, asked doctors to list specific patients they were scheduled to see and pressed the doctors to commit to put the patients on Purdue opioids. By the time a patient walked into a clinic, the doctor, in Purdue’s words, had already “guaranteed” that he would prescribe Purdue’s drugs.

227. Purdue judged its sales representatives by how many opioids they got doctors to prescribe. Sales representatives who generated the most prescriptions won bonuses and prizes. These incentives included a “Toppers Club sales contest” for sales representatives to win bonuses, based on how much a representative increased OxyContin use in her territory and how much the representative increased the broader prescribing of opioids — the same “availability of product” and “prescribing practices” factors that worsen the risk of diversion and abuse.

228. Purdue continued to incentivize its representatives to sell opioids even after some competitors had ended that practice. Representatives who failed to get enough patients on opioids were placed on probation, put on performance improvement plans, and they would be threatened with loss of their jobs if they did not generate more opioid sales. Those unable to generate more sales were fired. In 2015 alone, Purdue replaced 14% of its sales representatives and 20% of its District Managers for failing to create enough opioid sales.

229. Sales representatives focused on prolific (and potentially prolific) prescribers, described internally at Purdue as “core,” “super core,” and “high potential” prescribers at times, even though the Marketing Defendants and Purdue were all well aware of the heightened risk of improper prescriptions and diversion through these prescribers. Purdue Co-Conspirator Richard

Sackler once chastised his senior marketing officer, Co-Conspirator Gasdia, for Purdue's managers permitting sales representatives to target "non-high potential prescribers," asking "[h]ow can our managers have allowed this to happen?" Co-Conspirator Richard Sackler personally insisted that sales representatives push the doctors who prescribed the most drugs.

230. To make sure doctors prescribed more opioids, Purdue tracked doctors' prescriptions, visited their offices, bought them meals, and asked them to put specific patients on Purdue drugs. Purdue selected doctors for target lists based on its estimates of which doctors could be influenced to increase opioid prescriptions the most. Purdue managers told representatives to visit most often the doctors who were most likely to change their prescribing to benefit Purdue. Purdue Sales representatives visited Purdue's targets, including top targets in Kentucky. Those visits cost Purdue more than \$40,000 for each doctor. Purdue did not spend \$40,000 per doctor so sales representatives could watch doctors write prescriptions that they were already going to write anyway. Instead, Purdue paid to lobby these doctors because Purdue knew its representatives would convince them to put more patients on opioids, at higher doses, for longer periods. Those extra prescriptions paid back Purdue's investment many times over.

231. Compared to Kentucky doctors and nurses who prescribed Purdue opioids without lobbying from sales reps, Purdue's top targets wrote far more dangerous prescriptions. Purdue's top targets prescribed Purdue opioids to more of their patients, at higher doses, and for longer periods of time. Compared to doctors and nurses who prescribed Purdue opioids without seeing reps, Purdue's top targets were ***at least ten times more likely*** to prescribe Purdue opioids to patients who overdosed and died.

232. As of the fourth quarter of 2013, Purdue employed 632 sales representatives and, during that quarter they visited prescribers 176,227 times – an annualized rate of over 700,000

visits. These statistics were regularly reported to the Sackler Co-Conspirators and Purdue Officer Co-Conspirators. Purdue's budget for Sales and Promotion for 2013 was \$312,563,000. In 2013, Purdue spent over \$9 million on meals alone for its prescribers.

233. The sales visits of its staff were so important to the Sackler Co-Conspirators that Co-Conspirator Richard Sackler himself went into the field in 2013 to promote opioids to doctors alongside a sales representative. Co-Conspirator Gasdia and Purdue's Chief Compliance Officer were well aware that this was "a potential compliance risk." To make sure the Sackler Co-Conspirators' involvement in marketing stayed secret, staff instructed: "Richard needs to be mum and be anonymous." When he returned, Richard Sackler argued to the Vice President of Sales that a legally required warning about Purdue's opioids wasn't needed. He asserted that the warning "implies a danger of untoward reactions and hazards that simply aren't there." Richard Sackler insisted there should be "less threatening" ways to describe Purdue opioids.

234. Purdue intensified its marketing efforts in subsequent years, in an effort to counteract decreasing sales (sales of OxyContin peaked in 2010, and decreased somewhat in subsequent years). For 2018, the Sacklers approved a target for sales representatives to visit prescribers 1,050,000 times – which would include thousands of visits to Kentucky prescribers — almost double the number of sales visits they had ordered during the peak of OxyContin sales in 2010.

2. **The Marketing Defendants and Purdue Deceptively Directed Front Groups to Promote Opioid Use**

235. Patient advocacy groups and professional associations also became vehicles to reach prescribers, patients, and policymakers. Marketing Defendants and Purdue exerted influence and effective control over the messaging by these groups by providing major funding directly to them, as well as through KOLs who served on their boards. These "Front Groups" put

out patient education materials, treatment guidelines and CMEs that supported the use of opioids for chronic pain, overstated the benefits of opioids, and understated their risks.¹⁸² Defendants funded these Front Groups in order to ensure supportive messages from these seemingly neutral and credible third parties, and their funding did, in fact, ensure such supportive messages—often at the expense of the Front Groups own constituencies.

236. “Patient advocacy organizations and professional societies like the Front Groups ‘play a significant role in shaping health policy debates, setting national guidelines for patient treatment, raising disease awareness, and educating the public.’”¹⁸³ “Even small organizations—with ‘their large numbers and credibility with policymakers and the public’—have ‘extensive influence in specific disease areas.’ Larger organizations with extensive funding and outreach capabilities ‘likely have a substantial effect on policies relevant to their industry sponsors.’”¹⁸⁴ Indeed, the U.S. Senate’s report, *Fueling an Epidemic: Exposing the Financial Ties Between Opioid Manufacturers and Third Party Advocacy Groups*,¹⁸⁵ which arose out of a 2017 Senate investigation and, drawing on disclosures from Purdue, Janssen, Insys, and other opioid manufacturers, “provides the first comprehensive snapshot of the financial connections between opioid manufacturers and advocacy groups and professional societies operating in the area of

¹⁸² U.S. Senate Homeland Security & Governmental Affairs Committee, Ranking Members’ Office, *Fueling an Epidemic, Report Two: Exposing the Financial Ties Between Opioid Manufacturers and Third Party Advocacy Groups* (Feb. 12, 2018), available at <https://www.hsdl.org/?abstract&did=808171> (“*Fueling an Epidemic*”), at p. 3.

¹⁸³ *Id.* at p. 2.

¹⁸⁴ *Id.*

¹⁸⁵ *Id.* at p. 1.

Office opioids policy,”¹⁸⁶ found that the Marketing Defendants and Purdue made millions of dollars’ worth of contributions to various Front Groups.¹⁸⁷

237. The Marketing Defendants and Purdue also “made substantial payments to individual group executives, staff members, board members, and advisory board members” affiliated with the Front Groups subject to the Senate Committee’s study.¹⁸⁸

238. As the Senate’s Report *Fueling an Epidemic* found, the Front Groups “amplified or issued messages that reinforce industry efforts to promote opioid prescription and use, including guidelines and policies minimizing the risk of addiction and promoting opioids for chronic pain.”¹⁸⁹ They also “lobbied to change laws directed at curbing opioid use, strongly criticized landmark CDC guidelines on opioid prescribing, and challenged legal efforts to hold physicians and industry executives responsible for over prescription and misbranding.”¹⁹⁰

239. The Marketing Defendants and Purdue took an active role in guiding, reviewing, and approving many of the false and misleading statements issued by the Front Groups, ensuring that Defendants were consistently in control of their content. By funding, directing, editing, approving, and distributing these materials, Defendants exercised control over and adopted their false and deceptive messages and acted in concert with the Front Groups and through the Front groups, with each working with the other to deceptively promote the use of opioids for the treatment of chronic pain.

¹⁸⁶ *Id.*

¹⁸⁷ *Id.* at p. 3.

¹⁸⁸ *Id.* at p. 10.

¹⁸⁹ *Id.* at 12-15.

¹⁹⁰ *Id.* at 12.

a. **American Pain Foundation**

240. The most prominent of the Front Groups was APF. While APF held itself out as an independent patient advocacy organization, in reality it received 90% of its funding in 2010 from the drug and medical-device industry, including from Purdue, Endo, Janssen and Cephalon. APF received more than \$10 million in funding from opioid manufacturers from 2007 until it closed its doors in May 2012. By 2011, APF was entirely dependent on incoming grants from Purdue, Cephalon, Endo, and others to avoid using its line of credit. Endo was APF's largest donor and provided more than half of its \$10 million in funding from 2007 to 2012.

241. For example, APF published a guide sponsored by Cephalon and Purdue titled *Treatment Options: A Guide for People Living with Pain* and distributed 17,200 copies of this guide in one year alone, according to its 2007 annual report. This guide contains multiple misrepresentations regarding opioid use which are discussed *supra*.

242. APF also developed the National Initiative on Pain Control ("NIPC"), which ran a facially unaffiliated website, www.painknowledge.org. NIPC promoted itself as an education initiative led by its expert leadership team, including purported experts in the pain management field. NIPC published unaccredited prescriber education programs (accredited programs are reviewed by a third party and must meet certain requirements of independence from pharmaceutical companies), including a series of "dinner dialogues." But it was Endo that substantially controlled NIPC, by funding NIPC projects, developing, specifying, and reviewing its content, and distributing NIPC materials. Endo's control of NIPC was such that Endo listed it as one of its "professional education initiative[s]" in a plan Endo submitted to the FDA. Yet, Endo's involvement in NIPC was nowhere disclosed on the website pages describing NIPC or www.painknowledge.org. Endo estimated it would reach 60,000 prescribers through NIPC.

243. APF was often called upon to provide “patient representatives” for the Marketing Defendants’ and Purdue’s promotional activities, including for Purdue’s “*Partners Against Pain*” and Janssen’s “*Let’s Talk Pain*.” Although APF presented itself as a patient advocacy organization, it functioned largely as an advocate for the interests of the Marketing Defendants and Purdue, not patients. As Purdue told APF in 2001, the basis of a grant to the organization was Purdue’s desire to strategically align its investments in nonprofit organizations that shared its business interests.

244. In practice, APF operated in close collaboration with Defendants, submitting grant proposals seeking to fund activities and publications suggested by Defendants and assisting in marketing projects for Defendants.

245. This alignment of interests was expressed most forcefully in the fact that Purdue hired APF to provide consulting services on its marketing initiatives. Purdue and APF entered into a “Master Consulting Services” Agreement on September 14, 2011. That agreement gave Purdue substantial rights to control APF’s work related to a specific promotional project. Moreover, based on the assignment of particular Purdue “contacts” for each project and APF’s periodic reporting on their progress, the agreement enabled Purdue to be regularly aware of the misrepresentations APF was disseminating regarding the use of opioids to treat chronic pain in connection with that project. The agreement gave Purdue—but not APF—the right to end the project (and, thus, APF’s funding) for any reason.

246. APF’s Board of Directors was largely comprised of doctors who were on the Marketing Defendants’ and Purdue’s payrolls, either as consultants or as speakers for medical events. The close relationship between APF and the Marketing Defendants and Purdue demonstrates APF’s lack of independence in its finances, management, and mission, and APF’s

willingness to allow Marketing Defendants and Purdue to control its activities and messages supports an inference that each Defendant that worked with it was able to exercise editorial control over its publications—even when Defendants’ messages contradicted APF’s internal conclusions.

247. In May 2012, the U.S. Senate Finance Committee began looking into APF to determine the links, financial and otherwise, between the organization and the manufacturers of opioid painkillers. Within days of being targeted by the Senate investigation, APF’s board voted to dissolve the organization “due to irreparable economic circumstances.” APF then “cease[d] to exist, effective immediately.” Without support from Marketing Defendants and Purdue, to whom APF could no longer be helpful, APF was no longer financially viable.

b. American Academy of Pain Medicine and the American Pain Society

248. The American Academy of Pain Medicine (“AAPM”) and the American Pain Society (“APS”) are professional medical societies, each of which received substantial funding from Defendants from 2009 to 2013. In 1997, AAPM issued a “consensus” statement that endorsed opioids to treat chronic pain and claimed that the risk that patients would become addicted to opioids was low.¹⁹¹ The Chair of the committee that issued the statement, Dr. J. David Haddox, was at the time a paid speaker for Purdue. The sole consultant to the committee was Dr. Russell Portenoy, who was also a spokesperson for Purdue. The consensus statement, which also formed the foundation of the 1998 Guidelines, was published on the AAPM’s website.

¹⁹¹ *The Use of Opioids for the Treatment of Chronic Pain*, APS & AAPM (1997), available at <http://www.stgeorgeutah.com/wp-content/uploads/2016/05/OPIOIDES.DOLORCRONICO.pdf> (last accessed August 1, 2018).

249. AAPM's corporate council includes Purdue, Assertio, Teva and other pharmaceutical companies. AAPM's past presidents include Haddox (1998), Dr. Scott Fishman ("Fishman") (2005), Dr. Perry G. Fine ("Fine") (2011) and Dr. Lynn R. Webster ("Webster") (2013), all of whose connections to the opioid manufacturers are well-documented as set forth below.

250. Fishman, who also served as a KOL for Marketing Defendants and Purdue, stated that he would place the organization "at the forefront" of teaching that "the risks of addiction are . . . small and can be managed."¹⁹²

251. AAPM has received over \$2.2 million in funding since 2009 from opioid manufacturers. 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 AAPM's marquee event – its annual meeting held in Palm Springs, California, or other resort locations.

252. More specifically, Purdue paid \$725,584.95 from 2012-2017 to AAPM.¹⁹³ Janssen paid \$83,975 from 2012-2017 to AAPM.¹⁹⁴ Insys paid \$57,750 from 2012-2017 to AAPM.¹⁹⁵ Endo funded AAPM CMEs. Teva is on AAPM's corporate relations council.

253. As to APS, Purdue paid \$542,259.52 from 2012-2017.¹⁹⁶ Janssen paid \$88,500 from 2012-2017.¹⁹⁷ Insys paid \$22,965 from 2012-2017.¹⁹⁸

¹⁹² 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), available at <http://www.medscape.org/viewarticle/500829>.

¹⁹³ *Id.*

¹⁹⁴ *Fueling an Epidemic*, *supra* n. 182.

¹⁹⁵ *Id.*

254. AAPM describes its annual meeting as an “exclusive venue” for offering CME 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, and Cephalon were members of the council and presented deceptive programs to doctors who attended this annual event. The conferences sponsored by AAPM heavily emphasized CME sessions on opioids – 37 out of roughly 40 at one conference alone.

255. AAPM’s staff understood that they and their industry funders were engaged in a common task. Defendants were able to influence AAPM through both their significant and regular funding and the leadership of pro-opioid KOLs within the organization.

256. In 1996, AAPM and APS 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 of a patients’ addiction to opioids was low. Dr. David Haddox, who co-authored the AAPM/APS statement, was a paid speaker for Purdue at the time. Dr. Portenoy was the sole consultant. The consensus statement remained on AAPM’s website until 2011.

257. AAPM and APS issued their own guidelines in 2009 (“2009 Guidelines”) AAPM, with the assistance, prompting, involvement, and funding of Defendants, issued the treatment guidelines discussed herein, and continued to recommend the use of opioids to treat chronic pain. Fourteen of the 21 panel members who drafted the 2009 Guidelines, including KOL Dr. Fine,

¹⁹⁶ *Id.*

¹⁹⁷ *Id.*

¹⁹⁸ *Id.*

received support from Janssen, Cephalon, Endo, and Purdue. Of these individuals, six received support from Purdue, eight from Teva, nine from Janssen, and nine from Endo.

258. Dr. Gilbert Fanciullo, now retired as a professor at Dartmouth College's Geisel School of Medicine, who served on the AAPM/APS Guidelines panel, has since described them as "skewed" by drug companies and "biased in many important respects," including the high presumptive maximum dose, lack of suggested mandatory urine toxicology testing, and claims of a low risk of addiction.

259. The 2009 Guidelines have been a particularly effective channel of deception. They have influenced not only treating physicians, but also the scientific literature on opioids; they were reprinted in the Journal of Pain, have been cited hundreds of times in academic literature, were disseminated during the relevant time period, and were and are available online. Treatment guidelines are especially influential with primary care physicians and family doctors to whom Marketing Defendants and Purdue promoted opioids, and whose lack of specialized training in pain management and opioids makes them more reliant on, and less able to evaluate, these guidelines.

260. For that reason, the CDC has recognized that treatment guidelines can "change prescribing practices."¹⁹⁹

261. The 2009 Guidelines are relied upon by doctors, especially general practitioners and family doctors who have no specific training in treating chronic pain.

262. The Marketing Defendants and Purdue widely cited and promoted the 2009 Guidelines without disclosing the lack of evidence to support their conclusions, their involvement in the development of the Guidelines or their financial backing of the authors of

¹⁹⁹ Dowell, CDC Guideline, *supra* n. 24.

these Guidelines. For example, a speaker presentation prepared by Endo in 2009 titled *The Role of Opana ER in the Management of Moderate to Severe Chronic Pain* relies on the AAPM/APS 2009 Guidelines while omitting their disclaimer regarding the lack of evidence for recommending the use of opioids for chronic pain.

c. Federation of State Medical Boards

263. The Federation of State Medical Boards (“FSMB”) is a trade organization representing the various state medical boards in the United States. The state boards that comprise the FSMB membership have the power to license doctors, investigate complaints, and discipline physicians.

264. The FSMB finances opioid- and pain-specific programs through grants from Defendants.

265. Since 1998, the FSMB has been developing treatment guidelines for the use of opioids for the treatment of pain. The 1998 version, Model Guidelines for the Use of Controlled Substances for the Treatment of Pain (“1998 Guidelines”) was produced “in collaboration with pharmaceutical companies.” The 1998 Guidelines—that the pharmaceutical companies helped author—taught not that opioids could be appropriate in only limited cases after other treatments had failed, but that opioids were “essential” for treatment of chronic pain, including as a first prescription option.

266. A 2004 iteration of the 1998 Guidelines and the 2007 book, *Responsible Opioid Prescribing*, also made the same claims as the 1998 Guidelines. These guidelines were posted online and were available to and intended to reach physicians nationwide, including in Kentucky.

267. FSMB's 2007 publication *Responsible Opioid Prescribing* was backed largely by drug manufacturers, including Purdue, Endo and Cephalon. Purdue paid \$100,000 for printing and distribution of FSMB's Guidelines.²⁰⁰

268. The publication also received support from the American Pain Foundation (APF) and the American Academy of Pain Medicine (AAPM). The publication was written by Dr. Fishman, and Dr. Fine served on the Board of Advisors. In all, 163,131 copies of *Responsible Opioid Prescribing* were distributed by state medical boards.²⁰¹ The FSMB website describes the book as "the leading continuing medical education (CME) activity for prescribers of opioid medications." This publication asserted that opioid therapy to relieve pain and improve function is a legitimate medical practice for acute and chronic pain of both cancer and non-cancer origins; that pain is under-treated, and that patients should not be denied opioid medications except in light of clear evidence that such medications are harmful to the patient.²⁰²

269. The Marketing Defendants and Purdue relied on the 1998 Guidelines to convey the alarming message that "under-treatment of pain" would result in official discipline, but no discipline would result if opioids were prescribed as part of an ongoing patient relationship and prescription decisions were documented. FSMB turned doctors' fear of discipline on its head: doctors, who used to believe that they would be disciplined if their patients became addicted to

²⁰⁰ John Fauber, *Follow the Money: Pain, Policy, and Profit*, MILWAUKEE JOURNAL SENTINEL/MEDPAGE TODAY (Feb. 19, 2012), available at <https://www.medpagetoday.com/neurology/painmanagement/31256>.

²⁰¹ Email from Dr. Scott Fishman to Charles Ornstein, ProPublica (Dec. 15, 2011), available at <https://assets.documentcloud.org/documents/279033/fishman-responses-to-propublica.pdf>.

²⁰² Scott M. Fishman, *Responsible Opioid Prescribing: A Physician's Guide* 8-9 (Waterford Life Sciences 2007).

opioids, were taught instead that they would be punished if they failed to prescribe opioids to their patients with chronic pain.

270. Dr. Fishman said that he did not receive any payments from FSMB or any royalties from the publisher because he wanted to avoid the perception of a potential conflict of interest in his authorship of the book or for the ongoing efforts of FSMB. This is because prior to 2011, he had been scrutinized for his involvement with the front groups/manufacturers and accepting payments.²⁰³

271. The Manufacturing Defendants made additional contributions to the FSMB to further their misleading advertising. For example, Purdue paid FSMB \$822,400.06 over 8 years.²⁰⁴ Cephalon paid FSMB \$180,000 over a 3-year period 2007-2008, and 2011.²⁰⁵ Endo paid FSMB \$371,620 over a 5-year period.²⁰⁶ Mallinckrodt paid FSMB \$100,000 in 2011.²⁰⁷

d. The Alliance for Patient Access

272. Founded in 2006, the Alliance for Patient Access (“APA”) is a self-described patient advocacy and health professional organization that styles itself as “a national network of physicians dedicated to ensuring patient access to approved therapies and appropriate clinical

²⁰³ Email from Dr. Scott Fishman to Charles Ornstein, ProPublica (Dec. 15, 2011), *available at* <https://assets.documentcloud.org/documents/279033/fishman-responses-to-propublica.pdf>.

²⁰⁴ Letter from Humayun J. Chaudhry, President and CEO, FSMB, to the Hon. Max Baucus and Hon. Charles Grassley, U.S. Senate (June 8, 2012), *available at* <https://www.documentcloud.org/documents/3109089-FSMB-Response-Letter-to-US-Senate.html>.

²⁰⁵ *Id.*

²⁰⁶ *Id.*

²⁰⁷ *Id.*

care.”²⁰⁸ It is run by Woodberry Associates LLC, a lobbying firm that was also established in 2006.²⁰⁹ As of June 2017, the APA listed 30 “Associate Members and Financial Supporters.” The list includes J&J, Endo, Mallinckrodt, Purdue and Cephalon.

273. APA’s board members have also directly received substantial funding from pharmaceutical companies.²¹⁰ For instance, board vice president Dr. Srinivas Nalamachu (“Nalamachu”), who practices in Kansas, received more than \$800,000 from 2013 through 2015 from pharmaceutical companies—nearly all of it from manufacturers of opioids or drugs that treat opioids’ side effects, including from defendants Endo, Purdue and Cephalon, and nonparty Insys. Nalamachu’s clinic was raided by FBI agents in connection with an investigation of Insys and its payment of kickbacks to physicians who prescribed Subsys.²¹¹ Other board members include Dr. Robert A. Yapundich from North Carolina, who received \$215,000 from 2013 through 2015 from pharmaceutical companies, including payments by defendants Cephalon and Mallinckrodt; Dr. Jack D. Schim from California, who received more than \$240,000 between 2013 and 2015 from pharmaceutical companies, including defendants Endo, Mallinckrodt and

²⁰⁸ The Alliance for Patient Access, *About AfPA*, available at <http://allianceforpatientaccess.org/about-afpa/#membership> (last accessed August 1, 2018). References herein to APA include two affiliated groups: the Global Alliance for Patient Access and the Institute for Patient Access.

²⁰⁹ Mary Chris Jaklevic, *Non-profit Alliance for Patient Access uses journalists and politicians to push Big Pharma’s agenda*, Health News Review (Oct. 2, 2017), available at <https://www.healthnewsreview.org/2017/10/non-profit-alliance-patient-access-uses-journalists-politicians-push-big-pharmas-agenda/> (“Jaklevic, *Non-profit Alliance for Patient Access*”).

²¹⁰ All information concerning pharmaceutical company payments to doctors in this paragraph is from ProPublica’s Dollars for Docs database, available at <https://projects.propublica.org/docdollars/>.

²¹¹ Andy Marso, *FBI seizes records of Overland Park pain doctor tied to Insys*, KANSAS CITY STAR (July 19, 2017), available at <http://www.kansascity.com/news/business/health-care/article162569383.html>.

Cephalon; Dr. Howard Hoffberg from Maryland, who received \$153,000 between 2013 and 2015 from pharmaceutical companies, including defendants Endo, Purdue, Mallinckrodt, Cephalon, and nonparty Insys; and Dr. Robin K. Dore from California, who received \$700,000 between 2013 and 2015 from pharmaceutical companies.

274. Among its activities, APA issued a “white paper” titled “Prescription Pain Medication: Preserving Patient Access While Curbing Abuse.”²¹² Among other things, the white paper criticizes prescription monitoring programs, purporting to express concern that they are burdensome, not user friendly, and of questionable efficacy:

Prescription monitoring programs that are difficult to use and cumbersome can place substantial burdens on physicians and their staff, ultimately leading many to stop prescribing pain medications altogether. This forces patients to seek pain relief medications elsewhere, which may be much less convenient and familiar and may even be dangerous or illegal.

In some states, physicians who fail to consult prescription monitoring databases before prescribing pain medications for their patients are subject to fines; those who repeatedly fail to consult the databases face loss of their professional licensure. Such penalties seem excessive and may inadvertently target older physicians in rural areas who may not be facile with computers and may not have the requisite office staff. Moreover, threatening and fining physicians in an attempt to induce compliance with prescription monitoring programs represents a system based on punishment as opposed to incentives. . . .

We cannot merely assume that these programs will reduce prescription pain medication use and abuse.²¹³

²¹² Institute for Patient Access, *Prescription Pain Medication: Preserving Patient Access While Curbing Abuse*, (Oct. 2013), available at http://1yh21u3cjpgtv3xjder1dco9mx5s.wpengine.netdna-cdn.com/wp-content/uploads/2013/01/PT_White-Paper_Finala.pdf.

²¹³ *Id.* at 4-5 (footnote omitted).

275. The white paper also purports to express concern about policies that have been enacted in response to the prevalence of pill mills:

Although well intentioned, many of the policies designed to address this problem have made it difficult for legitimate pain management centers to operate. For instance, in some states, [pain management centers] must be owned by physicians or professional corporations, must have a Board certified medical director, may need to pay for annual inspections, and are subject to increased record keeping and reporting requirements. . . . [I]t is not even certain that the regulations are helping prevent abuses.²¹⁴

276. In addition, in an echo of earlier industry efforts to push back against what they termed “opiophobia,” the white paper laments the stigma associated with prescribing and taking pain medication:

Both pain patients and physicians can face negative perceptions and outright stigma. When patients with chronic pain can’t get their prescriptions for pain medication filled at a pharmacy, they may feel like they are doing something wrong – or even criminal. . . . Physicians can face similar stigma from peers. Physicians in non-pain specialty areas often look down on those who specialize in pain management – a situation fueled by the numerous regulations and fines that surround prescription pain medications.²¹⁵

277. In conclusion, the white paper states that “[p]rescription pain medications, and specifically opioids, can provide substantial relief for people who are recovering from surgery, afflicted by chronic painful diseases, or experiencing pain associated with other conditions that does not adequately respond to over-the-counter drugs.”²¹⁶

278. The APA also issues “Patient Access Champion” financial awards to members of Congress, including 50 such awards in 2015. The awards were funded by a \$7.8 million donation

²¹⁴ *Id.* at 5-6.

²¹⁵ *Id.* at 6.

²¹⁶ *Id.* at 7.

from unnamed donors. While the awards are ostensibly given for protecting patients' access to Medicare and are thus touted by their recipients as demonstrating a commitment to protecting the rights of senior citizens and the middle class, they were generally given to members of Congress who supported the APA's agenda.²¹⁷

279. The APA also lobbies Congress directly. In 2015, the APA signed onto a letter supporting legislation proposed to limit the ability of the DEA to police pill mills by enforcing the "suspicious orders" provision of the Comprehensive Drug Abuse Prevention and Control Act of 1970, 21 U.S.C. § 801, *et seq.* ("CSA" or "Controlled Substances Act").²¹⁸ The AAPM is also a signatory to this letter. An internal DOJ memo stated that the proposed bill "'could actually result in increased diversion, abuse, and public health and safety consequences'"²¹⁹ and, according to DEA chief administrative law judge John J. Mulrooney ("Mulrooney"), the law would make it "all but logically impossible" to prosecute manufacturers and distributors, like Defendants here, in the courts.²²⁰ The law passed both Houses of Congress and was signed into law in 2016.

²¹⁷ Jaklevic, *Non-profit Alliance for Patient Access*, *supra* n. 209.

²¹⁸ Letter from Alliance for Patient Access, *et al.*, to Congressmen Tom Marino, Marsha Blackburn, Peter Welch, and Judy Chu (Jan. 26, 2015).

²¹⁹ Bill Whitaker, *Ex-DEA Agent: Opioid Crisis Fueled by Drug Industry and Congress*, CBS NEWS (last updated Oct. 17, 2017), available at <https://www.cbsnews.com/news/ex-dea-agent-opioid-crisis-fueled-by-drug-industry-and-congress/> ("Whitaker, Opioid Crisis Fueled by Drug Industry").

²²⁰ John J. Mulrooney, II & Katherine E. Legel, *Current Navigation Points in Drug Diversion Law: Hidden Rocks in Shallow, Murky, Drug-Infested Waters*, 101 Marquette L. Rev. 333 (2017), available at <https://www.documentcloud.org/documents/4108121-Marquette-Law-Review-Mulrooney-Legel.html>.

e. The U.S. Pain Foundation

280. The U.S. Pain Foundation (“USPF”) was another Front Group with systematic connections and interpersonal relationships with the Marketing Defendants and Purdue. The USPF was one of the largest recipients of contributions from the Marketing Defendants and Purdue, collecting nearly \$3 million in payments between 2012 and 2015 alone.²²¹ The USPF was also a critical component of the Marketing Defendants’ and Purdue’s lobbying efforts to reduce the limits on over-prescription. The U.S. Pain Foundation advertised its ties to the Marketing Defendants and Purdue, listing opioid manufacturers such as Pfizer, Teva, Assertio, Endo, Purdue, McNeil (*i.e.*, Janssen), and Mallinckrodt as “Platinum,” “Gold,” and “Basic” corporate members.²²² Industry Front Groups like the American Academy of Pain Management, the American Academy of Pain Medicine, the American Pain Society, and PhRMA are also members of varying levels in the USPF.

281. More specifically, Purdue paid \$359,300 from 2012-2017;²²³ Janssen paid \$41,500 from 2012-2017;²²⁴ and Insys paid \$2,500,000 from 2012-2017 to the USPF.²²⁵

f. American Geriatrics Society

282. The AGS was another Front Group with systematic connections and interpersonal relationships with the Marketing Defendants and Purdue. The AGS was a large recipient of contributions from the Marketing Defendants and Purdue, including Endo, Purdue and Janssen.

²²¹ *Fueling an Epidemic*, *supra* n. 182, at p. 4.

²²² *Id.* at 12; U.S. Pain Foundation, *Transparency*, available at <https://uspainfoundation.org/transparency/>. (last accessed on August 1, 2018).

²²³ *Id.*

²²⁴ *Id.*

²²⁵ *Id.*

AGS contracted with Purdue, Endo, and Janssen to disseminate guidelines regarding the use of opioids for chronic pain in 2002 (*The Management of Persistent Pain in Older Persons*, hereinafter “2002 AGS Guidelines”) and 2009 (*Pharmacological Management of Persistent Pain in Older Persons*,²²⁶ hereinafter “2009 AGS Guidelines”). According to news reports, AGS has received at least \$344,000 in funding from opioid manufacturers since 2009.²²⁷ AGS’s complicity in the common purpose with the Marketing Defendants and Purdue is evidenced by the fact that AGS internal discussions in August 2009 reveal that it did not want to receive up front funding from drug companies, which would suggest drug company influence, but would instead accept commercial support to disseminate pro-opioid publications.

283. More specifically, Purdue paid \$11,785 from 2012-2017²²⁸ and provided \$40,000 in “corporate roundtable dues” to AGS’s Health in Aging Foundation, a 501(c)(3) organization affiliated with the group between 2012 and 2015.²²⁹

284. The 2009 AGS Guidelines recommended that “[a]ll patients with moderate to severe pain . . . should be considered for opioid therapy.” The panel made “strong recommendations” in this regard despite “low quality of evidence” and concluded that the risk of

²²⁶ *Pharmacological Management of Persistent Pain in Older Persons*, 57 J. Am. Geriatrics Soc’y 1331 (2009), available at <https://www.ncbi.nlm.nih.gov/pubmed/19573219> (last accessed on August 1, 2018) (“2009 AGS Guidelines”).

²²⁷ John Fauber & Ellen Gabler, *Narcotic Painkiller Use Booming Among Elderly*, MILWAUKEE J. SENTINEL (May 30, 2012), available at <https://www.medpagetoday.com/geriatrics/painmanagement/32967> (“Narcotic Painkiller Use Booming Among Elderly”).

²²⁸ *Fueling an Epidemic*, *supra* n. 182.

²²⁹ Letter from Nancy E. Lundebjerg, Chief Executive Office, American Geriatrics Society, to Sen. Claire McCaskill (Oct. 11, 2017).

addiction is manageable for patients, even with a prior history of drug abuse.²³⁰ These Guidelines further recommended that “the risks [of addiction] are exceedingly low in older patients with no current or past history of substance abuse.” These recommendations are not supported by any study or other reliable scientific evidence. Nevertheless, they have been cited over 500 times in Google Scholar (which allows users to search scholarly publications that would be have been relied on by researchers and prescribers) since their 2009 publication and as recently as this year.

285. 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 Guidelines were influenced by contributions that drug companies, including Purdue, Endo, Janssen, and Teva, made to the sponsoring organizations and committee members.

286. Dr. Bruce Farrell was an AGS task force chairman for the 2009 Guidelines, but was also a paid speaker for Endo, and he helped conduct a CME for treating osteoarthritis pain, which was funded by Purdue.²³¹

287. Representatives of the Marketing Defendants and Purdue, often at informal meetings at conferences, suggested activities, lobbying efforts and publications for AGS to pursue. AGS 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.

²³⁰ 2009 AGS Guidelines, *supra* n. 226, at 1342.

²³¹ *Narcotic Painkiller Use Booming Among Elderly*, *supra* n. 227.

288. Members of AGS Board of Directors were doctors who were on the Marketing Defendants' and Purdue's payrolls, either as consultants or as speakers for medical events. As described below, many of the KOLs also served in leadership positions within the AGS.

g. American Chronic Pain Association

289. The Manufacturer Defendants also made substantial payments to the American Chronic Pain Association ("ACPA"). Founded in 1980, the ACPA offers support and education for people suffering with chronic pain.

290. Contributions to the ACPA from the Manufacturing Defendants include \$312,470 from Purdue and \$50,000 from Janssen from 2012-2017.²³² Between 2013 and 2016, 10 members of ACPA's Advisory Board received more than \$140,000 from opioid manufacturers, including Endo.

3. The Marketing Defendants and Purdue Deceptively Paid KOLs to Promote Opioid Use

291. To falsely promote their opioids, the Marketing Defendants and Purdue paid and cultivated a select circle of doctors who were chosen and sponsored by the Marketing Defendants and Purdue for their supportive messages. As set forth below, pro-opioid doctors have been at the hub of the Marketing Defendants' and Purdue's well-funded, pervasive marketing scheme since its inception and were used to create the grave misperception that science and legitimate medical professionals favored the wider and broader use of opioids. These doctors include Dr. Russell Portenoy, Dr. Lynn Webster, Dr. Perry Fine and Dr. Scott Fishman.

292. Although these KOLs were funded by the Marketing Defendants and Purdue, the KOLs were used extensively to present the appearance that unbiased and reliable medical

²³² *Fueling an Epidemic*, *supra* n. 182.

research supporting the broad use of opioid therapy for chronic pain had been conducted and was being reported on by independent medical professionals.

293. As the Marketing Defendants' and Purdue's false marketing scheme picked up steam, these pro-opioid KOLs wrote, consulted on, edited, and lent their names to books and articles, and gave speeches and CMEs supportive of opioid therapy for chronic pain. They served on committees that developed treatment guidelines that strongly encouraged the use of opioids to treat chronic pain and they were placed on boards of pro-opioid advocacy groups and professional societies that developed, selected, and presented CMEs.

294. Through use of their KOLs and strategic placement of these KOLs throughout every critical distribution channel of information within the medical community, the Marketing Defendants and Purdue were able to exert control of each of these modalities through which doctors receive their information.

295. In return for their pro-opioid advocacy, the Marketing Defendants' and Purdue's KOLs received money, prestige, recognition, research funding, and avenues to publish. For example, Dr. Webster has received funding from Endo, Purdue, and Cephalon. Dr. Fine has received funding from Janssen, Cephalon, Endo, and Purdue.

296. The Marketing Defendants and Purdue carefully vetted their KOLs to ensure that they were likely to remain on-message and supportive of the Marketing Defendants' and Purdue's agenda. The Marketing Defendants and Purdue also kept close tabs on the content of the materials published by these KOLs. Of course, the Marketing Defendants and Purdue also kept these KOLs well-funded enabling them to push the Marketing Defendants' and Purdue's deceptive message out to the medical community.

297. Once the Marketing Defendants and Purdue identified and funded KOLs and those KOLs began to publish “scientific” papers supporting the Marketing Defendants’ and Purdue’s false position that opioids were safe and effective for treatment of chronic pain, the Marketing Defendants and Purdue poured significant funds and resources into a marketing machine that widely cited and promoted their KOLs and studies or articles by their KOLs to drive prescriptions of opioids for chronic pain. The Marketing Defendants and Purdue cited to, distributed, and marketed these studies and articles by their KOLs as if they were independent medical literature so that it would be well-received by the medical community. By contrast, the Marketing Defendants and Purdue did not support, acknowledge, or disseminate the truly independent publications of doctors critical of the use of chronic opioid therapy.

298. In their promotion of the use of opioids to treat chronic pain, the Marketing Defendants’ and Purdue’s KOLs knew that their statements were false and misleading, or they recklessly disregarded the truth in doing so, but they continued to publish their misstatements to benefit themselves and the Marketing Defendants and Purdue.

a. Dr. Russell Portenoy

299. In 1986, Dr. Russell Portenoy, who later became Chairman of the Department of Pain Medicine and Palliative Care at Beth Israel Medical Center in New York while at the same time serving as a top spokesperson for drug companies, published an article reporting that “[f]ew substantial gains in employment or social function could be attributed to the institution of opioid therapy.”²³³

²³³ Russell Portenoy & Kathy Foley, *Chronic Use of Opioid Analgesics in Non-Malignant Pain: Report of 38 cases*, 25(2) Pain 171 (1986), available at <https://www.ncbi.nlm.nih.gov/pubmed/2873550>.

300. Writing in 1994, Dr. Portenoy described the prevailing attitudes regarding the dangers of long-term use of opioids:

*The traditional approach to chronic non-malignant pain does not accept the long-term administration of opioid drugs. This perspective has been justified by the perceived likelihood of tolerance, which would attenuate any beneficial effects over time, and the potential for side effects, worsening disability, and addiction. According to conventional thinking, the initial response to an opioid drug may appear favorable, with partial analgesia and salutary mood changes, but adverse effects inevitably occur thereafter. It is assumed that the motivation to improve function will cease as mental clouding occurs and the belief takes hold that the drug can, by itself, return the patient to a normal life. Serious management problems are anticipated, including difficulty in discontinuing a problematic therapy and the development of drug seeking behavior induced by the desire to maintain analgesic effects, avoid withdrawal, and perpetuate reinforcing psychic effects. There is an implicit assumption that little separates these outcomes from the highly aberrant behaviors associated with addiction.*²³⁴

(emphasis added). According to Dr. Portenoy, the foregoing problems could constitute “compelling reasons to reject long-term opioid administration as a therapeutic strategy in all but the most desperate cases of chronic nonmalignant pain.”²³⁵

301. Despite having taken this position on long-term opioid treatment, Dr. Portenoy ended up becoming a spokesperson for Purdue and Marketing Defendants, promoting the use of prescription opioids and minimizing their risks. A respected leader in the field of pain treatment, Dr. Portenoy was highly influential. Dr. Andrew Kolodny, cofounder of Physicians for Responsible Opioid Prescribing, described him “lecturing around the country as a religious- like figure. The megaphone for Portenoy is Purdue, which flies in people to resorts to hear him speak.

²³⁴ Russell Portenoy, *Opioid Therapy for Chronic Nonmalignant Pain: Current Status*, 1 Progress in Pain Res. & Mgmt., 247-287 (H.L. Fields and J.C. Liebeskind eds., 1994) (emphasis added).

²³⁵ *Id.*

It was a compelling message: ‘Docs have been letting patients suffer; nobody really gets addicted; it’s been studied.’”²³⁶

302. As one organizer of CME seminars who worked with Portenoy and Purdue pointed out, “had Portenoy not had Purdue’s money behind him, he would have published some papers, made some speeches, and his influence would have been minor. With Purdue’s millions behind him, his message, which dovetailed with their marketing plans, was hugely magnified.”²³⁷

303. Dr. Portenoy was also a critical component of the Marketing Defendants’ and Purdue’s control over their Front Groups. Specifically, Dr. Portenoy sat as a Director on the board of the APF. He was also the President of the APS.

304. In recent years, some of the Marketing Defendants’ and Purdue’s KOLs have conceded that many of their past claims in support of opioid use lacked evidence or support in the scientific literature.²³⁸ Dr. Portenoy has now admitted that he minimized the risks of opioids,²³⁹ and that he “gave innumerable lectures in the late 1980s and ‘90s about addiction that

²³⁶ *Dreamland*, *supra* n. 2, at 314.

²³⁷ *Id.* at 136.

²³⁸ See, e.g., John Fauber, *Painkiller boom fueled by networking*, MILWAUKEE JOURNAL SENTINEL (Feb. 18, 2012), available at <http://archive.jsonline.com/watchdog/watchdogreports/painkiller-boom-fueled-by-networking-dp3p2rn-139609053.html/> (reporting that a key Endo KOL acknowledged that opioid marketing went too far).

²³⁹ Celine Gounder, *Who Is Responsible for the Pain-Pill Epidemic?*, THE NEW YORKER (Nov. 8, 2013), available at <https://www.newyorker.com/business/currency/who-is-responsible-for-the-pain-pill-epidemic> (“Gounder, *Who Is Responsible*”).

weren't true."²⁴⁰ He mused, "Did I teach about pain management, specifically about opioid therapy, in a way that reflects misinformation? Well, against the standards of 2012, I guess I did . . ."²⁴¹

305. In a 2011 interview released by Physicians for Responsible Opioid Prescribing, Portenoy stated that his earlier work purposefully relied on evidence that was not "real" and left real evidence behind:

I gave so many lectures to primary care audiences in which the Porter and Jick article was just one piece of data that I would then cite, and I would cite six, seven, maybe ten different avenues of thought or avenues of evidence, *none of which represented real evidence*, and yet what I was trying to do was to create a narrative so that the primary care audience would look at this information in [total] and feel more comfortable about opioids in a way they hadn't before. *In essence this was education to destigmatize [opioids], and because the primary goal was to destigmatize, we often left evidence behind.*²⁴²

306. Several years earlier, when interviewed by journalist Barry Meier for his 2003 book, *Pain Killer*, Dr. Portenoy was more direct: "It was pseudoscience. I guess I'm going to have always to live with that one."²⁴³

b. Dr. Lynn Webster

307. Another KOL, Dr. Lynn Webster, was the co-founder and Chief Medical Director of the Lifetree Clinical Research & Pain Clinic in Salt Lake City, Utah. Dr. Webster was

²⁴⁰ Thomas Catan & Evan Perez, *A Pain-Drug Champion Has Second Thoughts*, The Wall Street Journal (Dec. 17, 2012, 11:36am), available at <https://www.wsj.com/articles/SB10001424127887324478304578173342657044604>.

²⁴¹ *Id.*

²⁴² Harrison Jacobs, *This one-paragraph letter may have launched the opioid epidemic*, BUSINESS INSIDER (May 26, 2016), available at <http://www.businessinsider.com/porter-and-jick-letter-launched-the-opioid-epidemic-2016-5>; Andrew Kolodny, *Opioids for Chronic Pain: Addiction is NOT Rare*, YouTube (Oct. 30, 2011), available at <https://www.youtube.com/watch?v=DgyuBWN9D4w&feature=youtu.be>.

²⁴³ *Pain Killer*, *supra* n. 109, at 277.

President in 2013 and was a board member of AAPM, a Front Group that ardently supported chronic opioid therapy. He was a Senior Editor of Pain Medicine, the same journal that published Endo's 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).

308. 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 industry-supported guidelines. Versions of Dr. Webster's Opioid Risk Tool ("ORT") appear on, or are linked to, websites run by Endo, Janssen, and Purdue. 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 to prevent "overuse of prescriptions" and "overdose deaths." This webinar was available to and was intended to reach doctors at hospitals such as Plaintiffs.

309. Dr. Webster was himself tied to numerous overdose deaths. He and the Lifetree Clinic were investigated by the DEA for overprescribing opioids after twenty patients died from overdoses. In keeping with the Marketing Defendants' and Purdue's promotional messages, Dr. Webster apparently believed the solution to patients' tolerance or addictive behaviors was more opioids: he prescribed staggering quantities of pills.

310. At an AAPM annual meeting held February 22 through 25, 2006, Cephalon sponsored a presentation by Webster and others titled, "Open-label study of fentanyl effervescent

buccal tablets in patients with chronic pain and breakthrough pain: Interim safety results.” The presentation’s agenda description states: “Most patients with chronic pain experience episodes of breakthrough pain, yet no currently available pharmacologic agent is ideal for its treatment.” The presentation purports to cover a study analyzing the safety of a new form of fentanyl buccal tablets in the chronic pain setting and promises to show the “[i]nterim results of this study suggest that [fentanyl buccal] is safe and well-tolerated in patients with chronic pain and [breakthrough pain].” This CME effectively amounted to off-label promotion of Cephalon’s opioids, even though they were approved only for cancer pain.

311. Cephalon sponsored a CME written by Dr. Webster, *Optimizing Opioid Treatment for Breakthrough Pain*, offered by Medscape, LLC from September 28, 2007 through December 15, 2008. The CME taught that non-opioid analgesics and combination opioids containing non-opioids such as aspirin and acetaminophen are less effective at treating breakthrough pain because of dose limitations on the non-opioid component.

c. Dr. Perry Fine

312. Dr. Perry Fine’s ties to the Marketing Defendants and Purdue have been well documented. He has authored articles and testified in court cases and before state and federal committees, and he, too, has argued against legislation restricting high-dose opioid prescription for non-cancer patients. He has served on Purdue’s advisory board, provided medical legal consulting for Janssen, and participated in CME activities for Endo, along with serving in these capacities for several other drug companies. He co-chaired the APS-AAPM Opioid Guideline

Panel, served as treasurer of the AAPM from 2007 to 2010 and as president of that group from 2011 to 2013, and was also on the board of directors of APF.²⁴⁴

313. Multiple videos feature Dr. Fine's delivering educational talks about prescription opioids. He even testified at trial that the 1,500 pills a month prescribed to celebrity Anna Nicole Smith before her death for pain did not make her an addict.

314. Dr. Fine has also acknowledged having failed to disclose numerous conflicts of interest. For example, Dr. Fine failed to fully disclose payments received as required by his employer, the University of Utah—telling the university that he had received under \$5,000 in 2010 from Johnson & Johnson for providing “educational” services, but Johnson & Johnson's website states that the company paid him \$32,017 that year for consulting, promotional talks, meals and travel.²⁴⁵

315. Dr. Fine and Dr. Portenoy co-wrote *A Clinical Guide to Opioid Analgesia*, in which they downplayed the risks of opioid treatment, such as respiratory depression and addiction:

At clinically appropriate doses . . . respiratory rate typically does not decline. Tolerance to the respiratory effects usually develops quickly, and doses can be steadily increased without risk.

Overall, the literature provides evidence that the outcomes of drug abuse and addiction are rare among patients who receive opioids for a short period (i.e., for

²⁴⁴ Scott M. Fishman, MD, *Incomplete Financial Disclosures in a Letter on Reducing Opioid Abuse and Diversion*, 306 (13) JAMA 1445 (Sept. 20, 2011), available at <https://jamanetwork.com/journals/jama/article-abstract/1104464?redirect=true>.

²⁴⁵ Tracy Weber & Charles Ornstein, *Two Leaders in Pain Treatment Have Long Ties to Drug Industry*, ProPublica (Dec. 23, 2011, 2:14 PM), available at <https://www.propublica.org/article/two-leaders-in-pain-treatment-have-long-ties-to-drug-industry>.

acute pain) and among those with no history of abuse who receive long-term therapy for medical indications.²⁴⁶

316. In November 2010, Dr. Fine and others published an article presenting the results of another Cephalon-sponsored study titled “Long-Term Safety and Tolerability of Fentanyl Buccal Tablet for the Treatment of Breakthrough Pain in Opioid-Tolerant Patients with Chronic Pain: An 18-Month Study.”²⁴⁷ In that article, Dr. Fine explained that the 18-month “open-label” study “assessed the safety and tolerability of FBT [Fentora] for the [long-term] treatment of BTP in a large cohort . . . of opioid-tolerant patients receiving around-the-clock . . . opioids for non-cancer pain.”²⁴⁸ The article acknowledged that: (a) “[t]here has been a steady increase in the use of opioids for the management of chronic non-cancer pain over the past two decades”; (b) the “widespread acceptance” had led to the publishing of practice guidelines “to provide evidence- and consensus-based recommendations for the optimal use of opioids in the management of chronic pain”; and (c) those guidelines lacked “data assessing the long-term benefits and harms of opioid therapy for chronic pain.”²⁴⁹

317. The article concluded: “[T]he safety and tolerability profile of FBT in this study was generally typical of a potent opioid. The [adverse events] observed were, in most cases,

²⁴⁶ Perry G. Fine, MD and Russell K. Portenoy, MD, *A Clinical Guide to Opioid Analgesia* 20 and 34, McGraw-Hill Companies (2004), available at <http://www.thblack.com/links/RSD/OpioidHandbook.pdf>.

²⁴⁷ Perry G. Fine, et al., *Long-Term Safety and Tolerability of Fentanyl Buccal Tablet for the Treatment of Breakthrough Pain in Opioid-Tolerant Patients with Chronic Pain: An 18-Month Study*, 40(5) J. Pain & Symptom Management 747-60 (Nov. 2010).

²⁴⁸ *Id.*

²⁴⁹ *Id.*

predictable, manageable, and tolerable.” They also conclude that the number of abuse-related events was “small.”²⁵⁰

318. Multiple videos feature Dr. Fine delivering educational talks about the drugs. In one video from 2011 titled “Optimizing Opioid Therapy,” he sets forth a “Guideline for Chronic Opioid Therapy” discussing “opioid rotation” (switching from one opioid to another) not only for cancer patients, but also for non-cancer patients, and suggests it may take four or five switches over a person’s “lifetime” to manage pain.²⁵¹ He states the “goal is to improve effectiveness which is different from efficacy and safety.” Rather, for chronic pain patients, effectiveness “is a balance of therapeutic good and adverse events *over the course of years*.”²⁵² The entire program assumes that opioids are appropriate treatment over a “protracted period of time” and even over a patient’s entire “lifetime.” He even suggests that opioids can be used to treat *sleep apnea*. He further states that the associated risks of addiction and abuse can be managed by doctors and evaluated with “tools,” but leaves that for “a whole other lecture.”²⁵³

e. Dr. Scott Fishman

319. Dr. Scott Fishman is a physician whose ties to the opioid drug industry are manifold. He has served as an APF board member and as president of the AAPM, and has participated yearly in numerous CME activities for which he received “market rate honoraria.” As discussed below, he has authored publications, including the seminal guides on opioid

²⁵⁰ *Id.*

²⁵¹ Perry A. Fine, M.D., *Safe and Effective Opioid Rotation*, YouTube (Nov. 8, 2012), https://www.youtube.com/watch?v=_G3II9yqgXI

²⁵² *Id.*

²⁵³ *Id.*

prescribing, which were funded by the Marketing Defendants and Purdue. He has also worked to oppose legislation requiring doctors and others to consult pain specialists before prescribing high doses of opioids to non- cancer patients. He has himself acknowledged his failure to disclose all potential conflicts of interest in a letter in the *Journal of the American Medical Association* titled “Incomplete Financial Disclosures in a Letter on Reducing Opioid Abuse and Diversion.”²⁵⁴

320. Dr. Fishman authored a physician’s guide on the use of opioids to treat chronic pain titled “Responsible Opioid Prescribing,” in 2007 which promoted the notion that long-term opioid treatment was a viable and safe option for treating chronic pain.

321. In 2012, Dr. Fishman updated the guide and continued emphasizing the “catastrophic” “under-treatment” of pain and the “crisis” such under-treatment created:

Given the magnitude of the problems related to opioid analgesics, it can be tempting to resort to draconian solutions: clinicians may simply stop prescribing opioids, or legislation intended to improve pharmacovigilance may inadvertently curtail patient access to care. As we work to reduce diversion and misuse of prescription opioids, it’s critical to remember that the problem of unrelieved pain remains as urgent as ever.²⁵⁵

322. The updated guide still assures that “[o]pioid therapy to relieve pain and improve function is legitimate medical practice for acute and chronic pain of both cancer and non-cancer origins.”²⁵⁶

323. In another guide by Dr. Fishman, he continues to downplay the risk of addiction: “I believe clinicians must be very careful with the label ‘addict.’ I draw a distinction between a

²⁵⁴ *Incomplete Financial Disclosures in a Letter on Reducing Opioid Abuse and Diversion*, supra n. 244.

²⁵⁵ Scott M. Fishman, *Responsible Opioid Prescribing: A Guide for Michigan Clinicians*, 10-11 (Waterford Life Sciences 2012).

²⁵⁶ *Id.*

‘chemical coper’ and an addict.”²⁵⁷ The guide also continues to present symptoms of addiction as symptoms of “pseudoaddiction.”

4. The Marketing Defendants and Purdue Also Spread Their Misleading Messages to Reputable Organizations

324. The Defendants also manipulated reputable organizations like the Joint Commission on Accreditation of Healthcare Organizations (the “Joint Commission”) in order to further advance their unlawful marketing of opioids. The Joint Commission certifies over 21,000 health care organizations and is the nation’s oldest and largest standards-setting and accrediting body in health care.²⁵⁸

325. In 2000, Purdue sponsored a book through the Joint Commission which claimed “there is no evidence that addiction is a significant issue when persons are given opioids for pain control.”²⁵⁹ It also called doctors’ concerns about addiction side effects “inaccurate and exaggerated.”²⁶⁰ Dr. David W. Baker, the Joint Commission’s executive vice president for health care quality evaluation, has acknowledged that “[t]he Joint Commission was one of the dozens of individual authors and organizations that developed educational materials for pain management that propagated this erroneous information.”²⁶¹

²⁵⁷ Scott M. Fishman, *Listening to Pain: A Physician’s Guide to Improving Pain Management Through Better Communication* 45 (Oxford University Press 2012).

²⁵⁸ Joint Commission, *FAQ Page*, available at <https://www.jointcommission.org/about/jointcommissionfaqs.aspx?CategoryId=10#2274> (last accessed August 1, 2018).

²⁵⁹ Sonia Moghe, *Opioid history: From ‘wonder drug’ to abuse epidemic*, CNN (Oct. 13, 2016), available at <https://www.cnn.com/2016/05/12/health/opioid-addiction-history/>.

²⁶⁰ *Id.*

²⁶¹ *Id.*

326. In 2001, due to the influence of the Marketing Defendants and Purdue, the Joint Commission, along with the National Pharmaceutical Council (founded in 1953 and supported by the nation's major research-based biopharmaceutical companies²⁶²) "introduced standards for [hospitals] to improve their care for patients with pain." The new standards for hospitals put patient pain front and center as the "fifth vital sign." This monograph, entitled *Pain: Current Understanding of Assessment, Management and Treatments* required assessment of pain in all patients.

327. The Joint Commission's first pain management standards placed responsibility for pain control on health care organizations (hospitals); and, emphasized the need for hospitals to do systematic assessments and use quantitative measures of pain which was consistent with the position of the Front Group APS.

328. As a result of the Marketing Defendants' and Purdue's efforts to manipulate the standard of care, many hospitals, including Plaintiffs, risked loss of their Joint Commission accreditation if they did not incorporate the "fifth vital sign" standard and put pain at the forefront of their treatment. Loss of accreditation by The Joint Commission can result in the loss of a huge amount of hospital resources to become reaccredited, despite having a patient satisfaction rating of 99% for the same period.²⁶³

329. Since 2001, The Joint Commission standards relating to pain assessment and management have been revised to lessen emphasis on pain. However, the damage caused by the Marketing Defendants' and Purdue's marketing campaigns could not be undone. Dr. Baker

²⁶² Currently funded by Johnson & Johnson, Purdue and Teva, among others.

²⁶³ Testimony of Tim Westlake, MD, FFSMB, FACEP, U.S. Senate Comm. on Homeland Sec. and Gov't Affairs (Apr 15, 2016) *available at* <https://www.hsgac.senate.gov/imo/media/doc/Testimony-Westlake-2016-04-15-REVISED.pdf>.

explains that “the concept that iatrogenic addiction was rare and that long acting opioids were less addictive had been greatly reinforced and widely repeated, and studies refuting these claims were not published until several years later.”

5. **The Marketing Defendants and Purdue Disseminated Their Misrepresentations Through CME Programs**

330. Now that the Marketing Defendants and Purdue had both a group of physician promoters and had built a false body of “literature,” Defendants needed to make sure their false marketing message was widely distributed.

331. One way the Marketing Defendants and Purdue aggressively distributed their false message was through countless CME programs.

332. Doctors are required to attend a certain number and, often, type of CME programs each year as a condition of their licensure. These programs are generally delivered in person, often in connection with professional organizations’ conferences, online, or through written publications. Doctors rely on CMEs not only to satisfy licensing requirements, but also to get information on new developments in medicine or to deepen their knowledge in specific areas of practice. Because CMEs typically are taught by KOLs who are highly respected in their fields, and are thought to reflect these physicians’ medical expertise, they can be especially influential with doctors.

333. The countless doctors and other health care professionals who participate in accredited CMEs constitute an enormously important audience for opioid reeducation. As one target, Defendants aimed to reach general practitioners, whose broad area of practice and lack of expertise and specialized training in pain management made them particularly dependent upon CMEs and, as a result, especially susceptible to the Marketing Defendants’ and Purdue’s deceptions.

334. The Marketing Defendants and Purdue sponsored CMEs that were delivered thousands of times, promoting chronic opioid therapy and supporting and disseminating the deceptive and biased messages described in this Complaint. These CMEs, while often generically titled to relate to the treatment of chronic pain, focused on opioids to the exclusion of alternative treatments, inflated the benefits of opioids, and frequently omitted or downplayed their risks and adverse effects.

335. Cephalon sponsored numerous CME programs, which were made widely available through organizations like Medscape, LLC (“Medscape”) and which disseminated false and misleading information to physicians across the country.

336. Another Cephalon-sponsored CME presentation titled *Breakthrough Pain: Treatment Rationale with Opioids* was available on Medscape starting September 16, 2003 and was given by a self-professed pain management doctor who “previously operated back, complex pain syndromes, the neuropathies, and interstitial cystitis.” He describes the pain process as a non-time-dependent continuum that requires a balanced analgesia approach using “targeted pharmaco therapeutics to affect multiple points in the pain-signaling pathway.”²⁶⁴ The doctor lists fentanyl as one of the most effective opioids available for treating breakthrough pain, describing its use as an expected and normal part of the pain management process.²⁶⁵ Nowhere in the CME is cancer or cancer-related pain even mentioned, despite FDA restrictions that fentanyl use be limited to cancer-related pain.

²⁶⁴ Daniel S. Bennett, *Breakthrough Pain: Treatment Rationale With Opioids*, Medscape, available at <http://www.medscape.org/viewarticle/461612> (last accessed August 1, 2018).

²⁶⁵ *Id.*

337. Teva 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 non-cancer-related has limited utility” and recommended Actiq and Fentora for patients with chronic pain. The CME is still available online.

338. *Responsible Opioid Prescribing* was sponsored by Purdue, Endo and Teva. The FSMB website described it as the “leading continuing medical education (CME) activity for prescribers of opioid medications.” Endo sales representatives distributed copies of *Responsible Opioid Prescribing* with a special introductory letter from Dr. Fishman.

339. In all, more than 163,000 copies of *Responsible Opioid Prescribing* were distributed nationally.

340. The American Medical Association (“AMA”) recognized the impropriety that pharmaceutical company-funded CMEs create, stating that support from drug companies with a financial interest in the content being promoted “creates conditions in which external interests could influence the availability and/or content” of the programs and urged that “[w]hen possible, CME[s] should be provided without such support or the participation of individuals who have financial interests in the education subject matter.”²⁶⁶

341. Physicians attended or reviewed CMEs sponsored by the Marketing Defendants during the relevant time period and were misled by them.

²⁶⁶ Opinion 9.0115, *Financial Relationships with Industry in CME*, Am. Med. Ass’n (Nov. 2011).

342. By sponsoring CME programs put on by Front Groups like APF, AAPM, and others, the Marketing Defendants and Purdue expected and understood that instructors would deliver messages favorable to them, as these organizations were dependent on the Marketing Defendants and Purdue for other projects. The sponsoring organizations honored this principle by hiring pro-opioid KOLs to give talks that supported chronic opioid therapy. Marketing Defendants and Purdue-driven content in these CMEs had a direct and immediate effect on prescribers' views on opioids. Producers of CMEs and the Marketing Defendants and Purdue both measure the effects of CMEs on prescribers' views on opioids and their absorption of specific messages, confirming the strategic marketing purpose in supporting them.

6. **The Marketing Defendants and Purdue Used “Branded” Advertising to Promote Their Products to Doctors and Consumers**

343. The Marketing Defendants and Purdue engaged in widespread advertising campaigns touting the benefits of their branded drugs. The Marketing Defendants and Purdue published print advertisements in a broad array of medical journals, ranging from those aimed at specialists, such as the Journal of Pain and Clinical Journal of Pain, to journals with wider medical audiences, such as the Journal of the American Medical Association. The Marketing Defendants and Purdue collectively spent more than \$14 million on medical journal advertising of opioids in 2011, nearly triple what they spent in 2001. The 2011 total includes \$8.3 million by Purdue, \$4.9 million by Janssen, and \$1.1 million by Endo.

344. The Marketing Defendants and Purdue also targeted consumers in their advertising. They knew that physicians are more likely to prescribe a drug if a patient

specifically requests it.²⁶⁷ They also knew that this willingness to acquiesce to such patient requests holds true even for opioids and for conditions for which they are not approved.²⁶⁸ Endo's research, for example, found that such communications resulted in greater patient "brand loyalty," with longer durations of Opana ER therapy and fewer discontinuations. The Marketing Defendants and Purdue thus increasingly took their opioid sales campaigns directly to consumers, including through patient- focused "education and support" materials in the form of pamphlets, videos, or other publications that patients could view in their physician's office.

7. **The Marketing Defendants and Purdue Used "Unbranded" Advertising to Promote Opioid Use for Chronic Pain Without FDA Review**

345. The Marketing Defendants and Purdue also aggressively promoted opioids through "unbranded advertising" to generally tout the benefits of opioids without specifically naming a particular brand-name opioid drug. Instead, unbranded advertising is usually framed as "disease awareness"—encouraging consumers to "talk to your doctor" about a certain health condition without promoting a specific product and, therefore, without providing balanced disclosures about the product's limits and risks. In contrast, a pharmaceutical company's "branded" advertisement that identifies a specific medication and its indication (i.e., the condition which the drug is approved to treat) must also include possible side effects and contraindications—what the FDA Guidance on pharmaceutical advertising refers to as "fair balance." Branded advertising is also subject to FDA review for consistency with the drug's

²⁶⁷ In one study, for example, nearly 20% of sciatica patients requesting oxycodone received a prescription for it, compared with 1% of those making no specific request. J.B. McKinlay et al., *Effects of Patient Medication Requests on Physician Prescribing Behavior*, 52(2) Med. Care 294 (2014) available at <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4151257/>.

²⁶⁸ *Id.*

FDA-approved label. Through unbranded materials, the Marketing Defendants and Purdue expanded the overall acceptance of and demand for chronic opioid therapy without the restrictions imposed by regulations on branded advertising.

346. Many of the Marketing Defendants and Purdue utilized unbranded websites to promote opioid use without promoting a specific branded drug, such as Purdue's pain-management website, *www.inthefaceofpain.com*. The website contained testimonials from several dozen "advocates," including health care providers, urging more pain treatment. The website presented the advocates as neutral and unbiased, but an investigation by the New York Attorney General later revealed that Purdue paid the advocates hundreds of thousands of dollars.

8. The Marketing Defendants and Purdue Funded, Edited and Distributed Publications That Supported Their Misrepresentations

347. The Marketing Defendants and Purdue created a body of false, misleading, 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 calculated to shape the perceptions of prescribers, patients, and payors. This literature served marketing goals, rather than scientific standards, and was intended to persuade doctors and consumers that the benefits of long-term opioid use outweighed the risks.

348. To accomplish their goal, the Marketing Defendants and Purdue — sometimes through third-party consultants and/or Front Groups — commissioned, edited, and arranged for the placement of favorable articles in academic journals.

349. The Marketing Defendants' and Purdue's plans for these materials did not originate in the departments with the organizations that were responsible for research, development, or any other area that would have specialized knowledge about the drugs and their

effects on patients; rather, they originated in the Marketing Defendants' and Purdue's marketing departments.

350. The Marketing Defendants and Purdue made sure that favorable articles were disseminated and cited widely in the medical literature, even when the Marketing Defendants and Purdue knew that the articles distorted the significance or meaning of the underlying study, as with the Porter & Jick letter. The Marketing Defendants and Purdue also frequently relied on unpublished data or posters, neither of which are subject to peer review, but were presented as valid scientific evidence.

351. The Marketing Defendants and Purdue published or commissioned deceptive review articles, letters to the editor, commentaries, case-study reports, and newsletters aimed at discrediting or suppressing negative information that contradicted their claims or raised concerns about chronic opioid therapy.

352. For example, in 2007, Cephalon sponsored the publication of an article titled "Impact of Breakthrough Pain on Quality of Life in Patients with Chronic, Non-cancer Pain: Patient Perceptions and Effect of Treatment with Oral Transmucosal Fentanyl Citrate,"²⁶⁹ published in the nationally circulated Journal of Pain Medicine, to support its effort to expand the use of its branded fentanyl products. The article's authors (including Dr. Webster, discussed above) stated that the "OTFC [fentanyl] has been shown to relieve BTP [breakthrough pain] more rapidly than conventional oral, normal-release, or 'short acting' opioids" and that "[t]he purpose of [the] study was to provide a qualitative evaluation of the effect of BTP on the [quality

²⁶⁹ Donald R. Taylor, *et al.*, *Impact of Breakthrough Pain on Quality of Life in Patients With Chronic, Non-cancer Pain: Patient Perceptions and Effect of Treatment With Oral Transmucosal Fentanyl Citrate (OTFC, ACTIQ)*, 8(3) Pain Med. 281-88 (Mar. 2007), available at <https://academic.oup.com/painmedicine/article/8/3/281/1829094>.

of life] of non-cancer pain patients.” The number-one-diagnosed cause of chronic pain in the patients studied was back pain (44%), followed by musculoskeletal pain (12%) and head pain (7%). The article cites Portenoy and recommends fentanyl for non-cancer BTP patients:

In summary, BTP appears to be a clinically important condition in patients with chronic non-cancer pain and is associated with an adverse impact on QoL. This qualitative study on the negative impact of BTP and the potential benefits of BTP-specific therapy suggests several domains that may be helpful in developing BTP-specific, QoL assessment tools.²⁷⁰

9. The Marketing Defendants and Purdue Used Speakers’ Bureaus and Programs to Spread Their Deceptive Messages.

353. In addition to making sales calls, the Marketing Defendants’ and Purdue’s detailers also identified doctors to serve, for payment, on their speakers’ bureaus and to attend programs with speakers with meals paid for by the Marketing Defendants and Purdue. These speaker programs and associated speaker trainings served three purposes: they provided 1) an incentive to doctors to prescribe, or increase their prescriptions of, a particular drug; 2) an opportunity for doctors to be selected to attend a forum at which the drug companies could further market to the speaker himself or herself; and 3) an opportunity for the doctors to market to their peers. The Marketing Defendants and Purdue graded their speakers, and future opportunities were based on speaking performance, post-program sales, and product usage. Purdue, Janssen, Endo, Cephalon, and Mallinckrodt each made thousands of payments to physicians nationwide, for activities including participating on speakers’ bureaus, providing consulting services, and other services.

VI. THE MARKETING DEFENDANTS’ AND PURDUE’S GOAL WAS FOR MORE PATIENTS TO TAKE MORE OPIOIDS AT HIGHER DOSES FOR LONGER PERIODS OF TIME

²⁷⁰ *Id.*

A. Increasing the Patient Population

1. The Marketing Defendants and Purdue Focused on Vulnerable Populations

354. The Marketing Defendants and Purdue specifically targeted their marketing at two particularly vulnerable populations—the elderly and veterans – who tend to suffer from chronic pain.

355. Internal Purdue documents demonstrate that the Purdue Individual Co-Conspirators focused on elderly patients because they are frequent pain sufferers, and, of equal importance, are likely to be covered by Medicare. Purdue internal documents reflected that if it targeted “Patients over the age of 65 ... more Medicare Part D coverage is achieved.”

356. Elderly patients frequently suffer from osteoarthritis, but opioids are not approved to treat the condition. Purdue conducted a single study on osteoarthritis for its Butrans opioid, and it failed. Purdue admitted in internal documents that its opioids “are not indicated for a specific disease” and “it is very important that you never suggest to your HCP [health care professional] that OxyContin is indicated for the treatment of a specific disease state such as Rheumatoid Arthritis or Osteoarthritis.” Nevertheless, to meet its business goals, Purdue trained its representatives to mislead doctors by promoting opioids for osteoarthritis without disclosing Purdue’s failed trial. Purdue even measured how often it targeted osteoarthritis patients. A Purdue marketing presentation concluded that its sales reps were “identifying appropriate patients” because osteoarthritis was specifically mentioned during 35% of sales visits. Purdue also directed sales reps to use marketing materials that highlight patients with osteoarthritis, even though Purdue drugs were never indicated for that disease and Purdue’s Butrans trial had failed. At one point, the Purdue Individual Co-Conspirators wanted to know if sales reps could sell more by remaining silent about the failed trial: “What can be said in response to a prescriber who

asks directly or indirectly, ‘can this product be prescribed for my patient with OA?’ In responding are we required to specifically mention the failed trials in OA?”

357. The Marketing Defendants and Purdue targeted these vulnerable patients even though the risks of long-term opioid use were significantly greater for them. For example, a 2016 CDC Guideline observes that existing evidence confirms that elderly patients taking opioids suffer from elevated fall and fracture risks, reduced renal function and medication clearance, and a smaller window between safe and unsafe dosages.²⁷¹ Elderly patients taking opioids have also been found to have a greater risk for hospitalizations and increased vulnerability to adverse drug effects and interactions, such as respiratory depression. The 2016 CDC Guideline concludes that there must be “additional caution and increased monitoring” to minimize the risks of opioid use in elderly patients.²⁷²

2. **The Marketing Defendants and Purdue Focused on Having Opioids Perceived as a “First Line” of Medication for “Opioid-Naïve” Patients, Rather Than as a Last Resort for Cancer Patients and the Terminally Ill**

358. From the very beginning, Purdue and Abbott intended to position OxyContin as useful for more than just cancer pain. Internal documents from the 1995 “OxyContin Launch” indicate that they also intended it for a “secondary market . . . for non-malignant pain (musculoskeletal, injury and trauma)” and that it must be “reinforced that we do not want to niche OxyContin just for cancer pain.”

359. In 1996, Purdue envisioned OxyContin’s being prescribed for a long laundry list of conditions, and literally generated a “wish list” of clinical studies to support its prescription in

²⁷¹ Dowell, CDC Guideline, *supra* n. 24.

²⁷² *Id.* at 27.

a variety of contexts, including: (1) postoperative pain, with specific objectives of supporting the “Abbott agreement” to market to hospitals, removing “the prohibition of giving the product during the 12-24 hour immediate postop period,” and removing “the qualification limiting the indication to pain for more than a few days;” (2) “nonmalignant pain” (including low back pain, osteoarthritis); and (3) HIV/AIDS treatment.

360. Purdue, particularly after its overall OxyContin sales began to slow after 2010, instructed its sales representatives to focus on expanding the patient base, by promoting its drugs specifically for patients who had not previously taken opioids, who it described as “opioid-naïve” or simply “naïve” patients:

- “Your opportunity here is with the naïve community, let’s use the naïve trial to make your case.”
- “You created an epiphany with the doctor today (potentially) by reviewing the opiate naïve patient profile. What made him more pat to write for this patient, being an amiable doctor, is the fact that he would not have to talk patients out of their short acting [opioids].”
- “This was an example of what a good call looks like ... [Dr.] was particularly interested in the RM case study of Marjorie, which generated a robust discussion of opioid naïve patients ...”

361. Purdue also promoted its drugs for “opioid-naïve” patients using the deceptive term “first line opioid.” “First line” is a medical term for the preferred first step in treating a patient. Opioids are not an appropriate first line therapy. Nevertheless, Purdue’s internal documents and testimony from sales representatives shows that Purdue repeatedly promoted OxyContin as “first line” — “the first thing they would take to treat pain.”

362. A particularly insidious aspect of Purdue's focus on "naïve" patients, and on keeping patients on opioids longer, was its savings card program. The cards provided a discount on a patient's first five prescriptions. In 2012, Purdue's internal 10-year plan highlighted its discovery that opioid savings cards kept patients on opioids longer: "more patients remain on OxyContin after 90 days." The savings card program was incredibly lucrative -- the return on investment for Purdue was 4.28, so that every \$1,000,000 Purdue gave away in savings came back to Purdue as \$4,280,000 in revenue because patients stayed on dangerous opioids longer. Discounts could have cut Purdue's revenue *if* patients took opioids for a short time. But Purdue's internal 10-year plan highlighted its discovery that opioid savings cards kept patients on opioids longer: "more patients remain on OxyContin after 90 days."

363. Purdue sales representatives did not disclose to doctors that "opioid naïve" patients faced greater risks of overdose and death. Purdue focused on less sophisticated prescribers, such as its "core" prolific prescribers, and certain nurses and PAs who might be more vulnerable to persuasion by its sales representatives.

3. **Increasing Dosages and Increasing Them Quickly to Keep Patients on Longer**

364. In order to promote long-term sales, the Marketing Defendants and Purdue promoted the prescription of higher dosages of opioids. There were several dimensions to this. First, the Marketing Defendants and Purdue charged more for the higher dosages. More importantly, patients who took higher dosages would stay on opioids longer.

365. At Purdue, staff, from sales representatives to senior management including the Purdue Individual Co-Conspirators, regularly and candidly discussed internally the imperative of increasing prescribed dosages. Accordingly, Purdue's second most important sales tactic (after frequent sales representative visits, the most important strategy employed by Purdue) was to

cause prescribers to prescribe higher doses. This was manifested in Purdue's *Individualize the Dose* campaign, and was communicated to prescribers in sales representatives' visits, including by the sales representatives in Kentucky. Sales representatives were relentlessly pressured to increase the average doses prescribed by the prescribers in their territories. An aspect of this strategy was to encourage faster upward *titration*, that is moving quickly from smaller to larger doses. The lowest dosage of Purdue's Butrans product, for example, was described to prescribers as an "introductory" dose that would presumptively be increased for most if not all patients.

366. Purdue secretly determined that pushing patients to higher doses would keep them on opioids longer. Purdue developed tactics specifically to keep patients hooked on opioids longer, which it called by the euphemism: "*Improving the Length of Therapy*" — sometimes abbreviated as "LOT" or "LoT." Purdue taught its employees that there is "a direct relationship" between getting patients on higher doses and keeping them on Purdue's opioids longer.

367. The Marketing Defendants' and Purdue's focus on increasing dosages, and increasing the duration of opioid usage, had devastating consequences for patients. Patients exposed to higher dosages, and for longer periods of time, are many times more likely to become addicted, and to overdose.

VII. THE MARKETING DEFENDANTS' AND PURDUE'S SCHEME SUCCEEDED, CREATING A PUBLIC HEALTH EPIDEMIC

A. The Marketing Defendants and Purdue Dramatically Expanded Opioid Prescribing and Use

368. The Marketing Defendants and Purdue necessarily expected a return on the enormous investment they made in their deceptive marketing scheme, and they worked to measure and expand their success. Their own documents show that they knew they were influencing prescribers and increasing prescriptions. Studies also show that in doing so, they fueled an epidemic of addiction and abuse.

369. Cephalon also recognized the return of its efforts to market Actiq and Fentora off-label for chronic pain. In 2000, Actiq generated \$15 million in sales. By 2002, Actiq sales had increased by 92%, which Cephalon attributed to “a dedicated sales force for ACTIQ” and “ongoing changes to [its] marketing approach including hiring additional sales representatives and targeting our marketing efforts to pain specialists.”²⁷³ Actiq became Cephalon’s second best-selling drug. By the end of 2006, Actiq’s sales had exceeded \$500 million.²⁷⁴ Only 1% of the 187,076 prescriptions for Actiq filled at retail pharmacies during the first six months of 2006 were prescribed by oncologists. One measure suggested that “more than 80 percent of patients who use[d] the drug don’t have cancer.”²⁷⁵

370. Each of the Marketing Defendants and Purdue tracked the impact of their marketing efforts to measure their impact in changing doctors’ perceptions and prescribing of their drugs. They purchased prescribing and survey data that allowed them to closely monitor these trends, and they did actively monitor them. For instance, they monitored doctors’ prescribing before and after detailing visits, and before and after speaker programs. Defendants continued and, in many cases, expanded and refined their aggressive and deceptive marketing for one reason: it worked. As described in this Complaint, both in specific instances (e.g., the low abuse potential of various Defendants’ opioids), and more generally, Defendants’ marketing changed prescribers’ willingness to prescribe opioids, led them to prescribe more of their

²⁷³ Cephalon, Inc. Annual Report (Form 10-K) at 28 (Mar. 31, 2003), *available at* <https://www.sec.gov/Archives/edgar/data/873364/000104746903011137/a2105971z10-k.htm>.

²⁷⁴ John Carreyrou, *Narcotic ‘Lollipop’ Becomes Big Seller Despite FDA Curbs*, THE WALL STREET JOURNAL (Nov. 3, 2006), *available at* <https://www.wsj.com/articles/SB116252463810112292>.

²⁷⁵ *Id.*

opioids, and persuaded them not to stop prescribing opioids or to switch to “safer” opioids, such as ADF.

371. This success would have come as no surprise. Drug Company marketing materially impacts doctors’ prescribing behavior.²⁷⁶ The effects of sales calls on prescribers’ behavior is well documented in the literature. One study examined four practices, including visits by sales representatives, medical journal advertisements, direct-to-consumer advertising, and pricing, and found that sales representatives have the strongest effect on drug utilization. An additional study found that doctor meetings with sales representatives are related to changes in both prescribing practices and requests by physicians to add the drugs to hospitals’ formularies.

372. Marketing Defendants and Purdue spent millions of dollars to market their drugs to prescribers and patients and meticulously tracked their return on that investment. In one recent survey published by the AMA, even though nine in ten general practitioners reported prescription drug abuse to be a moderate to large problem in their communities, 88% of the respondents said they were confident in their prescribing skills, and nearly half were comfortable

²⁷⁶ See, e.g., P. Manchanda & P. Chintagunta, *Responsiveness of Physician Prescription Behavior to Salesforce Effort: An Individual Level Analysis*, 15 (2-3) Mktg. Letters 129 (2004) (detailing has a positive impact on prescriptions written); I. Larkin, *Restrictions on Pharmaceutical Detailing Reduced Off-Label Prescribing of Antidepressants and Antipsychotics in Children*, 33(6) Health Affairs 1014 (2014) (finding academic medical centers that restricted direct promotion by pharmaceutical sales representatives resulted in a 34% decline in on-label use of promoted drugs). See also A. Van Zee, *The Promotion and Marketing of OxyContin: Commercial Triumph, Public Health Tragedy*, 99(2) Am J. Pub. Health 221 (2009) (correlating an increase of OxyContin prescriptions from 670,000 annually in 1997 to 6.2 million in 2002 to a doubling of Purdue’s sales force and trebling of annual sales calls (“Commercial Triumph”).

using opioids for chronic non-cancer pain.²⁷⁷ These results are directly due to the Marketing Defendants' and Purdue's fraudulent marketing campaign focused on several misrepresentations.

373. Thus, both independent studies and Defendants' own tracking confirm that Defendants' marketing scheme dramatically increased their sales.

B. The Marketing Defendants' and Purdue's Deception in Expanding Their Market Created and Fueled the Opioid Epidemic.

374. Independent research demonstrates a close link between opioid prescriptions and opioid abuse. For example, a 2007 study found "a very strong correlation between therapeutic exposure to opioid analgesics, as measured by prescriptions filled, and their abuse."²⁷⁸ It has been estimated that 60% of the opioids that are abused come, directly or indirectly, through physicians' prescriptions.

375. There is a "parallel relationship between the availability of prescription opioid analgesics through legitimate pharmacy channels and the diversion and abuse of these drugs and associated adverse outcomes." The opioid epidemic is "directly related to the increasingly widespread misuse of powerful opioid pain medications."²⁷⁹

376. 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

²⁷⁷ CS Hwang, *et al.*, *Prescription Drug Abuse: A National Survey of Primary Care Physicians*, 175 JAMA Intern. Med. 302 (2014), doi: 10.1001/jamainternmed.2014.6520, available at <https://www.ncbi.nlm.nih.gov/pubmed/25485657>.

²⁷⁸ Theodore J. Cicero, *et al.*, *Relationship Between Therapeutic Use and Abuse of Opioid Analgesics in Rural, Suburban, and Urban Locations in the United States*, 16 Pharmacopidemiology and Drug Safety, 827-40 (2007), doi: 10.1002/pds.1452, available at <https://www.cdhs.udel.edu/content-sub-site/Documents/Publications/Relationship%20Between%20Therapeutic%20Use%20and%20Abuse%20of%20Opioid%20Analgesics.pdf>.

²⁷⁹ See Califf, *et al.*, *supra* n. 30.

opioid prescriptions 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.”

VIII. EACH OF THE MARKETING DEFENDANTS AND PURDUE MADE MATERIALLY DECEPTIVE STATEMENTS AND CONCEALED MATERIAL FACTS

377. As alleged herein, the Marketing Defendants and Purdue made and/or disseminated deceptive statements regarding material facts and further concealed material facts in the course of manufacturing, marketing, and selling prescription opioids. The Marketing Defendants’ and Purdue’s actions were intentional and/or unlawful. Such statements include, but are not limited to, those set out below and alleged throughout this Complaint.

378. As a part of their deceptive marketing scheme, the Marketing Defendants identified and targeted susceptible prescribers and vulnerable patient populations in the United States. For example, the Marketing Defendants and Purdue 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 the Marketing Defendants’ and Purdue’s misrepresentations.

A. Purdue

379. Purdue made and/or disseminated deceptive statements, and concealed material facts in such a way to make their statements deceptive, including, but not limited to, the following:

- a. Creating, sponsoring, and assisting in the distribution of patient education materials distributed to consumers that contained deceptive statements;
- b. Creating and disseminating advertisements that contained deceptive statements concerning the ability of opioids to improve function long-term and concerning the evidence supporting the

efficacy of opioids long-term for the treatment of chronic non-cancer pain;

- c. Disseminating misleading statements concealing the true risk of addiction and promoting the deceptive concept of pseudoaddiction through Purdue's own unbranded publications and on internet sites Purdue operated that were marketed to and accessible by consumers;
- d. Distributing brochures to doctors, patients, and law enforcement officials that included deceptive statements concerning the indicators of possible opioid abuse;
- e. Sponsoring, directly distributing, and assisting in the distribution of publications that promoted the deceptive concept of pseudoaddiction, even for high-risk patients;
- f. Endorsing, directly distributing, and assisting in the distribution of publications that presented an unbalanced treatment of the long-term and dose-dependent risks of opioids versus NSAIDs;
- g. Providing significant financial support to pro-opioid KOL doctors who made deceptive statements concerning the use of opioids to treat chronic non-cancer pain;
- h. Providing needed financial support to pro-opioid pain organizations that made deceptive statements, including in patient education materials, concerning the use of opioids to treat chronic non-cancer pain;
- i. Assisting in the distribution of guidelines that contained deceptive statements concerning the use of opioids to treat chronic non-cancer pain and misrepresented the risks of opioid addiction;
- j. Endorsing and assisting in the distribution of CMEs containing deceptive statements concerning the use of opioids to treat chronic non-cancer pain;
- k. Developing and disseminating scientific studies that misleadingly concluded opioids are safe and effective for the long-term treatment of chronic non-cancer pain and that opioids improve quality of life, while concealing contrary data;
- l. Assisting in the dissemination of literature written by pro-opioid KOLs that contained deceptive statements concerning the use of opioids to treat chronic non-cancer pain;

- m. Creating, endorsing, and supporting the distribution of patient and prescriber education materials that misrepresented the data regarding the safety and efficacy of opioids for the long-term treatment of chronic non-cancer pain, including known rates of abuse and addiction and the lack of validation for long-term efficacy;
- n. Targeting veterans by sponsoring and disseminating patient education marketing materials that contained deceptive statements concerning the use of opioids to treat chronic non-cancer pain;
- o. Targeting the elderly by assisting in the distribution of guidelines that contained deceptive statements concerning the use of opioids to treat chronic non-cancer pain and misrepresented the risks of opioid addiction in this population;
- p. Exclusively disseminating misleading statements in education materials to hospital doctors and staff while purportedly educating them on new pain standards;
- q. Making deceptive statements concerning the use of opioids to treat chronic non-cancer pain to prescribers through in-person detailing; and
- r. Withholding from law enforcement the names of prescribers Purdue believed to be facilitating the diversion of its opioid, while simultaneously marketing opioids to these doctors by disseminating patient and prescriber education materials and advertisements and CMEs they knew would reach these same prescribers.

380. More specifically, Purdue made and/or disseminated deceptive statements, and promoted a culture that mislead doctors and patients into believing opioids were safe for chronic care, including, but not limited to, the following:

In 1998, Purdue distributed 15,000 copies of an OxyContin video to physicians without submitting it to the FDA for review, an oversight later acknowledged by Purdue. In 2001, Purdue submitted to the FDA a second version of the video, which the FDA did not review until October 2002—after the General Accounting Office inquired about its content. After its review, the FDA concluded that the video minimized the risks from

OxyContin and made unsubstantiated claims regarding its benefits to patients.²⁸⁰

According to training materials, Purdue instructed sales representatives to assure doctors—repeatedly and without evidence—that “fewer than one per cent” of patients who took OxyContin became addicted. (In 1999, a Purdue-funded study of patients who used OxyContin for headaches found that the addiction rate was thirteen per cent.)²⁸¹

Andrew Kolodny, the co-director of the Opioid Policy Research Collaborative, at Brandeis University, has worked with hundreds of patients addicted to opioids. He has stated that, though many fatal overdoses have resulted from opioids other than OxyContin, the crisis was initially precipitated by a shift in the culture of prescribing—a shift carefully engineered by Purdue. “If you look at the prescribing trends for all the different opioids, it’s in 1996 that prescribing really takes off,” Kolodny said. “It’s not a coincidence. That was the year Purdue launched a multifaceted campaign that misinformed the medical community about the risks.”²⁸²

“Purdue had a speakers’ bureau, and it paid several thousand clinicians to attend medical conferences and deliver presentations about the merits of the drug. Doctors were offered all-expenses-paid trips to pain-management seminars in places like Boca Raton. Such spending was worth the investment: doctors who attended these seminars in 1996 wrote OxyContin prescriptions more than twice as often as those who didn’t. The company advertised in medical journals, sponsored Web sites about chronic pain, and distributed a dizzying variety of OxyContin swag: fishing hats, plush toys, luggage tags. Purdue also produced promotional videos featuring satisfied patients—like a construction worker who talked about how OxyContin had eased his chronic back pain, allowing him to return to work. The videos, which also included testimonials from pain specialists, were sent to tens of thousands of doctors. The marketing of OxyContin relied on an empirical circularity: the company convinced doctors of the drug’s safety

²⁸⁰ *Empire of Pain*, *supra* n. 112.

²⁸¹ *Id.*

²⁸² *Id.*

with literature that had been produced by doctors who were paid, or funded, by the company.”²⁸³

Purdue encouraged sales representatives to increase sales of OxyContin through a lucrative bonus system, which resulted in a large number of visits to physicians with high rates of opioid prescriptions. In 2001, Purdue paid \$40 million in bonuses to its sales representatives.²⁸⁴

Purdue claimed that the risk of addiction from OxyContin was extremely small and trained its sales representatives to carry the message that the risk of addiction was “less than one percent,” while knowing that there was no empirical support for that statement.

By 2003, the Drug Enforcement Administration had found that Purdue’s “aggressive methods” had “very much exacerbated OxyContin’s widespread abuse.” Rogelio Guevara, a senior official at the D.E.A., concluded that Purdue had “deliberately minimized” the risks associated with the drug.²⁸⁵

381. “From 1996 to 2001, Purdue conducted more than 40 national pain-management and speaker training conferences at resorts in Florida, Arizona, and California. More than 5000 physicians, pharmacists, and nurses attended these all-expenses-paid symposia, where they were recruited and trained for Purdue’s national speaker bureau. It is well documented that this type of pharmaceutical company symposium influences physicians’ prescribing even though the physicians who attend such symposia believe that such enticements do not alter their prescribing patterns.”²⁸⁶

²⁸³ *Id.*

²⁸⁴ *Commercial Triumph*, *supra* n. 276.

²⁸⁵ *Empire of Pain*, *supra* n. 112.

²⁸⁶ *Commercial Triumph*, *supra* n. 276.

382. As noted above, Purdue utilized Front Groups to help disseminate and defend its false messages. Between January 2012 and March 2017, Purdue made the following contributions:

Academy of Integrative Pain Management	\$1,091,024.86
American Academy of Pain Management	\$725,584.95
ACS Cancer Action Network	\$168,500.00 ²⁸⁷
American Chronic Pain Association	\$312,470.00
American Geriatrics Society	\$11,785.00 ²⁸⁸
American Pain Foundation	\$25,000
American Pain Society	\$542,259.52
American Society of Pain Educators	\$30,000
American Society of Pain Management Nursing	\$242,535.00
The Center for Practical Bioethics	\$145,095.00
U.S. Pain Foundation	\$359,300.00
Washington Legal Foundation	\$500,000.00
TOTAL	\$4,153,554.33

²⁸⁷ Payments from Purdue to the American Cancer Society Cancer Action Network include payments to the American Cancer Society that could potentially have applied to the Cancer Action Network. Production from Purdue Pharma to the Senate Homeland Security and Governmental Affairs Committee (Nov. 13, 2017).

²⁸⁸ The AGS reported that Purdue also provided \$40,000 in “corporate roundtable dues” to its AGS Health in Aging Foundation, a 501(c)(3) organization affiliated with the group, between 2012 and 2015. Letter from Nancy E. Lundebjerg, Chief Executive Office, American Geriatrics Society, to Sen. Claire McCaskill (Oct. 11, 2017).

383. The Purdue Individual Co-Conspirators reinforced Purdue's sales visits with dozens of other deceptive tactics aimed at Kentucky. The Purdue Individual Co-Conspirators wrote deceptive pamphlets and mailed them to doctors in Kentucky. The Purdue Individual Co-Conspirators used all these deceptive tactics to collect money in Kentucky, by getting more Kentucky patients on opioids, at higher doses, for longer periods of time.

384. Purdue streamed videos to Kentucky doctors on its OxyContin Physicians Television Network. Purdue hired the most prolific opioid prescribers in Kentucky as spokesmen to promote its drugs to other doctors.

385. Purdue promoted its opioids to Kentucky patients with marketing that was designed to obscure the risk of addiction and even the fact that Purdue was behind the campaign.

B. Endo

386. Defendant Endo made and/or disseminated deceptive statements, and concealed material facts in such a way to make their statements deceptive, including, but not limited to, the following:

Creating, sponsoring, and assisting in the distribution of patient education materials that contained deceptive statements;

Creating and disseminating advertisements that contained deceptive statements concerning the ability of opioids to improve function long-term and concerning the evidence supporting the efficacy of opioids long-term for the treatment of chronic non-cancer pain;

Creating and disseminating paid advertisement supplements in academic journals promoting chronic opioid therapy as safe and effective for long term use for high risk patients;

Creating and disseminating advertisements that falsely and inaccurately conveyed the impression that Endo's opioids would provide a reduction in oral, intranasal, or intravenous abuse;

Disseminating misleading statements concealing the true risk of addiction and promoting the misleading concept of pseudoaddiction through Endo's own unbranded publications and on internet sites Endo sponsored or operated;

Endorsing, directly distributing, and assisting in the distribution of publications that presented an unbalanced treatment of the long-term and dose-dependent risks of opioids versus NSAIDs;

Providing significant financial support to pro-opioid KOLs, who made deceptive statements concerning the use of opioids to treat chronic non-cancer pain;

Providing needed financial support to pro-opioid pain organizations – including over \$5 million to the organization responsible for many of the most egregious misrepresentations – that made deceptive statements, including in patient education materials, concerning the use of opioids to treat chronic non-cancer pain;

Targeting the elderly by assisting in the distribution of guidelines that contained deceptive statements concerning the use of opioids to treat chronic non-cancer pain and misrepresented the risks of opioid addiction in this population;

Endorsing and assisting in the distribution of CMEs containing deceptive statements concerning the use of opioids to treat chronic non-cancer pain;

Developing and disseminating scientific studies that deceptively concluded opioids are safe and effective for the long-term treatment of chronic non-cancer pain and that opioids improve quality of life, while concealing contrary data;

Directly distributing and assisting in the dissemination of literature written by pro- opioid KOLs that contained deceptive statements concerning the use of opioids to treat chronic non-cancer pain, including the concept of pseudoaddiction;

Creating, endorsing, and supporting the distribution of patient and prescriber education materials that misrepresented the data regarding the safety and efficacy of opioids for the long-term treatment of chronic non-cancer pain, including known rates of abuse and addiction and the lack of validation for long-term efficacy; and

Making deceptive statements concerning the use of opioids to treat chronic non- cancer pain to prescribers through in-person detailing.

C. Janssen

387. Defendant Janssen made and/or disseminated deceptive statements, and concealed material facts in such a way to make their statements deceptive, including, but not limited to, the following:

- a. Creating, sponsoring, and assisting in the distribution of patient education materials that contained deceptive statements;
- b. Directly disseminating deceptive statements through internet sites over which Janssen exercised final editorial control and approval stating that opioids are safe and effective for the long-term treatment of chronic non-cancer pain and that opioids improve quality of life, while concealing contrary data;
- c. Disseminating deceptive statements concealing the true risk of addiction and promoting the deceptive concept of pseudoaddiction through internet sites over which Janssen exercised final editorial control and approval;
- d. Promoting opioids for the treatment of conditions for which Janssen knew, due to the scientific studies it conducted, that opioids were not efficacious and concealing this information;
- e. Sponsoring, directly distributing, and assisting in the dissemination of patient education publications over which Janssen exercised final editorial control and approval, which presented an unbalanced treatment of the long-term and dose dependent risks of opioids versus NSAIDs;
- f. Providing significant financial support to pro-opioid KOLs, who made deceptive statements concerning the use of opioids to treat chronic non-cancer pain;
- g. Providing necessary financial support to pro-opioid pain organizations that made deceptive statements, including in patient education materials, concerning the use of opioids to treat chronic non-cancer pain;
- h. Targeting the elderly by assisting in the distribution of guidelines that contained deceptive statements concerning the use of opioids

to treat chronic non-cancer pain and misrepresented the risks of opioid addiction in this population;

- i. Targeting the elderly by sponsoring, directly distributing, and assisting in the dissemination of patient education publications targeting this population that contained deceptive statements about the risks of addiction and the adverse effects of opioids, and made false statements that opioids are safe and effective for the long-term treatment of chronic non-cancer pain and improve quality of life, while concealing contrary data;
- j. Endorsing and assisting in the distribution of CMEs containing deceptive statements concerning the use of opioids to treat chronic non-cancer pain;
- k. Directly distributing and assisting in the dissemination of literature written by pro-opioid KOLs that contained deceptive statements concerning the use of opioids to treat chronic non-cancer pain, including the concept of pseudoaddiction;
- l. Creating, endorsing, and supporting the distribution of patient and prescriber education materials that misrepresented the data regarding the safety and efficacy of opioids for the long-term treatment of chronic non-cancer pain, including known rates of abuse and addiction and the lack of validation for long-term efficacy;
- m. Targeting veterans by sponsoring and disseminating patient education marketing materials that contained deceptive statements concerning the use of opioids to treat chronic non-cancer pain; and
- n. Making deceptive statements concerning the use of opioids to treat chronic non- cancer pain to prescribers through in-person detailing.

D. Assertio

388. Defendant Assertio has, since at least October 2011, made and/or disseminated untrue, false and deceptive statements, and concealed material facts in such a way to make their statements deceptive with respect to Lazanda and (with the acquisition from Janssen in January 2015) of Nucynta and Nucynta ER, including, but not limited to:

- a. Promoting the usage of Lazanda with patients not suffering from cancer;
- b. Endorsing, supporting, and pressuring its sales representative to target

pain management physicians, particularly those who historically wrote large numbers of Lazanda-like drugs;

- c. Discouraging sales representatives from promoting sales of Lazanda to cancer patients against the FDA instruction that Lazanda is only indicated “for the management of breakthrough pain in cancer patients 18 years of age and older who are already receiving and who are tolerant to opioid therapy for their underlying persistent cancer pain;”
- d. Training of sales representatives on how to deal with pushback from physicians;
- e. Promoting of Nucynta and Nucynta ER for all manner of pain management while downplaying the drug’s addictive nature;
- f. Promoting its drugs as a safer alternative than other opioids;
- g. Telling investors that Depomed is safe. August Moretti, Assertio’s Senior Vice President and Chief Financial Officer, stated that “[a]lthough not in the label, there’s a very low abuse profile and side effect rate.”

E. Cephalon

389. Defendant Cephalon made and/or disseminated untrue, false and deceptive statements, and concealed material facts in such a way to make their statements deceptive, including, but not limited to, the following:

- a. Creating, sponsoring, and assisting in the distribution of patient education materials that contained deceptive statements;
- b. Sponsoring and assisting in the distribution of publications that promoted the deceptive concept of pseudoaddiction, even for high-risk patients;
- c. Providing significant financial support to pro-opioid KOL doctors who made deceptive statements concerning the use of opioids to treat chronic non-cancer pain and breakthrough chronic non-cancer pain;
- d. Developing and disseminating scientific studies that deceptively concluded opioids are safe and effective for the long-term treatment of chronic non-cancer pain in conjunction with Cephalon’s potent rapid-onset opioids;

- e. Providing needed financial support to pro-opioid pain organizations that made deceptive statements, including in patient education materials, concerning the use of opioids to treat chronic non-cancer pain;
- f. Endorsing and assisting in the distribution of CMEs containing deceptive statements concerning the use of opioids to treat chronic non-cancer pain;
- g. Endorsing and assisting in the distribution of CMEs containing deceptive statements concerning the use of Cephalon's rapid-onset opioids;
- h. Directing its marketing of Cephalon's rapid-onset opioids to a wide range of doctors, including general practitioners, neurologists, sports medicine specialists, and workers' compensation programs, serving chronic pain patients;
- i. Making deceptive statements concerning the use of Cephalon's opioids to treat chronic non-cancer pain to prescribers through in-person detailing and speakers' bureau events, when such uses are unapproved and unsafe; and
- j. Making deceptive statements concerning the use of opioids to treat chronic non- cancer pain to prescribers through in-person detailing and speakers' bureau events.

F. Actavis

390. Defendant Actavis made and/or disseminated deceptive statements, and concealed material facts in such a way to make their statements deceptive, including, but not limited to, the following:

- a. Making deceptive statements concerning the use of opioids to treat chronic non- cancer pain to prescribers through in-person detailing;
- b. Creating and disseminating advertisements that contained deceptive statements that opioids are safe and effective for the long-term treatment of chronic non-cancer pain and that opioids improve quality of life;
- c. Creating and disseminating advertisements that concealed the risk of addiction in the long-term treatment of chronic, non-cancer pain; and

- d. Developing and disseminating scientific studies that deceptively concluded opioids are safe and effective for the long-term treatment of chronic non-cancer pain and that opioids improve quality of life while concealing contrary data.

391. A Kadian prescriber guide deceptively represents that Kadian is more difficult to abuse and less addictive than other opioids. Kadian's prescriber guide is full of disclaimers that Actavis has not done any studies on the topic and that the guide is "only intended to assist you in forming your own conclusion." However, the guide includes the following statements: 1) "unique pharmaceutical formulation of KADIAN may offer some protection from extraction of morphine sulfate for intravenous use by illicit users," and 2) "KADIAN may be less likely to be abused by health care providers and illicit users" because of "Slow onset of action," "Lower peak plasma morphine levels than equivalent doses of other formulations of morphine," "Long duration of action," and "Minimal fluctuations in peak to trough plasma levels of morphine at steady state." The guide is copyrighted by Actavis in 2007, before Actavis officially purchased Kadian from Alpharma.

G. Mallinckrodt

392. Defendant Mallinckrodt made and/or disseminated deceptive statements, and concealed material facts in such a way to make their statements deceptive, including, but not limited to, the following:

393. Creating and promoting publications that misrepresented and trivialized the risks of addiction;

394. Creating and promoting publications that overstated the benefits of opioids for chronic pain; and

395. Making deceptive statements about pseudoaddiction.

IX. DEFENDANTS THROUGHOUT THE SUPPLY CHAIN DELIBERATELY DISREGARDED THEIR DUTIES TO MAINTAIN EFFECTIVE CONTROLS

AND TO IDENTIFY, REPORT, AND TAKE STEPS TO HALT SUSPICIOUS ORDERS

396. The Marketing Defendants and Purdue created a vastly and dangerously larger market for opioids. All of the Defendants compounded this harm by facilitating the supply of far more opioids than could have been justified to serve that market. The failure of the Defendants to maintain effective controls, and to investigate, report, and take steps to halt orders that they knew or should have known were suspicious breached both their statutory and common law duties.

397. Marketing Defendants' and Purdue's scheme was resoundingly successful. Chronic opioid therapy—the prescribing of opioids long-term to treat chronic pain—has become a commonplace, and often first-line, treatment. Marketing Defendants' and Purdue's deceptive marketing caused prescribing not only of their opioids, but also of opioids as a class, to skyrocket. According to the CDC opioid prescriptions, as measured by number of prescriptions and MME per person, tripled from 1999 to 2015. In 2015, on an average day, more than 650,000 opioid prescriptions were dispensed in the U.S. While previously a small minority of opioid sales, today between 80% and 90% of opioids (measured by weight) used are for chronic pain. Approximately 20% of the population between the ages of 30 and 44, and nearly 30% of the population over 45, have used opioids.

398. 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.”²⁸⁹ Patients receiving opioid prescriptions for chronic pain account for the majority of overdoses. For these

²⁸⁹ Centers for Disease Control and Prevention, Increases in Drug and Opioids Overdose Deaths — United States, 2000–2014, 64(50); 1378–82, Morbidity and Mortality Weekly Report (Jan. 2016), *available at* <https://www.cdc.gov/mmwr/preview/mmwrhtml/mm6450a3.htm>.

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.”²⁹⁰

X. **ALL DEFENDANTS HAVE, AND BREACHED, DUTIES TO GUARD AGAINST, AND REPORT, UNLAWFUL DIVERSION AND TO REPORT AND PREVENT SUSPICIOUS ORDERS**

399. Multiple sources impose duties on Defendants with respect to the supply of opioids, including the common law duty to exercise reasonable care. Each Defendant was also required to obtain a license from Kentucky’s Board of Pharmacy, and certify compliance with Kentucky law. The Defendants also had legal duties under Kentucky common law, statutes, and regulations to maintain adequate records, and prevent diversion, and to monitor, report, and prevent suspicious orders of prescription opioids. This includes the common law of fraud, statutes designed to generally prohibit unfair and deceptive acts in commerce, as well as statutes specifically prohibiting deceptive practice relating to drugs.

400. Each Defendant was required to register with the Commonwealth of Kentucky. 201 KAR 2:320, 2:105; KRS § 315.005.

401. The Defendants also had legal duties to prevent diversion, and to monitor, report, and prevent suspicious orders of prescription opioids under Kentucky law.

402. Pursuant to KRS § 218A.170(8), Defendants must adhere to Kentucky’s controlled substances law in the sale of controlled substances. See KRS § 218A.170(8) (“All sales and distributions shall be in accordance with KRS § 218A.200 and the federal controlled substances laws, including the requirements governing the use of order forms.”). Thus, all

²⁹⁰ *Id.*

Defendants have a duty to report suspicious orders in order to prevent diversion.²⁹¹ Pharmacies are required to ensure that opioid prescriptions they fill are written for a legitimate patient for a legitimate medical need. See KRS § 218A.180(3)(a) (“[T]o be valid, a prescription for a controlled substance shall be issued only for a legitimate medical purpose by a practitioner acting in the usual course of his professional practice[.]”).

403. Further, “[m]anufacturers and wholesalers shall keep records of all controlled substances compounded, mixed, cultivated, grown, or by any other process produced or prepared, and of all controlled substances received and disposed of by them.” KRS § 218A.200(2). “The record of controlled substances received shall in every case show the date of receipt, the name and address of the person from whom received, and the kind and quantity of drugs received. The record of all controlled substances sold, administered, dispensed, or otherwise disposed of, shall show the date of selling, administering, or dispensing, the name and address of the person to whom, or for whose use, or the owner and species of animal for which the drugs were sold, administered, or dispensed, and the kind and quantity” KRS § 218A.200(4).

404. Each Defendant’s actions were in violation of Chapter 218A of the Kentucky Revised Statutes, as set out above, and also including § 218A.1404(3), which forbids unlawful distribution of controlled substances; § 218A.1404(1), which forbids the trafficking of controlled substances; and, KRS §§ 506.040, and 218A.1402, which forbid criminal drug conspiracies; and

²⁹¹ Federal requirements impose a non-delegable duty upon registrants to design and operate a system to disclose to the registrant suspicious orders of controlled substances. “The registrant shall design and operate a system to disclose to the registrant suspicious orders of controlled substances. The registrant shall inform the Field Division Office of the Administration in his area of suspicious orders when discovered by the registrant. Suspicious orders include orders of unusual size, orders deviating substantially from a normal pattern, and orders of unusual frequency.” 21 C.F.R. § 1301.74(b).

KRS § 218A.1405, which forbids receipt of income from trafficking and utilizing that income to operate a commercial enterprise.

405. In addition to reporting all suspicious orders, the Supply Chain Defendants must also stop shipment on any order which is flagged as suspicious and only ship orders which were flagged as potentially suspicious if, after conducting due diligence, the recipient can determine that the order is not likely to be diverted into illegal channels. *See Southwood Pharm., Inc.*, 72 Fed. Reg. 36,487, 36,501 (Drug Enf't Admin. July 3, 2007); *Masters Pharmaceutical, Inc. v. Drug Enforcement Administration*, 861 F. 3d 206 (D.C. 2017). Regardless, all flagged orders must be reported.

406. These prescription drugs are regulated for the purpose of providing a “closed” system intended to reduce the widespread diversion of these drugs out of legitimate channels into the illicit market, while at the same time providing the legitimate drug industry with a unified approach to narcotic and dangerous drug control.²⁹²

²⁹² See 1970 U.S.C.C.A.N. 4566, 4571-72.

407. “Different entities supervise the discrete links in the chain that separate a consumer from a controlled substance. Statutes and regulations define each participant’s role and responsibilities.”²⁹³

408. The foreseeable harm resulting from a breach of these duties is the diversion of prescription opioids for nonmedical purposes and subsequent plague of opioid addiction, with costs and damages necessarily inflicted on and incurred by Plaintiffs and others.

409. The foreseeable harm resulting from the diversion of prescription opioids for nonmedical purposes is abuse, addiction, morbidity and mortality, along with the costs imposed upon Plaintiffs and others associated with the treatment of these conditions and related health consequences caused by opioid abuse.

410. Finding it impossible to legally achieve their ever-increasing sales ambitions, Defendants engaged in the common purpose of increasing the supply of opioids and fraudulently increasing the quotas that governed the manufacture and distribution of their prescription opioids.

411. Wholesale distributors such as Supply Chain Defendants had close financial relationships with Marketing Defendants, Purdue, and customers, for whom they provide a broad

²⁹³ Brief for Healthcare Distribution Mgmt. Association and National Ass’n of Chain Drug Stores as Amici Curiae in Support of Neither Party, *Masters Pharm., Inc. v. U.S. Drug Enf’t Admin.* (No. 15-1335) (D.C. Cir. Apr. 4, 2016), 2016 WL 1321983, at *22 (“Brief for HDMA and NACDS”). The Healthcare Distribution Mgmt. Ass’n (HDMA or HMA)—now known as the Healthcare Distribution Alliance (HDA)—is a national, not-for-profit trade association that represents the nation’s primary, full-service healthcare distributors whose membership includes, among others: AmerisourceBergen Drug Corporation and Cardinal Health, Inc. *See generally*, HDA, *About*, available at <https://www.healthcaredistribution.org/about> (last accessed Aug. 1, 2018). The National Association of Chain Drug Stores (NACDS) is a national, not-for-profit trade association that represents traditional drug stores and supermarkets and mass merchants with pharmacies whose membership includes, among others: Walgreen Company, CVS Health, Rite Aid Corporation and Walmart. *See generally* NACDS, *Mission*, available at <https://www.nacds.org/%20about/mission/> (last accessed Aug. 1, 2018).

range of value-added services that render them uniquely positioned to obtain information and control against diversion. These services often otherwise would not be provided by manufacturers to their dispensing customers and would be difficult and costly for the dispenser to reproduce. For example, “[w]holesalers have sophisticated ordering systems that allow customers to electronically order and confirm their purchases, as well as to confirm the availability and prices of wholesalers’ stock.” *Fed. Trade Comm’n v. Cardinal Health, Inc.*, 12 Supp. 2d 34, 41 (D.D.C. 1998). Through their generic source programs, wholesalers are also able “to combine the purchase volumes of customers and negotiate the cost of goods with manufacturers.” Wholesalers typically also offer marketing programs, patient services, and other software to assist their dispensing customers.

412. Distributor Defendants had financial incentives from the Marketing Defendants and Purdue to distribute higher volumes and thus to refrain from reporting or declining to fill suspicious orders. Wholesale drug distributors acquire pharmaceuticals, including opioids, from manufacturers at an established wholesale acquisition cost. Discounts and rebates from this cost may be offered by manufacturers based on market share and volume. As a result, higher volumes may decrease the cost per pill to distributors. Decreased cost per pill in turn, allows wholesale distributors to offer more competitive prices, or alternatively, pocket the difference as additional profit. Either way, the increased sales volumes result in increased profits.

413. The Marketing Defendants and Purdue engaged in the practice of paying rebates and/or chargebacks to the Distributor Defendants for sales of prescription opioids as a way to help them boost sales and better target their marketing efforts. The Washington Post has described the practice as industry-wide, and the Healthcare Distribution Alliance (“HDA”) includes a “Contracts and Chargebacks Working Group,” suggesting a standard practice.

414. Further, in a recent settlement with the DEA, Mallinckrodt acknowledged that “[a]s part of their business model Mallinckrodt collects transaction information, referred to as chargeback data, from their direct customers (distributors).” The transaction information contains data relating to the direct customer sales of controlled substances to “downstream registrants”, meaning pharmacies or other dispensaries, such as hospitals. Marketing Defendants and Purdue buy data from pharmacies as well. This exchange of information, upon information and belief, would have opened channels providing for the exchange of information revealing suspicious orders as well.

415. A dramatic example of the use of prescription information provided by IMS Health was described in Congressional testimony:

Mr. Greenwood: Well, why do you want that [IMS Health] information then?

Mr. Friedman: Well, we use that information to understand what is happening in terms of the development of use of our product in any area.

Mr. Greenwood. And so the use of it--and I assume that part of it--a large part of it you want is to see how successful your marketing techniques are so that you can expend money in a particular region or among a particular group of physicians-- you look to see if your marketing practices are increased in sales. And, if not, you go back to the drawing board with your marketers and say, how come we spent “X” number of dollars, according to these physicians, and sales haven't responded. You do that kind of thing. Right?

Mr. Friedman: Sure.²⁹⁴

416. The contractual relationships among the Defendants also include vault security programs. Defendants are required to maintain certain security protocols and storage facilities for the manufacture and distribution of their opiates. The Defendants negotiated agreements

²⁹⁴ *Oxycontin: Its Use and Abuse*, *supra* n. 123.

whereby the Marketing Defendants and Purdue installed security vaults for the Distributor Defendants in exchange for agreements to maintain minimum sales performance thresholds. These agreements were used by the Defendants as a tool to violate their reporting and diversion duties in order to reach the required sales requirements.

417. Under the common law, Defendants had a duty to exercise reasonable care in manufacturing and distributing dangerous narcotic substances. National Pharmacies further had a duty to exercise reasonable care in supervising the sale of such drugs. By flooding Kentucky with opioids and failing to effectively prevent diversion, including failing to monitor for red flags, Defendants breached their duties. By filling and failing to report or halt orders that they knew or should have realized were likely being diverted for illicit uses, Supply Chain Defendants further breached their duties. These breaches by Defendants both created and failed to prevent a foreseeable risk of harm to the Plaintiffs.

418. Defendants also assumed a duty, when speaking publicly about opioids and their efforts and commitment to combat diversion of prescription opioids, to speak accurately and truthfully. They breached the duty by making inaccurate or untruthful statements on their efforts to combat diversion. They also breached the duty by misrepresenting the efficacy of opioids, as stated in this complaint.

A. Defendants' Use of Trade and Other Organizations

419. In addition, Defendants worked together to achieve their common purpose through trade or other organizations, such as the Pain Care Forum ("PCF") and the HDA.

1. Pain Care Forum

420. PCF has been described as a coalition of drug makers, trade groups and dozens of non-profit organizations supported by industry funding, including the Front Groups described in this Complaint. The PCF recently became a national news story when it was discovered that

lobbyists for members of the PCF quietly shaped federal and state policies regarding the use of prescription opioids for more than a decade.

421. The Center for Public Integrity and The Associated Press obtained “internal documents shed[ding] new light on how drug makers and their allies shaped the national response to the ongoing wave of prescription opioid abuse.”²⁹⁵ Specifically, PCF members spent over \$740 million lobbying in the nation’s capital and in all 50 statehouses on an array of issues, including opioid-related measures.²⁹⁶

422. The Defendants who stood to profit from expanded prescription opioid use are members of and/or participants in the PCF.²⁹⁷ In 2012, membership and participating organizations included Endo, Purdue, Actavis and Cephalon. Each of the Marketing Defendants and Purdue worked together through the PCF. But the Marketing Defendants and Purdue were not alone. The Distributor Defendants actively participated, and continue to participate, in the PCF through, at a minimum, their trade organization, the HDA.²⁹⁸ The Distributor Defendants participated directly in the PCF as well.

²⁹⁵ Matthew Perrone, *Pro-Painkiller echo chamber shaped policy amid drug epidemic*, The Center for Public Integrity (Sept. 19, 2017, 12:01 a.m.), available at <https://www.publicintegrity.org/2016/09/19/20201/pro-painkiller-echo-chamber-shaped-policy-amid-drug-epidemic> (emphasis added).

²⁹⁶ *Id.*

²⁹⁷ *PAIN CARE FORUM 2012 Meetings Schedule*, (last updated Dec. 2011), available at <https://assets.documentcloud.org/documents/3108982/PAIN-CARE-FORUM-Meetings-Schedule-amp.pdf>.

²⁹⁸ *Id.* The Executive Committee of the HDA (formerly the HDMA) currently includes the Chief Executive Officer, Pharmaceutical Segment for Cardinal Health, Inc. and the Group President, Pharmaceutical Distribution and Strategic Global Source for AmerisourceBergen Corporation. *Executive Committee*, Healthcare Distribution Alliance (last accessed on Aug. 1, 2018), available at <https://www.healthcaredistribution.org/about/executive-committee%20>.

2. Healthcare Distribution Alliance (“HDA”)

423. Additionally, the HDA led to the formation of interpersonal relationships and an organization among the Defendants. Although the entire HDA membership directory is private, the HDA website confirms that each of the Distributor Defendants and the Marketing Defendants, including Actavis, Endo, Purdue, Mallinckrodt, Cephalon, and Purdue were members of the HDA.²⁹⁹ Additionally, the HDA and each of the Distributor Defendants, eagerly sought the active membership and participation of the Marketing Defendants and Purdue by advocating for the many benefits of members, including “strengthening . . . alliances.”³⁰⁰

424. Beyond strengthening alliances, the benefits of HDA membership included the ability to, among other things, “network one on one with manufacturer executives at HDA’s members-only Business and Leadership Conference,” “networking with HDA wholesale distributor members,” “opportunities to host and sponsor HDA Board of Directors events,” “participate on HDA committees, task forces and working groups with peers and trading partners,” and “make connections.”³⁰¹ The HDA and the Distributor Defendants used membership in the HDA as an opportunity to create interpersonal and ongoing organizational relationships and “alliances” between the Marketing and Distributor Defendants.

425. The application for manufacturer membership in the HDA further indicates the level of connection among the Defendants and the level of insight that they had into each other’s

²⁹⁹ *Manufacturer Membership*, Healthcare Distribution Alliance, available at <https://www.healthcaredistribution.org/about/membership/manufacturer> (last accessed Aug. 1, 2018).

³⁰⁰ *Id.*

³⁰¹ *Id.*

businesses.³⁰² For example, the manufacturer membership application must be signed by a “senior company executive,” and it requests that the manufacturer applicant identify a key contact and any additional contacts from within its company.

426. The HDA application also requests that the manufacturer identify its current distribution information, including the facility name and contact information. Manufacturer members were also asked to identify their “most recent year end net sales” through wholesale distributors, including the Distributor Defendants AmerisourceBergen, Anda, Cardinal, and Henry Schein and their subsidiaries.

427. The closed meetings of the HDA’s councils, committees, task forces and working groups provided the Marketing and Distributor Defendants with the opportunity to work closely together, confidentially, to develop and further the common purpose and interests of the enterprise.

428. The HDA also offers a multitude of conferences, including annual business and leadership conferences. The HDA and the Distributor Defendants advertise these conferences to the Marketing Defendants and Purdue as an opportunity to “bring together high-level executives, thought leaders and influential managers . . . to hold strategic business discussions on the most pressing industry issues.”³⁰³ The conferences also gave the Marketing and Distributor Defendants “unmatched opportunities to network with [their] peers and trading partners at all

³⁰² *Id.*

³⁰³ *Business and Leadership Conference – Information for Manufacturers*, Healthcare Distribution Alliance, available at <https://www.healthcaredistribution.org/events/2015-business-and-leadership-conference/blc-for-manufacturers> (last accessed Aug. 1, 2018, and no longer available).

levels of the healthcare distribution industry.”³⁰⁴ The HDA and its conferences were significant opportunities for the Marketing and Distributor Defendants to interact at a high-level of leadership. The Marketing Defendants and Purdue embraced this opportunity by attending and sponsoring these events.³⁰⁵

429. After becoming members of the HDA, Defendants were eligible to participate on councils, committees, task forces and working groups, including:

- a. Industry Relations Council: “This council, composed of distributor and manufacturer members, provides leadership on pharmaceutical distribution and supply chain issues.”
- b. Business Technology Committee: “This committee provides guidance to HDA and its members through the development of collaborative e-commerce business solutions. The committee’s major areas of focus within pharmaceutical distribution include information systems, operational integration and the impact of e-commerce.” Participation in this committee includes distributor and manufacturer members.
- c. Logistics Operation Committee: “This committee initiates projects designed to help members enhance the productivity, efficiency and customer satisfaction within the healthcare supply chain. Its major areas of focus include process automation, information systems, operational integration, resource management and quality improvement.” Participation in this committee includes distributor and manufacturer members.
- d. Manufacturer Government Affairs Advisory Committee: “This committee provides a forum for briefing HDA’s manufacturer members on federal and state legislative and regulatory activity affecting the pharmaceutical distribution channel. Topics discussed include such issues as prescription drug traceability, distributor licensing, FDA and DEA regulation of distribution, importation and Medicaid/Medicare reimbursement.” Participation in this committee includes manufacturer members.

³⁰⁴ *Id.*

³⁰⁵ *2015 Distribution Management Conference and Expo*, Healthcare Distribution Alliance, available at <https://www.healthcaredistribution.org/events/2015-distribution-management-conference> (last accessed Aug. 1, 2018).

- e. Contracts and Chargebacks Working Group: “This working group explores how the contract administration process can be streamlined through process improvements or technical efficiencies. It also creates and exchanges industry knowledge of interest to contract and chargeback professionals.” Participation in this group includes manufacturer and distributor members.

430. The Distributor Defendants, Marketing Defendants, and Purdue also participated, through the HDA, in Webinars and other meetings designed to exchange detailed information regarding their prescription opioid sales, including purchase orders, acknowledgements, ship notices, and invoices.³⁰⁶ For example, on April 27, 2011, the HDA offered a Webinar to “accurately and effectively exchange business transactions between distributors and manufacturers...” The Marketing Defendants and Purdue used this information to gather high-level data regarding overall distribution and to direct the Distributor Defendants on how to most effectively sell prescription opioids.

431. Taken together, the interaction and length of the relationships between and among the Marketing and Distributor Defendants reflect a deep level of interaction and cooperation between two groups in a tightly knit industry. The Marketing and Distributor Defendants were not two separate groups operating in isolation or two groups forced to work together in a closed system. Defendants operated together as a united entity, working together on multiple fronts, to engage in the unlawful sale of prescription opioids.

432. The HDA and the Pain Care Forum are but two examples of the overlapping relationships and concerted joint efforts to accomplish common goals and demonstrates that the leaders of each of the Defendants were in communication and cooperation.

³⁰⁶ *Webinars*, Healthcare Distribution Alliance, (last accessed on Sept. 14, 2017), *available at* <https://www.healthcaredistribution.org/resources/webinar-leveraging-edl>.

433. Publications and guidelines issued by the HDA confirm that the Defendants utilized their membership in the HDA to form agreements. Specifically, in the fall of 2008, the HDA published the *Industry Compliance Guidelines: Reporting Suspicious Orders and Preventing Diversion of Controlled Substances* (the “Industry Compliance Guidelines”) regarding diversion. As the HDA explained in an amicus brief, the Industry Compliance Guidelines were the result of “[a] committee of HDMA members contribut[ing] to the development of this publication” beginning in late 2007.

434. This statement by the HDA and the Industry Compliance Guidelines support the allegation that Defendants utilized the HDA to form agreements about their approach to their legal duties with respect to the distribution of controlled substances. As John M. Gray, President/CEO of the HDA stated to the Energy and Commerce Subcommittee on Health in April 2014, it is “difficult to find the right balance between proactive anti-diversion efforts while not inadvertently limiting access to appropriately prescribed and dispensed medications.” Here, it is apparent that all of the Defendants found the same balance – an overwhelming pattern and practice of failing to identify, report or halt suspicious orders, and failure to prevent diversion. Discovery, including discovery of meeting minutes within the HDA, will further reveal that Defendants utilized the HDA to combat their legal duties and avoid compliance with the law and regulations.

435. The Defendants worked together to control the flow of information and to influence governments to pass legislation that supported the use of opioids and limited the authority of law enforcement to rein in illicit or inappropriate prescribing and distribution. The Marketing and Distributor Defendants did this through their participation in the PCF and HDA.

436. The Defendants also had obligations to report suspicious orders of other parties if they became aware of them. Defendants were thus collectively responsible for each other's compliance with their reporting obligations.

437. Defendants thus knew that their own conduct could be reported by other distributors or manufacturers and that their failure to report suspicious orders they filled could be revealed. As a result, Defendants had an incentive to communicate with each other about the reporting of suspicious orders to ensure consistency.

438. The desired consistency was achieved. As described below, none of the Defendants reported suspicious orders and the flow of opioids continued unimpeded.

B. Defendants Were Aware of and Have Acknowledged Their Obligations to Prevent Diversion and to Report and Take Steps to Halt Suspicious Orders

439. The reason for the reporting rules is to create a “closed” system intended to control the supply and reduce the diversion of these drugs out of legitimate channels into the illicit market, while at the same time providing the legitimate drug industry with a unified approach to narcotic and dangerous drug control. Both because distributors handle such large volumes of controlled substances, and because they are uniquely positioned, based on their knowledge of their customers and orders, as the first line of defense in the movement of legal pharmaceutical controlled substances from legitimate channels into the illicit market, distributors' obligation to maintain effective controls to prevent diversion of controlled substances is critical. Should a distributor deviate from these checks and balances, the closed system of distribution, designed to prevent diversion, collapses.³⁰⁷

³⁰⁷ See Rannazzisi Decl. ¶ 10, *Cardinal Health, Inc. v. Holder*, 1:12-cv-00185-RBW, Doc. No. 14-2 (D.D.C. Feb. 10, 2012).

440. Defendants were well aware they had an important role to play in this system, and also knew or should have known that their failure to comply with their obligations would have serious consequences.

C. **Defendants Kept Careful Track of Prescribing Data and Knew About Suspicious Orders and Prescribers**

441. The data that reveals and/or confirms the identity of each wrongful opioid distributor is hidden from public view in the DEA's Confidential Automation of Reports and Consolidated Orders System (ARCOS) database. The data necessary to identify with specificity the transactions that were suspicious is in possession of the Distributor Defendants, Marketing Defendants, and Purdue but has not been disclosed to the public.

442. Publicly available information confirms that Distributor Defendants, Marketing Defendants, and Purdue funneled far more opioids into Kentucky and communities across the United States than could have been expected to serve legitimate medical use and ignored other red flags of suspicious orders. This information, along with the information known only to Distributor Defendants, Marketing Defendants, and Purdue, would have alerted them to potentially suspicious orders of opioids.

443. This information includes the following facts:

- a. distributors and manufacturers have access to detailed transaction-level data on the sale and distribution of opioids, which can be broken down by zip code, prescriber, and pharmacy and includes the volume of opioids, dose, and the distribution of other controlled and non-controlled substances;
- b. manufacturers make use of that data to target their marketing and, for that purpose, regularly monitor the activity of doctors and pharmacies;
- c. manufacturers and distributors regularly visit pharmacies and doctors to promote and provide their products and services, which allows them to observe red flags of diversion;

- d. Distributor Defendants together account for approximately 90% of all revenues from prescription drug distribution in the United States, and each plays such a large part in the distribution of opioids that its own volume provides a ready vehicle for measuring the overall flow of opioids into a pharmacy or geographic area; and
- e. Marketing Defendants and Purdue purchased chargeback data (in return for discounts to Distributor Defendants) that allowed them to monitor the combined flow of opioids into a pharmacy or geographic area.

444. The conclusion that Defendants were on notice of the problems of abuse and diversion follows inescapably from the fact that they flooded communities with opioids in quantities that they knew or should have known exceeded any legitimate market for opioids-even the wider market for chronic pain.

445. At all relevant times, the Defendants were in possession of national, regional, state, and local prescriber-and patient-level data that allowed them to track prescribing patterns over time. They obtained this information from data companies, including but not limited to: IMS Health, QuintilesIMS, IQVIA, Pharmaceutical Data Services, Source Healthcare Analytics, NDS Health Information Services, Verispan, Quintiles, SDI Health, ArcLight, Scriptline, Wolters Kluwer, and/or PRA Health Science, and all of their predecessors or successors in interest (the “Data Vendors”).

446. The Distributor Defendants developed “know your customer” questionnaires and files. This information, compiled pursuant to comments from the DEA in 2006 and 2007, was intended to help the Defendants identify suspicious orders or customers who were likely to divert prescription opioids.³⁰⁸ The “know your customer” questionnaires informed the Defendants of

³⁰⁸ *Suggested Questions a Distributor should ask prior to shipping controlled substances, available at https://www.dea diversion.usdoj.gov/mtgs/pharm_industry/14th_pharm/levinl_ques.pdf; Richard Widup, Jr. & Kathleen H. Dooley, Esq. *Pharmaceutical Product Diversion: Beyond the PDMA*,*

the number of pills that the pharmacies sold, how many non-controlled substances were sold compared to controlled substances, whether the pharmacy purchased opioids from other distributors, and the types of medical providers in the area, including pain clinics, general practitioners, hospice facilities, cancer treatment facilities, and others. These questionnaires put the recipients on notice of suspicious orders.

447. Defendants purchased nationwide, regional, state, and local prescriber- and patient-level data from the Data Vendors that allowed them to track prescribing trends, identify suspicious orders, identify patients who were doctor shopping, identify pill mills, etc. The Data Vendors' information purchased by the Defendants allowed them to view, analyze, compute, and track their competitors' sales, and to compare and analyze market share information.³⁰⁹

448. IMS Health, for example, provided Defendants with reports detailing prescriber behavior and the number of prescriptions written between competing products.³¹⁰

449. Similarly, Wolters Kluwer, an entity that eventually owned data mining companies that were created by Cardinal (ArcLight), provided the Defendants with charts analyzing the weekly prescribing patterns of multiple physicians, organized by territory, regarding competing drugs, and analyzed the market share of those drugs.³¹¹

Purdue Pharma and McGuireWoods LLC, available at https://www.mcguirewoods.com/news-resources/publications/lifesciences/product_diversion_beyond_pdma.pdf.

³⁰⁹ A Verispan representative testified that the Distributor Defendants use the prescribing information to "drive market share." *Sorrell v. IMS Health Inc.*, No. 10-779, 2011 WL 661712, *9-10 (Feb. 22, 2011).

³¹⁰ Paul Kallukaran & Jerry Kagan, *Data Mining at IMS HEALTH: How we Turned a Mountain of Data into a Few Information-rich Molehills*, available at <http://citeseerx.ist.psu.edu/viewdoc/download?doi=10.1.1.198.349&rep=rep1&type=pdf>, Figure 2 at p. 3 (last accessed Aug. 1, 2018).

³¹¹ *Sorrell v. IMS Health Inc.*, No. 10-779, 2011 WL 705207, at *467-471 (Feb. 22, 2011).

450. This information allowed the Defendants to track and identify instances of overprescribing. In fact, one of the Data Vendors' experts testified that the Data Vendors' information could be used to track, identify, report and halt suspicious orders of controlled substances.³¹² Defendants were, therefore, collectively aware of the suspicious orders that flowed from their facilities.

451. Defendants refused to identify, investigate, and report suspicious orders to the DEA when they became aware of the same despite their actual knowledge of drug diversion rings. As described in detail below, Defendants refused to identify suspicious orders and diverted drugs despite the DEA issuing final decisions against the Distributor Defendants in 178 registrant actions between 2008 and 2012³¹³ and 117 recommended decisions in registrant actions from The Office of Administrative Law Judges. These numbers include 76 actions involving orders to show cause and 41 actions involving immediate suspension orders, all for failure to report suspicious orders.³¹⁴

452. Sales representatives were also aware that the prescription opioids they were promoting were being diverted, often with lethal consequences. As a sales representative wrote on a public forum:

³¹² In *Sorrell*, expert Eugene "Mick" Kolassa testified, on behalf of the Data Vender, that "a firm that sells narcotic analgesics was able to use prescriber-identifiable information to identify physicians that seemed to be prescribing an inordinately high number of prescriptions for their product." *Id.* See also Joint Appendix in *Sorrell v. IMS Health*, 2011 WL 687134, at *204 (Feb. 22, 2011).

³¹³ Evaluation and Inspections Div., Office of the Inspector Gen., U.S. Dep't of Justice, *The Drug Enforcement Administration's Adjudication of Registrant Actions* 6 (2014), available at <https://oig.justice.gov/reports/2014/e1403.pdf> ("The Drug Enforcement Administration's Adjudication of Registrant Actions").

³¹⁴ *Id.*

Actions have consequences - so some patient gets Rx'd the 80mg OxyContin when they probably could have done okay on the 20mg (but their doctor got "sold" on the 80mg) and their teen son/daughter/child's teen friend finds the pill bottle and takes out a few 80's... next they're at a pill party with other teens and some kid picks out a green pill from the bowl... they go to sleep and don't wake up (because they don't understand respiratory depression) Stupid decision for a teen to make...yes... but do they really deserve to die?

453. Moreover, Defendants' sales incentives rewarded sales representatives who happened to have pill mills within their territories, enticing those representatives to look the other way even when their in-person visits to such clinics should have raised numerous red flags. In one example, a pain clinic in South Carolina was diverting massive quantities of OxyContin. People traveled to the clinic from towns as far as 100 miles away to get prescriptions, the DEA's diversion unit raided the clinic, and prosecutors eventually filed criminal charges against the doctors. But Purdue's sales representative for that territory, Eric Wilson, continued to promote OxyContin sales at the clinic. He reportedly told another local physician that this clinic accounted for 40% of the OxyContin sales in his territory. At that time, Wilson was Purdue's top-ranked sales representative.³¹⁵ In response to news stories about this clinic, Purdue issued a statement, declaring that "if a doctor is intent on prescribing our medication inappropriately, such activity would continue regardless of whether we contacted the doctor or not."³¹⁶

454. In another example, a Purdue sales manager informed her supervisors in 2009 about a suspected pill mill in Los Angeles, reporting over email that when she visited the clinic with her sales representative, "it was packed with a line out the door, with people who looked

³¹⁵ *Pain Killer*, *supra* n. 109, at 298-300.

³¹⁶ *Id.*

like gang members,” and that she felt “very certain that this an organized drug ring[.]”³¹⁷ She wrote, “This is clearly diversion. Shouldn’t the DEA be contacted about this?” But her supervisor at Purdue responded that while they were “considering all angles,” it was “really up to [the wholesaler] to make the report.”³¹⁸ This pill mill was not only distributing opioids locally - over a million pills were transported to the City of Everett, Washington, a city of around 100,000 people. Couriers drove up I-5 through California and Oregon, or flew from Los Angeles to Seattle. The Everett-based dealer who received the pills from southern California wore a diamond necklace in the shape of the West Coast states with a trail of green gemstones—the color of 80-milligram OxyContin—connecting Los Angeles and Washington state. Purdue waited until after the clinic was shut down in 2010 to inform the authorities.

455. At Purdue, the Purdue Individual Co-Conspirators were well aware of the importance of prolific prescribers, which they and their staff referred to internally, at times, as “core,” “super core,” “high value” and “high potential” prescribers. In fact, it was an explicit, and significant, sales strategy to pay particular attention to actual and potential prolific prescribers, which the Purdue Individual Co-Conspirators understood to account for approximately 10% of overall revenues. At Purdue, Sackler Co-Conspirators and Purdue Officer Co-Conspirators were aware that Purdue regularly received “Reports of Concern” about abuse and diversion of opioids, as well as reports of other adverse events, and also calls to Purdue’s compliance “hotline.” In July 2007, staff told the Sackler Co-Conspirators and Purdue Officer Co-Conspirators that more than 5,000 cases of adverse events had been reported to

³¹⁷ Harriet Ryan, *et al.*, *More than 1 million OxyContin pills ended up in the hands of criminals and addicts. What the drug maker knew*, LOS ANGELES TIMES (July 10, 2016), available at <http://www.latimes.com/projects/la-me-oxycontin-part2/>.

³¹⁸ *Id.*

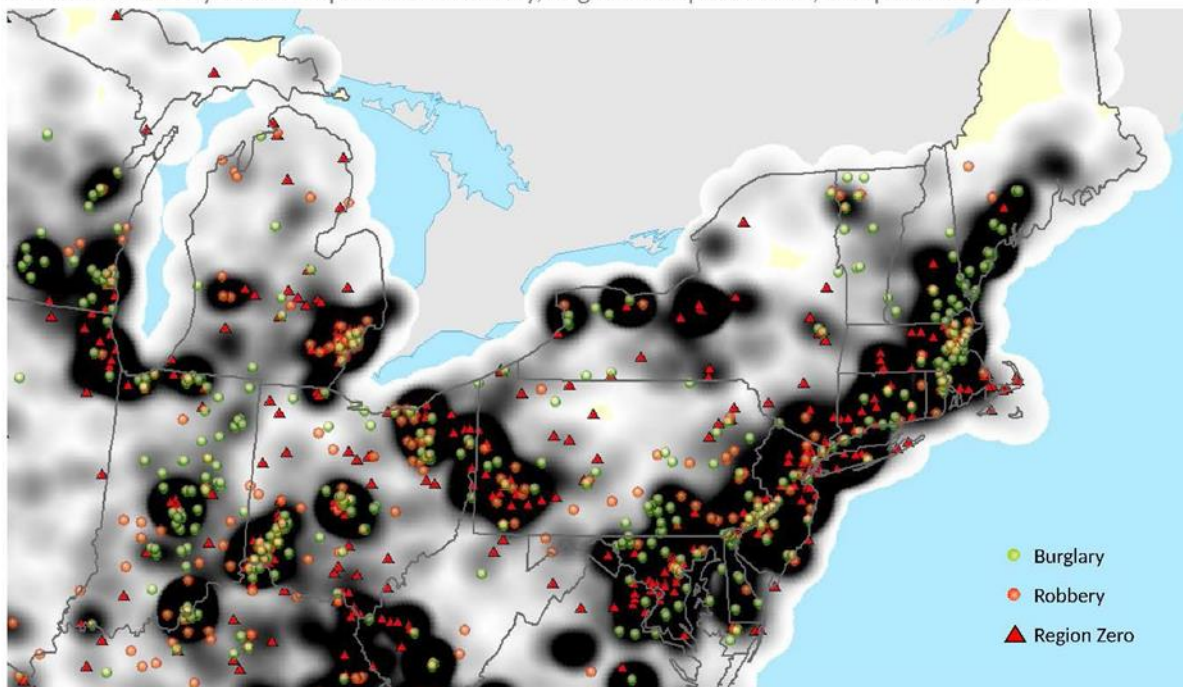
Purdue in just the first three months of 2007. Staff also told the Sackler Co-Conspirators and Purdue Officer Co-Conspirators that Purdue received 572 Reports of Concern about abuse and diversion of Purdue opioids during Q2 2007. Staff reported to the Sackler Co-Conspirators that they completed only 21 field inquiries in response. Staff also told the Sackler Co-Conspirators that they received more than 100 calls to Purdue's compliance hotline during the quarter, which was a "significant increase," but Purdue did not report any of the hotline calls or Reports of Concern to the FDA, DEA, Department of Justice, or state authorities. Purdue's self-interested failure to report abuse and diversion would continue, quarter after quarter, even though the 2007 Judgment required Purdue to report "potential abuse or diversion to appropriate medical, regulatory or law enforcement authorities." Instead of reporting dangerous prescribers, or even directing sales reps to stop visiting them, the Sackler Co-Conspirators chose to keep pushing opioids to whoever prescribed the most.

456. Purdue also tracked prescribers from whom there was a substantial possibility of opioids having been diverted, or, at a minimum, grossly over-prescribed. It described these prescribers as, collectively, "Region Zero," and even generated a map, given to members of the Board, correlating these prescribers with poison control calls and pharmacy thefts.

We are examining the spatial relationship between different aspects of the abuse environment

ILLUSTRATIVE

Poison Control oxycodone exposure call density, Region Zero prescribers, and pharmacy theft



SOURCE: AAPCC, PPLP, RxPatrol

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Map presented to the Purdue Board in 2011

457. Once prescribers were categorized as part of “Region Zero,” Purdue would eventually stop promoting to them, but it would *not* stop selling to them, and it would *not* report them to authorities. This would have been costly. Staff told Co-Conspirator Stewart, the Sackler Co-Conspirators and the Board that the company was receiving a steadily rising volume of hotline calls and other compliance matters in this timeframe, reaching an all-time high during

October, November, and December 2010. Purdue made a calculated economic decision *not* to report suspicious prescribers and orders. Indeed, an internal Purdue study showed that the financial penalties imposed on drug companies for illegal marketing were “relatively small” when “compared to the perpetrating companies’ profits.” When the CDC issued a national warning against the highest and most dangerous doses of opioids, Purdue studied prescription data to calculate how much profit it would lose if doctors followed the CDC’s advice, and it elected not to.

458. Defendants’ obligation to report suspicious prescribing ran head on into their marketing strategy. Defendants did identify doctors who were their most prolific prescribers. However, this was done not to report them, but to market to them. It would make little sense to focus on marketing to doctors who may be engaged in improper prescribing only to report them to law enforcement.

459. Defendants purchased data from IMS Health (now IQVIA) or other proprietary sources to identify doctors to target for marketing and to monitor their own and competitors’ sales. Marketing visits were focused on increasing, sustaining, or converting the prescriptions of the biggest prescribers, particularly through aggressive, high frequency detailing visits.

460. This focus on marketing to the highest prescribers demonstrates that manufacturers were keenly aware of the doctors who were writing large quantities of opioids. But instead of investigating or reporting those doctors, Defendants were singularly focused on maintaining, capturing, or increasing their sales.

461. Whenever examples of opioid diversion and abuse have drawn media attention, Co-Conspirator Purdue and other Marketing Defendants and Purdue have consistently blamed “bad actors.” For example, in 2001, during a Congressional hearing, Purdue’s attorney Howard

Udell answered pointed questions about how it was that Purdue could utilize IMS Health data to assess their marketing efforts but not notice a particularly egregious pill mill in Pennsylvania run by a doctor named Richard Paolino. Udell asserted that Purdue was “fooled” by the doctor: “The picture that is painted in the newspaper [of Dr. Paolino] is of a horrible, bad actor, someone who preyed upon this community, who caused untold suffering. And he fooled us all. He fooled law enforcement. He fooled the DEA. He fooled local law enforcement. He fooled us.”³¹⁹

462. But given the closeness with which they monitored prescribing patterns through IMS Health data, the Defendants either knew or chose not to know of the obvious drug diversions. In fact, a local pharmacist had noticed the volume of prescriptions coming from Paolino’s clinic and alerted authorities. Purdue had the prescribing data from the clinic and alerted no one. Indeed, a Purdue executive referred to Purdue’s tracking system and database as a “gold mine” and acknowledged that Purdue could identify highly suspicious volumes of prescriptions.

463. As discussed below, Endo knew that Opana ER was being widely abused. Yet, the New York Attorney General revealed, based on information obtained in an investigation into Endo, that Endo sales representatives were not aware that they had a duty to report suspicious activity and were not trained on the company’s policies or duties to report suspicious activity, and Endo paid bonuses to sales representatives for detailing prescribers who were subsequently arrested for illegal prescribing.

464. Sales representatives making in-person visits to such clinics were likewise not fooled. But as pill mills were lucrative for the manufacturers and individual sales representatives alike, Marketing Defendants and their employees turned a collective blind eye, allowing certain

³¹⁹ *Pain Killer*, *supra* n. 109, at 179.

clinics to dispense staggering quantities of potent opioids and feigning surprise when the most egregious examples eventually made the nightly news.

D. Defendants Failed to Report Suspicious Orders or Otherwise Act to Prevent Diversion

465. As discussed above, Defendants failed to report suspicious orders, prevent diversion, or otherwise control the supply of opioids flowing into communities across America. Despite the notice described above, Defendants continued to pump massive quantities of opioids into communities in disregard of their legal duties to control the supply, prevent diversion, and report and take steps to halt suspicious orders.

466. Governmental agencies and regulators have confirmed (and in some cases Defendants have admitted) that Defendants did not meet their obligations and have uncovered especially blatant wrongdoing.

467. For example, in 2017, the Department of Justice fined Mallinckrodt \$35 million for failure to report suspicious orders of controlled substances, including opioids, and for violating recordkeeping requirements. The government alleged that “Mallinckrodt failed to design and implement an effective system to detect and report ‘suspicious orders’ for controlled substances - orders that are unusual in their frequency, size, or other patterns . . . [and] Mallinckrodt supplied distributors, and the distributors then supplied various U.S. pharmacies and pain clinics, an increasingly excessive quantity of oxycodone pills without notifying DEA of these suspicious orders.”

468. On December 23, 2016, Cardinal agreed to pay the United States \$44 million to resolve allegations that it violated reporting requirements in Maryland, Florida, and New York by failing to report suspicious orders of controlled substances, including oxycodone, to the DEA.

In the settlement agreement, Cardinal admitted, accepted, and acknowledged that it had violated the CSA between January 1, 2009 and May 14, 2012 by failing to:

- a. “timely identify suspicious orders of controlled substances and inform the DEA of those orders, as required by 21 C.F.R. §1301.74(b);”
- b. “maintain effective controls against diversion of particular controlled substances into other than legitimate medical, scientific, and industrial channels, as required by 21 C.F.R. §1301.74, including the failure to make records and reports required by the CSA or DEA’s regulations for which a penalty may be imposed under 21 U.S.C. §842(a)(5);” and
- c. “execute, fill, cancel, correct, file with the DEA, and otherwise handle DEA ‘Form 222’ order forms and their electronic equivalent for Schedule II controlled substances, as required by 21 U.S.C. §828 and 21.F.R. Part 1305.”

469. In 2012, the State of West Virginia sued AmerisourceBergen and Cardinal, as well as several smaller wholesalers, for numerous causes of action, including violations of the CSA, consumer credit and protection laws, antitrust laws, and the creation of a public nuisance. Unsealed court records from that case demonstrate that AmerisourceBergen, along with Cardinal, shipped 423 million pain pills to West Virginia between 2007 and 2012. AmerisourceBergen itself shipped 80.3 million hydrocodone pills and 38.4 million oxycodone pills during that time period. These quantities demonstrate that the Defendants failed to control the supply chain or to report and take steps to halt suspicious orders. In 2016, AmerisourceBergen agreed to settle the West Virginia lawsuit for \$16 million to the state; Cardinal settled for \$20 million.

470. Henry Schein, too, is a repeat offender. Since the company’s inception, it has been subjected to repeated disciplinary actions across the United States for its sale and/or

distribution of dangerous drugs to persons or facilities not licensed or otherwise authorized to possess such drugs.

471. In 2014, Henry Schein Animal Health was investigated by the State of Ohio Board of Pharmacy due to its sale/distribution of wholesale dangerous drugs to an entity not holding a valid Ohio license. It reached a settlement with the Ohio Board of Pharmacy related to this investigation in 2015.

472. Records from a disciplinary proceeding against a Wisconsin-licensed medical practitioner reveal that from May 2005 through September 2006, Henry Schein continued to deliver opioids to the provider, despite the fact that his license had been suspended for inappropriate prescribing of opioids.

473. Thus, Defendants have admitted to disregarding their duties. They have admitted that they pumped massive quantities of opioids into communities around the country despite their obligations to control the supply, prevent diversions, and report and take steps to halt suspicious orders.

474. The National Retail Pharmacies continuously paid other Defendants to supply large quantities of prescription opioids and continuously dispensed them in order to satisfy demand for the drugs, despite knowing of their illegitimate or, at best, suspicious nature, despite knowing that Manufacturer Defendants and Distributor Defendants were habitually violating state law, and despite Retail Defendants' duty to prevent diversion.

E. Defendants Delayed a Response to the Opioid Crisis by Pretending to Cooperate with Law Enforcement

475. When a manufacturer or distributor does not report or stop suspicious orders, prescriptions for controlled substances may be written and dispensed to individuals who abuse them or who sell them to others to abuse. This, in turn, fuels and expands the illegal market and

results in opioid-related overdoses. Without reporting by those involved in the supply chain, law enforcement may be delayed in taking action - or may not know to take action at all.

476. After being caught failing to comply with particular obligations at particular facilities, Supply Chain Defendants made broad promises to change their ways and insisted that they sought to be good corporate citizens.

477. More generally, Defendants publicly portrayed themselves as committed to working with law enforcement, opioid manufacturers, and others to prevent diversion of these dangerous drugs. For example, Defendant Cardinal claims that: “We challenge ourselves to best utilize our assets, expertise and influence to make our communities stronger and our world more sustainable, while governing our activities as a good corporate citizen in compliance with all regulatory requirements and with a belief that doing ‘the right thing’ serves everyone.” Defendant Cardinal likewise claims to “lead [its] industry in anti-diversion strategies to help prevent opioids from being diverted for misuse or abuse.” Along the same lines, it claims to “maintain a sophisticated, state-of-the-art program to identify, block and report to regulators those orders of prescription-controlled medications that do not meet [its] strict criteria.” Defendant Cardinal also promotes funding it provides for “Generation Rx,” which funds grants related to prescription drug misuse. A Cardinal executive recently claimed that Cardinal uses “advanced analytics” to monitor its supply chain; Cardinal assured the public it was being “as effective and efficient as possible in constantly monitoring, identifying, and eliminating any outside criminal activity.”

478. Along the same lines, Defendant AmerisourceBergen has taken the public position that it is “work[ing] diligently to combat diversion and [is] working closely with regulatory agencies and other partners in pharmaceutical and healthcare delivery to help find

solutions that will support appropriate access while limiting misuse of controlled substances.” A company spokeswoman also provided assurance that: “At AmerisourceBergen, we are committed to the safe and efficient delivery of controlled substances to meet the medical needs of patients.”

479. Moreover, in furtherance of their effort to affirmatively conceal their conduct and avoid detection, the Distributor Defendants, through their trade associations, HDMA and NACDS, filed an amicus brief in *Masters Pharmaceuticals*, which made the following statements:³²⁰

- a. “HDMA and NACDS members not only have statutory and regulatory responsibilities to guard against diversion of controlled prescription drugs, but undertake such efforts as responsible members of society.”
- b. “Distributors take seriously their duty to report suspicious orders, utilizing both computer algorithms and human review to detect suspicious orders based on the generalized information that is available to them in the ordering process.”

480. Through the above statements made on their behalf by their trade associations, and other similar statements assuring their continued compliance with their legal obligations, the Distributor Defendants not only acknowledged that they understood their obligations under the law, but they further asserted that their conduct was in compliance with those obligations.

481. Defendant Mallinckrodt similarly claims to be “committed . . . to fighting opioid misuse and abuse,” and further asserts that: “In key areas, our initiatives go beyond what is required by law. We address diversion and abuse through a multidimensional approach that includes educational efforts, monitoring for suspicious orders of controlled substances . . .”

³²⁰ Brief for HDMA and NACDS, *supra* n. 293, 2016 WL 1321983, at *3-4, *25.

482. Other Marketing Defendants and Purdue also misrepresented their compliance with their legal duties and their cooperation with law enforcement. Purdue serves as a hallmark example of such wrongful conduct. Purdue deceptively and unfairly failed to report to authorities illicit or suspicious prescribing of its opioids, even as it has publicly and repeatedly touted its “constructive role in the fight against opioid abuse,” including its commitment to ADF opioids and its “strong record of coordination with law enforcement.”³²¹

483. At the heart of Purdue’s public outreach is the claim that it works hand-in-glove with law enforcement and government agencies to combat opioid abuse and diversion. Purdue has consistently trumpeted this partnership since at least 2008, and the message of close cooperation is in virtually all of Purdue’s recent pronouncements in response to the opioid epidemic.

484. Touting the benefits of ADF opioids, Purdue’s website asserts: “[W]e are acutely aware of the public health risks these powerful medications create That’s why we work with health experts, law enforcement, and government agencies on efforts to reduce the risks of opioid abuse and misuse”³²² Purdue’s statement on “Opioids Corporate Responsibility” likewise states that “[f]or many years, Purdue has committed substantial resources to combat opioid abuse

³²¹ Purdue, *Setting The Record Straight On OxyContin’s FDA-Approved Label* (May 5, 2016), available at <http://www.purduepharma.com/news-media/get-the-facts/setting-the-record-straight-on-oxycontin-fda-approved-label/>; Purdue, *Setting The Record Straight On Our Anti-Diversion Programs* (July 11, 2016), available at <http://www.purduepharma.com/news-media/get-the-facts/setting-the-record-straight-on-our-anti-diversion-programs/>.

³²² Purdue website, *Opioids With Abuse-Deterrent Properties*, available at <http://www.purduepharma.com/healthcare-professionals/responsible-use-of-opioids/opioids-with-abuse-deterrent-properties/> (last accessed Aug. 1, 2018).

by partnering with . . . communities, law enforcement, and government.”³²³ And, responding to criticism of Purdue’s failure to report suspicious prescribing to government regulatory and enforcement authorities, the website similarly proclaims that Purdue “ha[s] a long record of close coordination with the DEA and other law enforcement stakeholders to detect and reduce drug diversion.”³²⁴

485. These public pronouncements create the false impression that Purdue is proactively working with law enforcement and government authorities nationwide to root out drug diversion, including the illicit prescribing that can lead to diversion. It aims to distance Purdue from its past conduct in deceptively marketing opioids and make its current marketing seem more trustworthy and truthful.

486. Public statements by the Defendants and their associates created the false and misleading impression to regulators, prescribers, and the public that the Defendants rigorously carried out their legal duties, including their duty to report suspicious orders and exercise due diligence to prevent diversion of these dangerous drugs, and further created the false impression that these Defendants also worked voluntarily to prevent diversion as a matter of corporate responsibility to the communities their business practices would necessarily impact.

XI. THE MARKETING DEFENDANTS’ AND PURDUE’S UNLAWFUL FAILURE TO PREVENT DIVERSION AND MONITOR, REPORT, AND PREVENT SUSPICIOUS ORDERS

487. The same legal duties to prevent diversion, and to monitor, report, and prevent suspicious orders of prescription opioids that were incumbent upon the Supply Chain Defendants

³²³ *Id.*

³²⁴ *Setting The Record Straight*, *supra* n. 321. Contrary to its public statements, Purdue seems to have worked behind the scenes to push back against law enforcement.

were also legally required of the Marketing Defendants and Purdue under Kentucky law. Like the Supply Chain Defendants, the Marketing Defendants and Purdue were required to register with the Kentucky Board of Pharmacy and the DEA to manufacture and distribute Schedule II controlled substances, like prescription opioids. *See* KRS § 218A.010(10), (11), (12), (38); KRS § 218A.150(1) (repealed 2018); KRS § 218.170(1), (2); KRS § 315.010; KRS § 315.400(9); 902 KAR 55:010 Section 1(4), 201 KAR 2:230. Under Kentucky state law, it has been declared that “[t]he regulation of controlled substances in this Commonwealth is important and necessary for the preservation of public safety and public health.” KRS § 218A.005(1).

488. Like the Supply Chain Defendants, the Marketing Defendants breached these duties. Kentucky state law requires that a “manufacturer, distributor, or wholesaler” must comply with “KRS § 218A.200 and the federal controlled substances laws.” KRS § 218A.170.

489. Pursuant to KRS § 218A.200, manufacturers and wholesalers of opioids “shall keep records of all controlled substances compounded, mixed, cultivated, grown, or by any other process produced or prepared, and all of controlled substances received and disposed of by them.”

490. The Marketing Defendants and Purdue have specialized and detailed knowledge of the potential suspicious prescribing and dispensing of opioids through their regular visits to doctors’ offices and pharmacies, and from the data they purchase from commercial sources, such as IMS Health (now IQVIA). Their extensive boots-on-the-ground through their sales force, allows them to observe the signs of suspicious prescribing and dispensing discussed elsewhere in the Complaint—lines of seemingly healthy patients, out-of-state license plates, and cash transactions, to name only a few.

491. In addition, Marketing Defendants and Purdue had access to and possession of the information necessary to monitor, report, and prevent suspicious orders and to prevent diversion. Marketing Defendants and Purdue regularly mine data, including, upon information and belief, chargeback data, that allows them to monitor the volume and type of prescribing of doctors, including sudden increases in prescribing and unusually high dose prescribing, that would have alerted them, independent of their sales representatives, to suspicious prescribing.

492. A chargeback is a payment made by a manufacturer to a distributor after the distributor sells the manufacturer's product at a price below a specified rate. After a distributor sells a manufacturer's product to a pharmacy, for example, the distributor requests a chargeback from the manufacturer and, in exchange for the payment, the distributor identifies to the manufacturer the product, volume and the pharmacy to which it sold the product. Thus, Marketing Defendants and Purdue knew – just as the Supply Chain Defendants knew – the volume, frequency, and pattern of opioid orders being placed and filled. The Marketing Defendants and Purdue built receipt of this information into the payment structure for the opioids provided to the opioid distributors. These information points give Manufacturer Defendants insight into prescribing and dispensing conduct that enables them to play a valuable role in preventing diversion and fulfilling their obligations under the law.

493. The Department of Justice has recently confirmed the suspicious order obligations clearly imposed by law upon opioid manufacturers, fining Mallinckrodt \$35 million for failure to report suspicious orders of controlled substances, including opioids, and for violating recordkeeping requirements.³²⁵

³²⁵ See Press Release, U.S. Dep't of Justice, Mallinckrodt Agrees to Pay Record \$35 Million Settlement for Failure to Report Suspicious Orders of Pharmaceutical Drugs and for

494. In the press release accompanying the settlement, the Department of Justice stated: “[Mallinckrodt] did not meet its obligations to detect and notify DEA of suspicious orders of controlled substances such as oxycodone, the abuse of which is part of the current opioid epidemic. These suspicious order monitoring requirements exist to prevent excessive sales of controlled substances, like oxycodone.” . . . “Mallinckrodt’s actions and omissions formed a link in the chain of supply that resulted in millions of oxycodone pills being sold on the street. . . . Manufacturers and distributors have a crucial responsibility to ensure that controlled substances do not get into the wrong hands. . . .”³²⁶

495. Among the allegations resolved by the settlement, the government alleged “Mallinckrodt failed to design and implement an effective system to detect and report ‘suspicious orders’ for controlled substances – orders that are unusual in their frequency, size, or other patterns . . . [and] Mallinckrodt supplied distributors, and the distributors then supplied various U.S. pharmacies and pain clinics, an increasingly excessive quantity of oxycodone pills without notifying DEA of these suspicious orders.”³²⁷

496. The Memorandum of Agreement entered into by Mallinckrodt (“2017 Mallinckrodt MOA”) avers “[a]s a registrant under the CSA, Mallinckrodt had a responsibility to

Recordkeeping Violations (July 11, 2017), available at <https://www.justice.gov/opa/pr/mallinckrodt-agrees-pay-record-35-million-settlement-failure-report-suspicious-orders>.

³²⁶ *Id.*

³²⁷ *Id.*

maintain effective controls against diversion, including a requirement that it review and monitor these sales and report suspicious orders to DEA.”³²⁸

497. Mallinckrodt further stated that it “recognizes the importance of the prevention of diversion of the controlled substances they manufacture” and agreed that it would “design and operate a system that meets the requirements of 21 C.F.R. § 1301.74(b) . . . [such that it would] utilize all available transaction information to identify suspicious orders of any Mallinckrodt product.” Mallinckrodt specifically agreed “to notify DEA of any diversion and/or suspicious circumstances involving any Mallinckrodt controlled substances that Mallinckrodt discovers.”

498. The 2017 Mallinckrodt MOA further details the DEA’s allegations regarding Mallinckrodt’s failures to fulfill its legal duties as an opioid manufacturer:

- a. With respect to its distribution of oxycodone and hydrocodone products, Mallinckrodt’s alleged failure to distribute these controlled substances in a manner authorized by its registration and Mallinckrodt’s alleged failure to operate an effective suspicious order monitoring system and to report suspicious orders to the DEA when discovered as required by and in violation of 21 C.F.R. § 1301.74(b). The above includes, but is not limited to Mallinckrodt’s alleged failure to: conduct adequate due diligence of its customers;
- b. Detect and report to the DEA orders of unusual size and frequency;
- c. Detect and report to the DEA orders deviating substantially from normal patterns including, but not limited to, those identified in letters from the DEA Deputy Assistant Administrator, Office of Diversion Control, to registrants dated September 27, 2006 and December 27, 2007:
 - i. orders that resulted in a disproportionate amount of a substance which is most often abused going to a

³²⁸ Administrative Memorandum of Agreement between the U.S. Dep’t of Justice, the Drug Enf’t Admin., and Mallinckrodt, plc. and its subsidiary Mallinckrodt, LLC (July 10, 2017), available at <https://www.justice.gov/usao-edmi/press-release/file/986026/download> (“2017 Mallinckrodt MOA”).

particular geographic region where there was known diversion,

- ii. orders that purchased a disproportionate amount of substance which is most often abused compared to other products, and
- iii. orders from downstream customers to distributors who were purchasing from multiple different distributors, of which Mallinckrodt was aware;
- d. Use “chargeback” information from its distributors to evaluate suspicious orders. Chargebacks include downstream purchasing information tied to certain discounts, providing Mallinckrodt with data on buying patterns for Mallinckrodt products; and
- e. Take sufficient action to prevent recurrence of diversion by downstream customers after receiving concrete information of diversion of Mallinckrodt product by those downstream customers.³²⁹

499. Mallinckrodt agreed that its “system to monitor and detect suspicious orders did not meet the standards outlined in letters from the DEA Deputy Administrator, Office of Diversion Control, to registrants dated September 27, 2006 and December 27, 2007.” Mallinckrodt further agreed that it “recognizes the importance of the prevention of diversion of the controlled substances they manufacture” and would “design and operate a system that meets the requirements of 21 C.F.R. 1301.74(b) [such that it would] utilize all available transaction information to identify suspicious orders of any Mallinckrodt product. Further, Mallinckrodt agrees to notify DEA of any diversion and/or suspicious circumstances involving any Mallinckrodt controlled substances that Mallinckrodt discovers.”³³⁰

³²⁹ *Id.* at 2-3.

³³⁰ *Id.* at 3-4.

500. Mallinckrodt acknowledged that “[a]s part of their business model Mallinckrodt collects transaction information, referred to as chargeback data, from their direct customers (distributors). The transaction information contains data relating to the direct customer sales of controlled substances to ‘downstream’ registrants.” Mallinckrodt agreed that, from this data, it would “report to the DEA when Mallinckrodt concludes that the chargeback data or other information indicates that a downstream registrant poses a risk of diversion.”³³¹

501. The same duties imposed by law on Mallinckrodt were imposed upon all Marketing Defendants and Purdue.

502. The same business practices utilized by Mallinckrodt regarding “charge backs” and receipt and review of data from opioid distributors regarding orders of opioids were utilized industry-wide among opioid manufacturers and distributors, including the other Marketing and Distributor Defendants.

503. Through the charge back data, the Marketing Defendants could monitor suspicious orders of opioids.

504. The Marketing Defendants and Purdue failed to monitor, report, and halt suspicious orders of opioids as required by law.

505. The Marketing Defendants’ and Purdue’s failures to monitor, report, and halt suspicious orders of opioids were intentional and unlawful.

506. The Marketing Defendants and Purdue have misrepresented their compliance with the laws regulating controlled substances.

507. The wrongful actions and omissions of the Marketing Defendants and Purdue that caused the diversion of opioids and which were a substantial contributing factor to and/or

³³¹ *Id.* at 5.

proximate cause of the opioid crisis are alleged in greater detail in Plaintiffs' allegations of Defendants' unlawful acts below.

508. The Marketing Defendants' and Purdue's actions and omissions in failing to effectively prevent diversion and failing to monitor, report, and prevent suspicious orders have enabled the unlawful diversion of opioids throughout the United States, including in Kentucky.

XII. THE DISTRIBUTOR DEFENDANTS' UNLAWFUL DISTRIBUTION OF OPIOIDS

509. The Distributor Defendants owe a duty under Kentucky common law and statutory law to monitor, detect, investigate, refuse to fill, and report suspicious orders of prescription opioids as well as those orders which the Distributor Defendants knew or should have known were likely to be diverted.

510. The foreseeable harm from a breach of these duties was the medical, social, and financial consequences rippling through society, arising from the abuse of diverted opioids for nonmedical purposes.

511. Each Distributor Defendant repeatedly and purposefully breached its duties under Kentucky law. Such breaches are a direct and proximate causes of the widespread diversion of prescription opioids for nonmedical purposes, with the resultant medical and financial damages.

512. For over a decade, all the Defendants aggressively sought to bolster their revenue, increase profit, and grow their share of the prescription painkiller market by unlawfully and surreptitiously increasing the volume of opioids they sold. However, Defendants are not permitted to engage in a limitless expansion of their sales through the unlawful sales of regulated painkillers. Rather, as described below, Defendants are subject to various duties to report the quantity of Schedule II controlled substances in order to monitor such substances and prevent oversupply and diversion into the illicit market.

513. The unlawful diversion of prescription opioids is a direct and proximate cause of the opioid epidemic, prescription opioid abuse, addiction, morbidity and mortality, with social and financial costs borne by, among others, individuals, families and hospitals.

514. The Distributor Defendants intentionally continued their conduct, as alleged herein, with knowledge that such conduct was creating the opioid epidemic and causing the damages alleged herein.

A. The Distributor Defendants Breached Their Duties

515. Opioids are a controlled substance. Schedule II controlled substances have “high potential for abuse,” which “may lead to severe psychic or physical dependence.” *See* KRS § 218A.060; KRS § 218A.070; KRS § 218A.080.

516. Each Distributor Defendant was required to obtain a license from Kentucky’s Board of Pharmacy. Each Distributor Defendant is a wholesaler that engaged in the chain of distribution or resale of Schedule II controlled substances with a duty to comply with all security requirements imposed under that statutory scheme. In failing to maintain effective controls against their diversion and illegitimate use, it is foreseeable that controlled substances will be prescribed for illegitimate purposes, diverted by corrupt retailers, and abused by the public that have fallen victim to their “high potential for abuse.” *See* KRS § 218A.070.

517. Each Distributor Defendant has an affirmative duty to act as a gatekeeper guarding against the diversion of the highly addictive, dangerous opioid drugs. In addition, the Kentucky law imposes specific record-keeping requirements on manufacturers and wholesalers who are required to maintain detailed records of all inventory of narcotic drugs received by and disposed of by them. *See, e.g.*, KRS § 315.0351; KRS § 315.036; KRS § 315.402 The information required to be collected and maintained includes dates of production and

distribution and contact information of the persons to whom or for whose use the drugs were sold, administered or dispensed.

518. “Suspicious orders” include orders of an unusual size, orders of unusual frequency or orders deviating substantially from a normal pattern. These criteria are disjunctive and are not all inclusive. For example, if an order deviates substantially from a normal pattern, the size of the order does not matter and the order should be reported as suspicious. Likewise, a wholesale distributor need not wait for a normal pattern to develop over time before determining whether a particular order is suspicious. The size of an order alone, regardless of whether it deviates from a normal pattern, is enough to trigger the wholesale distributor’s responsibility to report the order as suspicious. The determination of whether an order is suspicious depends not only on the ordering patterns of the particular customer but also on the patterns of the entirety of the wholesale distributor’s customer base and the patterns throughout the relevant segment of the wholesale distributor industry.

519. In addition to reporting all suspicious orders, distributors must also stop shipment on any order which is flagged as suspicious and only ship orders which were flagged as potentially suspicious if, after conducting due diligence, the distributor can determine that the order is not likely to be diverted into illegal channels. *See Southwood Pharm., Inc.*, 72 Fed. Reg. 36,487, 36,501 (Drug Enf’t Admin. July 3, 2007); *Masters Pharmaceutical, Inc. v. Drug Enforcement Administration*, No. 15-11355 (D.C. Cir. June 30, 2017). Regardless, all flagged orders must be reported. *Id.*

520. These prescription drugs are regulated for the purpose of providing a “closed” system intended to reduce the widespread diversion of these drugs out of legitimate channels

into the illicit market, while at the same time providing the legitimate drug industry with a unified approach to narcotic and dangerous drug control.

521. Because distributors are the first major line of defense in the movement of legal pharmaceutical controlled substances from legitimate channels into the illicit market, it is incumbent on them to maintain effective controls to prevent diversion of controlled substances.

522. As the DEA advised the Distributor Defendants in a letter dated September 27, 2006, wholesale distributors are “one of the key components of the distribution chain. If the closed system is to function properly ... distributors must be vigilant in deciding whether a prospective customer can be trusted to deliver controlled substances only for lawful purposes. This responsibility is critical, as ... the illegal distribution of controlled substances has a substantial and detrimental effect on the health and general welfare of the American people.”³³²

523. The Distributor Defendants have admitted that they are responsible for reporting suspicious orders.³³³

524. The DEA’s September 27, 2006 letter also warned the Distributor Defendants that it would use its authority to revoke and suspend registrations when appropriate. The letter expressly states that a distributor, in addition to reporting suspicious orders, has a “statutory

³³² See Letter from Joseph T. Rannazzisi, Deputy Assistant Adm’r, Office of Diversion Control, Drug Enf’t Admin., U.S. Dep’t of Justice, to Cardinal Health (Sept. 27, 2006) (“This letter is being sent to every commercial entity in the United States registered with the Drug Enf’t Admin. (DEA) to distribute controlled substances. The purpose of this letter is to reiterate the responsibilities of controlled substance distributors in view of the prescription drug abuse problem our nation currently faces.”), *Cardinal Health, Inc. v. Holder*, No. 1:12-cv-00185-RBW, ECF No. 14-51 (D.D.C. Feb. 10, 2012) (“Rannazzisi Letter to Cardinal Health”).

³³³ See Brief for HDMA and NACDS, *supra* n. 293, 2016 WL 1321983, at *4 (“[R]egulations . . . in place for more than 40 years require distributors to report suspicious orders of controlled substances to DEA based on information readily available to them (e.g., a pharmacy’s placement of unusually frequent or large orders).”).

responsibility to exercise due diligence to avoid filling suspicious orders that might be diverted into other than legitimate medical, scientific, and industrial channels.”³³⁴ The letter also instructs that “distributors must be vigilant in deciding whether a prospective customer can be trusted to deliver controlled substances only for lawful purposes.”³³⁵ The DEA warns that “even just one distributor that uses its DEA registration to facilitate diversion can cause enormous harm.”

525. The DEA sent a second letter to each of the Distributor Defendants on December 27, 2007.³³⁶ This letter reminds the Distributor Defendants of their statutory and regulatory duties to “maintain effective controls against diversion” and “design and operate a system to disclose to the registrant suspicious orders of controlled substances.”³³⁷ The letter further explains:

The regulation also requires that the registrant inform the local DEA Division Office of suspicious orders when discovered by the registrant. Filing a monthly report of completed transactions (e.g., “excessive purchase report” or “high unity purchases”) does not meet the regulatory requirement to report suspicious orders.

The regulation specifically states that suspicious orders include orders of unusual size, orders deviating substantially from a normal pattern, and orders of an unusual frequency. These criteria are disjunctive and are not all inclusive.

³³⁴ Rannazzisi Letter to Cardinal Health, *supra* note 332, at 2.

³³⁵ *Id.* at 1.

³³⁶ *Id.* at 2.

³³⁷ See Rannazzisi Letter to Cardinal Health, *supra* n. 332.

Lastly, registrants that routinely report suspicious orders, yet fill these orders without first determining that order is not being diverted into other than legitimate medical, scientific, and industrial channels, may be failing to maintain effective controls against diversion. Failure to maintain effective controls against diversion is inconsistent with the public interest as that term is used in 21 USC 823 and 824, and may result in the revocation of the registrant's DEA Certificate of Registration.³³⁸

526. Finally, the DEA letter references the Revocation of Registration issued in *Southwood Pharmaceuticals, Inc.*, 72 Fed. Reg. 36,487-01 (July 3, 2007), which discusses the obligation to report suspicious orders and “some criteria to use when determining whether an order is suspicious.”³³⁹

527. The Distributor Defendants admit that they “have not only statutory and regulatory responsibilities to detect and prevent diversion of controlled prescription drugs, but undertake such efforts as responsible members of society.”³⁴⁰

528. The Distributor Defendants knew they were required to monitor, detect, and halt suspicious orders. Industry compliance guidelines established by the Healthcare Distribution Management Association (now known as the HDA, a front group of the Defendants, discussed below), the trade association of pharmaceutical distributors, explain that distributors are “[a]t the

³³⁸ *Id.*

³³⁹ *Id.*

³⁴⁰ See Amicus Curiae Brief of Healthcare Distribution Mgmt. Ass'n in Support of App. Cardinal Health, Inc., *Cardinal Health, Inc. v. U.S. Dep't of Justice*, No. 12- 5061 (D.C. Cir. May 9, 2012), 2012 WL 1637016, at *10 (“Brief of HDMA in Support of Cardinal”).

center of a sophisticated supply chain” and therefore “are uniquely situated to perform due diligence in order to help support the security of the controlled substances they deliver to their customers.” The guidelines set forth recommended steps in the “due diligence” process, and note in particular: If an order meets or exceeds a distributor’s threshold, as defined in the distributor’s monitoring system, or is otherwise characterized by the distributor as an order of interest, the distributor should not ship to the customer, in fulfillment of that order, any units of the specific drug code product as to which the order met or exceeded a threshold or as to which the order was otherwise characterized as an order of interest.³⁴¹

529. The FTC has recognized the unique role of distributors. Since their inception, Distributor Defendants have continued to integrate vertically by acquiring businesses that are related to the distribution of pharmaceutical products and health care supplies. In addition to the actual distribution of pharmaceuticals, as wholesalers, Distributor Defendants also offer their pharmacy, or dispensing, customers a broad range of added services. For example, Distributor Defendants offer their pharmacies sophisticated ordering systems and access to an inventory management system and distribution facility that allows customers to reduce inventory carrying costs. Distributor Defendants are also able to use the combined purchase volume of their customers to negotiate the cost of goods with manufacturers and offer services that include software assistance and other database management support. *See Fed. Trade Comm’n v. Cardinal Health, Inc.*, 12 F. Supp. 2d 34, 41 (D.D.C. 1998) (granting the FTC’s motion for preliminary injunction and holding that the potential benefits to customers did not outweigh the

³⁴¹ Healthcare Distribution Mgmt. Ass’n (HDMA)), Industry Compliance Guidelines: Reporting Suspicious Orders and Preventing Diversion of Controlled Substances, *filed in Cardinal Health, Inc. v. Holder*, Doc. No. 1362415 (App’x B), No. 12-5061 (D.C. Cir. Mar. 7, 2012), Doc. No. 1362415 (App’x B).

potential anti-competitive effect of a proposed merger between Cardinal, Inc. and Bergen Brunswig Corp.). As a result of their acquisition of a diverse assortment of related businesses within the pharmaceutical industry, as well as the assortment of additional services they offer, Distributor Defendants have a unique insight into the ordering patterns and activities of their dispensing customers.

530. The DEA also repeatedly reminded the Defendants of their obligations to report and decline to fill suspicious orders. Responding to the proliferation of pharmacies operating on the internet that arranged illicit sales of enormous volumes of opioids to drug dealers and customers, the DEA began a major push to remind distributors of their obligations to prevent these kinds of abuses and educate them on how to meet these obligations. Since 2007, the DEA has hosted at least five conferences that provided registrants with updated information about diversion trends and regulatory changes. Each of the Distributor Defendants attended at least one of these conferences. The DEA has also briefed wholesalers regarding legal, regulatory, and due diligence responsibilities since 2006. During these briefings, the DEA pointed out the red flags wholesale distributors should look for to identify potential diversion.

531. Each of the Distributor Defendants sold prescription opioids, including hydrocodone and/or oxycodone, to retailers from which the Distributor Defendants knew prescription opioids were likely to be diverted.

532. Each Distributor Defendant owes a duty to monitor, detect and refuse suspicious orders of prescription opioids, to report suspicious orders of prescription opioids and to prevent the diversion of prescription opioids into illicit markets.

533. The laws at issue here concerning the sale and distribution of controlled substances are also the public safety statutes and regulations of states in which Plaintiffs' hospitals operate.

534. The Distributor Defendants' violations of public safety statutes constitute *prima facie* evidence of negligence under state law.

535. The unlawful conduct by the Distributor Defendants is purposeful and intentional. The Distributor Defendants refuse to abide by the duties imposed by state law which are required to legally acquire and maintain a license to distribute prescription opiates.

536. The Distributor Defendants acted with actual malice in breaching their duties, i.e., they have acted with a conscious disregard for the rights and safety of other persons, and said actions have a great probability of causing substantial harm.

B. Inadequate Compliance, Staffing and Training

537. First, the Distributor Defendants routinely failed to staff their compliance functions with qualified personnel, and failed to provide those compliance employees and their sales representatives with appropriate training. Even front-line compliance functions, such as approving threshold increases, detecting, blocking, and reporting suspicious orders, and terminating and/or suspending customers, were often assigned to operations, sales and administrative employees who had no experience with regulatory compliance of any kind.

C. Inadequate Scrutiny of Customers

538. None of the Distributor Defendants had a consistent practice of conducting appropriate due diligence of either prospective new customers or their existing customers. New customers were routinely on-boarded despite the acknowledged presence of unresolved red flags, and none of the Distributor Defendants ensured that additional investigations were conducted

when existing customers made suspicious orders, even when compliance staff flagged those orders as suspicious, blocked them, and reported them to the State.

539. Indeed, the Distributor Defendants routinely allowed their customers to make multiple suspicious orders within the same month, week, or even year, without conducting any additional due diligence of those customers. In fact, salespeople would warn customers when they were approaching their monthly threshold limits for ordering certain categories of controlled substances, putting them in a position to assist their customers in *evading* compliance reviews that would have otherwise occurred by manipulating the timing and volume of their orders.

540. Even where customers had to be blocked from ordering opioids in excess of their monthly threshold allowance multiple times within that month, the Distributor Defendants would allow those customers to resume ordering opioids the next month, at the same volume levels as before, without requiring any follow up investigation.

541. And none of the Distributor Defendants conducted periodic, unexpected due diligence audits of their customers, even among the easily identifiable and relatively small groups of pharmacies that consistently ordered the highest volumes of opioids. Instead, these pharmacies could go for years without the Distributor Defendants updating their knowledge of those customers' prescriber base, customer traffic patterns, and other relevant store conditions. Even when those pharmacies were scrutinized, the customer was often warned in advance.

D. Failure to Detect, Block and Report Suspicious Orders

542. The Distributor Defendants failed to report "suspicious orders," which the Distributor Defendants knew were likely to be diverted, to the relevant governmental authorities.

543. The Distributor Defendants unlawfully filled suspicious orders of unusual size, orders deviating substantially from a normal pattern, and/or orders of unusual frequency, and/or in areas from which the Distributor Defendants knew opioids were likely to be diverted.

544. The Distributor Defendants breached their duty to monitor, detect, investigate, refuse and report suspicious orders of prescription opiates, and/or in areas from which the Distributor Defendants knew opioids were likely to be diverted.

545. The Distributor Defendants breached their duty to maintain effective controls against diversion of prescription opiates into other than legitimate medical, scientific, and industrial channels.

546. The Distributor Defendants breached their duty to “design and operate a system to disclose to the registrant suspicious orders of controlled substances” and failed to inform the authorities, including the DEA, of suspicious orders when discovered in violation of their duties under state law.

547. The Distributor Defendants breached their duty to exercise due diligence to avoid filling suspicious orders that might be diverted into channels other than legitimate medical, scientific, and industrial channels.³⁴²

548. While the Distributor Defendants’ policies nominally allowed for compliance staff to identify any order as suspicious, as a matter of practice, only orders that exceeded a customer’s monthly threshold limit for a particular category of controlled substances would actually trigger a compliance review. As a result, untold numbers of opioid orders that should have been reviewed due to their unusual size or frequency, or their departure from the customers’ normal ordering patterns, were never even checked to determine whether they were suspicious. Because the Distributor Defendants routinely allowed their customers to obtain information about the monthly threshold limits governing their orders of opioid products, orders customers made within the limits after being enabled to “game” them were improperly excluded from

³⁴² See *Cardinal Health, Inc. v. Holder*, 846 F. Supp. 2d 203, 206 (D.D.C. 2012).

compliance review, when they all should have been checked to see whether the customers were deliberately structuring their orders to evade scrutiny.

549. Even as to orders that exceeded customers' monthly thresholds, the Distributor Defendants, over varying time periods, routinely failed to accurately identify those orders as suspicious. Instead, they released those orders for delivery based on perfunctory and unverified information provided by the customer, or for no documented reason at all. Moreover, even when the Distributor Defendants did identify orders as suspicious and did block them from delivery to customers, they routinely failed to report those suspicious orders to the State, sometimes going months or years without reporting any at all. When they did make suspicious-order reports, the reports were routinely incomplete, for example, by failing to identify all of the relevant suspicious orders for a customer, even when they were made within the same month, week, or even day.

550. The sheer volume of prescription opioids distributed to pharmacies in various areas, and/or to pharmacies from which the Distributor Defendants knew the opioids were likely to be diverted, was excessive for the medical need of the community and facially suspicious. Some red flags are so obvious that no one who engages in the legitimate distribution of controlled substances can reasonably claim ignorance of them.³⁴³

E. Distributor Defendants Failed to Suspend Suspicious Customers

551. The Distributor Defendants failed to act to suspend customers from ordering controlled substances, let alone terminate their accounts, even after compliance staff had blocked and reported dozens, or even hundreds, of suspicious orders from those customers. In the

³⁴³ *Masters Pharmaceuticals, Inc.*, 80 Fed. Reg. 55,418-01, 55,482 (Sept. 15, 2015) (citing *Holiday CVS, L.L.C., d/b/a CVS/Pharmacy*, Nos. 219 and 5195, 77 Fed. Reg. 62,316, 62,322 (2012)).

relatively rare instances where a customer had been terminated or suspended, the Distributor Defendants allowed them to reinstate their accounts, or open accounts under new business names, without investigating and resolving the issues that had led to the initial termination or suspension.

F. Distributor Defendants Failed to Adequately Maintain Accessible Data Concerning Customers and Prescribers

552. None of the Distributor Defendants systematically stored, organized, and made accessible for reference information about their customers or their owners, pharmacists, and top prescribers, in order to allow for meaningful future compliance efforts.

553. The Distributor Defendants did not require compliance staff to obtain customers' prescriber information, and some actually changed their policies to *forbid* such inquiries, willfully blinding themselves to one of the most important indicators of diversion. While compliance staff and/or third-party investigators retained by the Distributor Defendants would sometimes flag prescribers as suspicious in the course of conducting due diligence of a pharmacy, that information was not stored or shared in any useable format. As a result, when the same suspicious prescriber appeared among another pharmacy's top prescribers, the compliance staff handling that subsequent due diligence investigation would have no way of knowing about this risk that had already been identified, unless they had personally handled the earlier investigation, and happened to remember the prescriber's name. Similarly, they made no effort to collect and compare information about pharmacies that made high-volume orders of opioids, had been flagged for making suspicious orders, or had been suspended or terminated for suspicious or illegal practices. As a result, compliance staff had no way of knowing that a pharmacy they were investigating shared ordering patterns or top prescribers with another risky, suspicious, and/or previously disciplined customer.

G. The Distributor Defendants Failed to Report Violations to Government Authorities

554. The Distributor Defendants failed to promptly report compliance violations to the Commonwealth of Kentucky, and other governments. Indeed, even when they actually detected failures in their compliance systems, they made no effort to report those known incidents. More broadly, due to the combination of systematic failures riddling their compliance systems described above, none of the Distributor Defendants had the competence to effectively detect their own violations.

555. For example, if any of the relevant Distributor Defendants had conducted periodic audits of their own records of customers' orders, those customers' patterns of ordering in excess of their monthly threshold allowance for opioid products, the number of times those orders were released without justification, and the number of times those orders were blocked as suspicious without being reported to government agencies and/or triggering additional investigations, suspensions, or terminations, they would have each been obliged to report hundreds, if not thousands, of violations at a time.

556. In short, the Distributor Defendants deliberately lied to Kentucky and other states, both expressly and by omission, year in and year out, about the effectiveness of their compliance systems and the incidence of violations, so that they could fraudulently maintain their licenses to continue doing business in Kentucky and elsewhere.

557. The Distributor Defendants' repeated shipments of suspicious orders, over an extended period of time, in violation of public safety statutes, and without reporting the suspicious orders to the relevant authorities demonstrates wanton, willful, or reckless conduct or criminal indifference to civil obligations affecting the rights of others and justifies an award of punitive damages.

H. Each of the Distributor Defendants Engaged in Wrongful Conduct

1. Cardinal

558. Defendant Cardinal Health breached its duties under federal and state law.

559. As shown by the ARCOS Data, Cardinal Health distributed an extraordinary amount of prescription opioids into Plaintiffs' communities. From 2006 to 2014, Cardinal Health distributed 328,472,955 pills of hydrocodone and oxycodone into Kentucky, making it the third largest distributor of these opioid pills during this eight-year period. Cardinal Health's excessive distribution was made possible by, and is evidence of, Cardinal Health's failures to comply with its duties under state and federal law.

560. From 1996 to 2008, Cardinal Health did not have an anti-diversion program that could adequately monitor and detect suspicious orders of opioids or timely report any suspicious orders.

a. Cardinal's Flawed Written Policies Enabled Opioid Diversion

561. Cardinal's written policies for compliance were and are contained in Standard Operating Procedures ("SOPs") that apply to its various operating and sales departments. These SOPs were first implemented in 2008 and have since undergone several revisions.

562. These policies were fundamentally flawed in that they were not coordinated within the context of a consistent, unified umbrella policy to prevent the diversion of controlled substances, resulting in employees governed by one of the SOPs being unaware of the obligations imposed by other SOPs on other employees, even when effective anti-diversion measures required that understanding and coordination. Furthermore, these documents are not readily available even to the employees charged with implementing them.

563. In addition, Cardinal's SOPs and policies contained numerous gaps that would have prevented them from effectively preventing diversion, even if enforced. For example, these policies:

- a. Allowed new accounts with no formal mechanism to ensure review and approval by a supervisor;
- b. Allowed onboarding of new accounts even where customers failed to provide requested information about other suppliers, dispensing data, and top prescriber information; and
- c. Allowed compliance staff to release a customer's first order in excess of its monthly threshold, regardless of whether the customer made other orders in excess of the same drug threshold at the same time.

b. Cardinal's Failure to Effectively Prevent Diversion in Practice

564. At all relevant times, Cardinal failed to employ qualified compliance staff to implement these policies, failed to adequately train those compliance staff or its sales representatives concerning Cardinal's anti-diversion duties, and failed to enforce even the defective policies it had in place.

565. Cardinal failed to install qualified personnel in key compliance positions. For example, Cardinal's front-line "New Account Specialists" and "Analysts," responsible for onboarding new customers and monitoring existing customers, respectively, were routinely recruited from the ranks of the company's existing pool of administrative assistants. These employees, who had no experience in regulatory compliance, were generally supervised by pharmacists or other professionals with no prior experience in supervising investigative functions.

566. Moreover, Cardinal failed to provide meaningful training to either these unqualified compliance personnel or sales representatives. Instead, Cardinal expected the compliance staff to "learn on the job" through informal in-person "team meetings." Due to the

lack of proper training and clear guidelines, compliance staff did not fully understand critical components of their jobs and often developed their own procedures and benchmarks for reviewing customers.

567. Unsurprisingly, these unqualified and untrained staff routinely failed to follow even the most basic procedures required under the company's various SOPs. In addition, Cardinal allowed customers to reinstate their accounts through the new account onboarding process despite having compliance red flags.

568. Even to staff charged with investigations and anti-diversion, the message was clear: without sales, there is no Cardinal. Indeed, many of Cardinal's policies and practices have prioritized sales over regulatory obligations.

569. In 2012 and 2013, Cardinal took significant steps to renew focus on increased sales at the cost of a robust and responsible compliance structure, thereby keeping as customers pharmacies that it knew or should have known were high risk for diversion of opioids. For example, Cardinal:

- a. Continuously reduced the due diligence information collected from prospective and existing customers, diluting the customer questionnaire, removing the requirements to collect photos of the pharmacies, and ceasing to ask about top prescribers;
- b. Expanded the geographic scope of investigators with essential regional knowledge of, for example, top prescribers and their locations relative to the pharmacies where their prescriptions were being filled, thus reducing the investigators' efficacy;
- c. Restricted the information reviewed from site visits by first removing the investigator comment section and for a time eliminating written reports entirely; and
- d. Demoted, moved to non-compliance functions, or let go several staff members who articulated an interest in expanding the company's compliance functions, aggressively scrutinizing pharmacy customers, and/or terminating problematic customers.

570. As to existing customers, Cardinal routinely failed to follow the SOP's procedures for detecting, monitoring, and reporting suspicious orders. Cardinal's compliance staff routinely released orders in excess of a customer's threshold without conducting the follow-up investigation and providing the detailed written justification called for by the SOPs.

571. Even when Cardinal did block customers' orders and report them as, it routinely took no steps to suspend or terminate those customers pending further investigation, and instead allowed them to continue receiving their threshold amount of opioids month after month thereafter, regardless of whether the customer continued to make additional suspicious orders.

572. Between 2012 and 2017, for example, Cardinal reported twelve or more opioid related suspicious orders for at least one year-the equivalent of one per month-for hundreds of pharmacies nationwide. Those pharmacies had several known red flags in their shipment orders and prescription data. More than half of these pharmacies: (a) exceeded the 90th percentile in the State in terms of opioid volume shipped; (b) exceeded the 90th percentile in the State in terms of oxycodone volume shipped; and (c) exceeded the 90th percentile in the State in terms of median strength of opioids prescribed per day. Nonetheless, even after reporting twelve or more opioid-related suspicious orders for one of these pharmacies, Cardinal continued to ship opioids, on average, for *more than three years*. Within this group of suspect pharmacies that Cardinal did nothing to control, these included particularly egregious cases in which Cardinal reported more than 50 opioid-related suspicious orders per year-the equivalent of *one suspicious order per week* to the authorities for *three or more consecutive years*.

573. In still other instances, neither Cardinal nor other distributors reported numerous suspicious orders, but almost certainly should have, given that a handful of prescribers were responsible for writing an unusually high percentage of the pharmacy's opioid prescriptions. By

itself, having a high concentration of opioid prescriptions written by a small number of providers is a known red flag for opioid diversion. Subsequently, these pharmacies had among the highest percentage of prescriptions written by providers who were indicted or convicted on opioid-related prescribing and distribution charges.

574. Examples of egregious cases identified in an investigation by a state attorney general included:

- a. A pharmacy in the 99th percentile in the state, to which Cardinal reported an average of 85 suspicious orders per year for five years, the equivalent of more than once a week, yet as of 2018, as of 2018, this pharmacy continued to receive opioids from Cardinal.
- b. A pharmacy in the 95th percentile in the state, to which Cardinal, from 2012 to 2018, shipped more than 20,000 grams of opioids, the equivalent of about thirteen 30mg oxycodone pills for every person in the county.
- c. A pharmacy in the 90th percentile where more than 20% of its customers have received opioid prescriptions by three or more doctors in a six-year period, and to which Cardinal continued to ship opioids after other distributors had issued 223 SORs.
- d. A pharmacy in the 99th percentile where approximately 60% of prescriptions were written by prescribers who were later indicted or convicted, and to which Cardinal has failed to issue a single SOR as of December 2017.

575. Finally, even if Cardinal had conducted due diligence to investigate its high-volume opioids customers, Cardinal's failure to implement any system to store and share information about their suspicious customers and/or suspicious prescribers would have compromised the effectiveness of any such investigation.

576. Due to these flaws, Cardinal routinely continued to supply pharmacies that filled prescriptions for prescribers that had been flagged in its own (infrequent) investigations of other pharmacies as likely sources of diversion.

c. **Cardinal Was Put on Notice of its Wrongful Conduct**

577. In addition to numerous instances, including examples cited above, in which Cardinal's own employees acknowledged failures in its compliance systems, the company was explicitly put on notice on multiple occasions by government agencies that it was not fulfilling its duties.

578. To date, Cardinal has paid a total of \$98 million in fines and other amounts involving multiple DEA and various state actions relating to its improper management and distribution of opioids to pharmacies across the United States.

579. In 2008, Cardinal paid a \$34 million penalty to settle allegations about opioid diversion taking place at seven warehouses³⁴⁴ around the United States (the “2008 Cardinal Settlement Agreement”).³⁴⁵ These allegations included failing to report to the DEA thousands of suspicious orders of hydrocodone that Cardinal then distributed to pharmacies that filled illegitimate prescriptions originating from rogue Internet pharmacy websites.³⁴⁶

³⁴⁴ Including its Lakeland, Florida facility. See <https://www.dea.gov/pubs/pressrel/pr100608.html>. In 2012, Cardinal described the Lakeland facility as shipping “an average of about 4 million dosage units of prescription drugs, including about 500,000 dosage units of controlled substances, on a monthly basis to more than 5,200 customers in Florida, Georgia and South Carolina. The volume of prescription drugs distributed makes the Lakeland facility the largest prescription drug wholesaler in Florida.” *Cardinal Health, Inc. v. Eric Holder, Jr., Att’y Gen.*, D.D.C. Case No. 12-185, ECF No. 3-1, at 6; 3-13 at 2; 3-15 (Feb. 3, 2012).

³⁴⁵ Settlement and Release Agreement and Administrative Memorandum of Agreement (Sept. 30, 2008), a cached version is available at https://webcache.googleusercontent.com/search?q=cache:O7Te0HbVfpIJ:https://www.dea.gov/divisions/hq/2012/cardinal_agreement.pdf+&cd=2&hl=en&ct=clnk&gl=us; Press Release, U.S. Att’y Office, Dist. of Colo., Cardinal Health Inc., Agrees to Pay \$34 Million to Settle Claims that it Failed to Report Suspicious Sales of Widely-Abused Controlled Substances (Oct. 2, 2008), available at https://www.justice.gov/archive/usao/co/news/2008/October08/10_2_08.html.

³⁴⁶ *Id.*

580. In connection with the 2008 Cardinal Settlement Agreement, the DEA stated that “[d]espite [its] repeated attempts to educate Cardinal on diversion awareness and prevention, Cardinal engaged in a pattern of failing to report blatantly suspicious orders for controlled substances filled by its distribution facilities located throughout the United States.”³⁴⁷ The DEA concluded that “Cardinal’s conduct allowed the ‘diversion’ of millions of dosage units of hydrocodone from legitimate to non-legitimate channels.”³⁴⁸

581. As part of the 2008 Cardinal Settlement Agreement, Cardinal agreed to “maintain a compliance program designed to detect and prevent diversion of controlled substances as required by the CSA and applicable DEA regulations.”³⁴⁹ However, in 2012, the DEA issued an “immediate suspension order,” suspending Cardinal’s registration with respect to Cardinal’s drug distribution facility in Lakeland, Florida. That order stated that “Despite the [2008 Cardinal Settlement Agreement], the specific guidance provided to Cardinal by DEA, and despite the public information readily available regarding the oxycodone epidemic in Florida, Cardinal has failed to maintain effective controls against diversion of controlled substances into other than legitimate medical, scientific, and industrial channels, in violation of [the CSA].”³⁵⁰ For example, from “2008-2009, Cardinal’s sales to its top four retail pharmacies [in the State of

³⁴⁷ U.S. Att’y Office, Dist. of Colo., *Cardinal Health Inc. Agrees to Pay \$34 Million to Settle Claims that It Failed to Report Suspicious Sales of Widely-Abused Controlled Substances* (Oct. 2, 2008), available at https://www.justice.gov/archive/usao/co/news/2008/October08/10_2_08.html.

³⁴⁸ *Id.*

³⁴⁹ *Cardinal Health, Inc. v. Eric Holder, Jr., Att’y Gen.*, D.D.C. Case No. 12-185, ECF No. 3-4, at ¶ 2 (Feb. 3, 2012).

³⁵⁰ *Id.* at ¶ 3.

Florida] increased approximately 803%. From 2009 to 2010, Cardinal's sales to its top four retail pharmacies [in the State of Florida] increased 162%.”³⁵¹

582. In 2012, Cardinal reached another settlement with the DEA relating to its failure to “conduct meaningful due diligence to ensure that the controlled substances were not diverted into other than legitimate channels” resulting in systemic opioid diversion in its Florida distribution center (the “2012 Cardinal Settlement Agreement”).³⁵² Cardinal's Florida center received a two-year license suspension for supplying more than 12 million dosage units to only four area pharmacies, nearly fifty times as much oxycodone as it shipped to the rest of Florida and an increase of 241% in only two years.³⁵³ The DEA found that Cardinal's own investigator warned Cardinal against selling opioids to these pharmacies, but that Cardinal did nothing to notify the DEA or cut off the supply of drugs to the suspect pharmacies.³⁵⁴ Instead, Cardinal's opioid shipments to the pharmacies increased.³⁵⁵

583. In the 2012 Cardinal Settlement Agreement, Cardinal agreed that it had (i) failed to maintain effective controls against the diversion of controlled substances, including failing to conduct meaningful due diligence to ensure that controlled substances were not diverted; (ii) failed to detect and report suspicious orders of controlled substances as required by the CSA, on

³⁵¹ *Id.* at ¶ 4.

³⁵² Administrative Memorandum of Agreement (May 14, 2012), *available at* https://www.dea.gov/divisions/hq/2012/cardinal_agreement.pdf (last accessed August 1, 2018); Press Release, Drug Enf't Admin., DEA Suspends for Two Years Pharmaceutical Wholesale Distributor's Ability to Sell Controlled Substances from Lakeland, Florida Facility (May 15, 2012), *available at* <https://www.dea.gov/pubs/pressrel/pr051512.html>.

³⁵³ *Id.*

³⁵⁴ *Id.*

³⁵⁵ *Id.*

or before May 14, 2012; and (iii) failed to adhere to the provisions of the 2008 Cardinal Settlement Agreement.³⁵⁶

584. In December 2016, Cardinal again settled charges that it had violated the CSA by failing to prevent diversion of oxycodone for illegal purposes, this time for \$44 million (the “2016 Cardinal Settlement Agreement”).³⁵⁷ The settlement covered DEA allegations that Cardinal had failed to report suspicious orders across Washington, Maryland, New York, and Florida.³⁵⁸ The same Florida distribution center at the heart of the 2012 settlement was again implicated in this case.³⁵⁹ The settlement also covered a Cardinal subsidiary, Kinray, LLC, which failed to report a single suspicious order despite shipping oxycodone and hydrocodone to more than 20 New York-area pharmacy locations that placed unusually high orders of controlled substances at an unusually frequent rate.³⁶⁰

d. Cardinal Actively Marketed Prescription Opioids

585. Cardinal worked to increase sales of opioids through a range of in-house marketing platforms directed at prescribers, pharmacists, and consumers, implemented nationally.

³⁵⁶ Administrative Memorandum of Agreement, *supra* n. 352.

³⁵⁷ U.S. Att’y Office, Dist. of Md., *Cardinal Health Agrees to \$44 Million Settlement for Alleged Violations of Controlled Substances Act* (Dec. 23, 2016), available at <https://www.justice.gov/usao-md/pr/cardinal-health-agrees-44-million-settlement-alleged-violations-controlled-substances-act>.

³⁵⁸ *Id.*

³⁵⁹ *Id.*

³⁶⁰ *Id.*

586. Cardinal not only offers marketing services to its drug manufacturer clients, it incentivizes and encourages manufacturers to use these marketing channels as a way of building their business and increasing sales of prescription opioids.

587. Purdue and other manufacturers worked hand-in-glove with Cardinal to promote their products through the distributors to pharmacies and pharmacists.

588. Cardinal profited in two ways from its marketing activities: (1) it was paid by the drug manufacturers to promote their prescription opioids, and/or (2) it was paid from increases in pharmacy drug sales that resulted from these marketing efforts.

589. The targeting of pharmacists by Cardinal in its marketing activities was particularly problematic because of Cardinal's existing and often long-term business relationships with pharmacies—with whom Cardinal shared a legal responsibility to prevent diversion. Opioid distributors, like Cardinal, were in a unique and trusted position in the controlled substances supply chain from which they could have spoken truthfully to their pharmacy customers about the serious risks posed by opioids (including the risk of diversion). They could have remained silent about the benefits and risks of opioids, and simply filled orders and shipped drugs. Instead, Cardinal abused its unique position for profit, by contributing to the chorus of deception surrounding opioids.

590. To engage in the promotion of controlled substances at all, under the circumstances detailed in this Complaint, was a dereliction of Cardinal's duties to prevent opioid diversion. Through these marketing activities, Cardinal contributed to and reinforced the deceptive and misleading marketing messages that healthcare providers received about opioids through other channels. Moreover, much of the Cardinal's marketing content was deceptive, because it either affirmatively misrepresented the benefits and risks of prescription opioids, or it

omitted important information about the risks of prescription opioids. Cardinal knew or should have known that these marketing messages—particularly those that misrepresented or omitted material information about the potential for diversion or risks of addiction associated with prescription opioids—were deceptive.

591. Through marketing activities, Cardinal built upon, reinforced, and profited from the drug manufacturers' campaign to deceive healthcare providers about the risks and benefits of prescription opioid use—a campaign that encouraged and normalized over-prescribing and over-dispensing of prescription opioids.

592. Cardinal made false statements that it had no role in influencing the prescribing or dispensing of prescription opioids and did not promote and market any pharmaceuticals-including opioids-directly to consumers.

2. AmerisourceBergen

593. Defendant AmerisourceBergen breached its duties under federal and state law.

594. As shown by the ARCOS Data, AmerisourceBergen distributed an extraordinary amount of prescription opioids into Plaintiffs' communities. AmerisourceBergen's excessive distribution was made possible by, and is evidence of, AmerisourceBergen's failures to comply with its duties under state and federal law.

a. AmerisourceBergen's Flawed Written Policies Enabled Opioid Diversion

595. AmerisourceBergen is the nation's third largest drug distributor. AmerisourceBergen's written policies for compliance were and are contained within its Diversion Control Program and its Order Monitoring Program ("COMP"). The programs are administered by AmerisourceBergen's Corporate Security and Regulatory Affairs ("CSRA"). From 2007 to 2015, the program's specifics were scattered through a series of policy and

procedure documents, and which were not uniform for AmerisourceBergen and its subsidiary, Bellco Health, which it acquired in 2007.

596. AmerisourceBergen compliance policies are flawed from the point of initial new customer on boarding. Since 2007, AmerisourceBergen has generally required a customer questionnaire, a site visit, license verification, and online investigation as part of its new customer due diligence process. A central component of AmerisourceBergen's new customer procedure is its Retail Pharmacy Questionnaire ("590 Form"). The form asks for information about other distributors, disciplinary history, customer payment methods, percentages of controlled substances, usage numbers for specific high-risk drugs, and top prescribers of opioids, among other questions. Though the form requests information about prescribing physicians, it is not AmerisourceBergen's policy to perform news searches on those prescribers as part of the new customer procedure, and controlled substances could account for up to-of prescriptions dispensed before triggering additional investigation.

597. AmerisourceBergen does not require new customers to provide usage reports or dispensing data as part of the on boarding process. By relying on these customers to self-report without any documented verification, AmerisourceBergen does not fulfill its obligation of truly knowing its customers' business practices.

598. Both prior to and after program revision, AmerisourceBergen's policies have allowed for frequent threshold manipulation to avoid orders being held for review, rejected from shipment, or reported as suspicious. Staff reviewing the form have high benchmarks for these numbers before considering them red flags.

599. AmerisourceBergen's policies are not sufficient to comply with the requirements of Kentucky law and regulations and similar requirements of other states. Under

AmerisourceBergen's deficient policies, it does not hold for review orders that only meet one of these qualifications. By limiting the orders even held for review, AmerisourceBergen's policy does not fulfill its obligation to identify even orders of interest, much less suspicious orders.

600. Examples of egregious cases identified recently in a complaint filed by a state attorney general included:

- a. A pharmacy at or above both the 99th percentile in terms of both number of opioid orders and total opioid weight, at which, between 2014 and 2016, more than 10% of its prescriptions were written by prescribers who were later indicted or convicted of opioid-related prescribing and distribution charges, concerning which AmerisourceBergen reported nearly 200 SORs in 2013-14, and to which as of 2018, AmerisourceBergen was still serving as this pharmacy's primary opioid distributor;
- b. A pharmacy where, between 2013 and 2017, 77% of its prescriptions, on average, were written by prescribers who were later indicted or convicted, including 90% in 2014, and to which Amerisource appears to have only stopped shipping in 2017; and
- c. A pharmacy that exceeded the 95th percentile for the percentage of oxycodone volume shipped for five years straight (2012 to 2016), where on average 58% of its opioid prescriptions were paid in cash (99th percentile), where for three consecutive years (2013 to 2015) approximately half of all opioid scripts were filled by prescribers who were later convicted, and which, as of 2018, was still a customer of AmerisourceBergen.

b. AmerisourceBergen's Failure to Effectively Prevent Diversion in Practice

601. At all relevant times, AmerisourceBergen failed to employ sufficient numbers of qualified compliance staff to implement these policies, failed to ensure those compliance staff were meeting AmerisourceBergen's anti-diversion duties, and failed to enforce even the defective policies it had in place. Among other deficiencies, AmerisourceBergen failed to sufficiently staff its compliance departments.

602. Since the integration of Bellco into AmerisourceBergen and the revamp of its Diversion Control Program in 2015, the company has increased anti-diversion staffing, but has not significantly increased the number of fully trained ground level employees. Since that time, AmerisourceBergen has maintained only five to seven front-line employees on its Diversion Control Team, responsible for reviewing new customers and monitoring its existing customers.

603. Many of AmerisourceBergen's compliance violations begin with its new customer policy. The process relies heavily on the customer 590 Form, given that AmerisourceBergen only requests dispensing information from new customers when it already knows of potential issues. For example, dispensing data was requested recently in considering customers moving from distributor Morris & Dickson Company-including customers that prompted a DEA investigation because of their high-volume opioid purchasing.

604. Despite the 590 Form's being so critical to understanding its customers and ensuring it can fulfill its regulatory obligations, and despite numerous other AmerisourceBergen procedures relying on reviewing or updating this form, AmerisourceBergen has had significant issues related to failing to perform even this baseline screening. Bellco Generics customers, for example, regularly completed the 590 Form independently, submitted it to Bellco, and were on boarded thereafter without receiving a site visit.

605. Disjunction between AmerisourceBergen and Bellco has led to many compliance failures. Until system integration in or around November 2015, staff had no systematic way of identifying dual customers. The lack of an integrated system also meant that thresholds were not coordinated between AmerisourceBergen and Bellco at any point. As a result, a dual customer could have high thresholds set with both, could be exceeding both thresholds, or even having its threshold periodically increased with both, without detection. In or around April 2013,

AmerisourceBergen implemented a policy for dual customers that prevented both AmerisourceBergen and Bellco from supplying controlled substances to the same customer, but implementation was spotty, and, in practice, only a small percentage of orders flagged for review are cancelled, and even fewer are deemed suspicious.

606. AmerisourceBergen has a high tolerance for apparent compliance issues before it will terminate a customer. It lacked an internal rule or policy that requires investigation of a customer based on a specific number of suspicious order reports. Even when customers were restricted, blocked, or terminated, AmerisourceBergen's system failed to ensure their accounts were de-activated.

607. The one area in which AmerisourceBergen has consistently stood out as compared to its major competitors is its unwillingness to identify suspicious orders, even among customers that regularly exceeded their thresholds and presented multiple red flags of diversion. During this time, numerous AmerisourceBergen opioid customers exhibited several common indicators of suspicious activity for multiple years. These flags included:

- a. Scoring above the 90th percentile in the county for opioid order volume;
- b. Scoring above the 90th percentile in the county for total opioid orders;
- c. Scoring above the 90th percentile in the county for oxycodone order volume;
- d. Scoring above the 90th percentile in the county for total oxycodone orders;
- e. Scoring above the 90th percentile in the state for the percentage of oxycodone volume shipped out of all controlled substances shipped;
- f. Filling prescriptions by prescribers who were later indicted or convicted on opioid-related prescribing and distribution charges;
- g. Scoring above the 90th percentile in terms of percentage of patient doctor-shoppers;

- h. Scoring above the 90th percentile in terms of percentage of cash payments; and
- i. Scoring above the 90th percentile in terms of the median MME prescribed per day.

c. **AmerisourceBergen Was Put on Notice of its Wrongful Conduct**

608. AmerisourceBergen's deficiencies and failures did not go undetected. The company was explicitly put on notice on multiple occasions by government agencies that it was not fulfilling its duties.

609. AmerisourceBergen has paid \$16 million in settlements and had certain licenses revoked as a result of allegations related to the diversion of prescription opioids.

610. In 2007, AmerisourceBergen lost its license to send controlled substances from a distribution center amid allegations that it was not controlling shipments of prescription opioids to Internet pharmacies.³⁶¹ Over the course of one year, AmerisourceBergen had distributed 3.8 million dosage units of hydrocodone to "rogue pharmacies."³⁶² The DEA suspended AmerisourceBergen's registration after determining that "the continued registration of this company constitutes an imminent danger to public health and safety."³⁶³

³⁶¹ Press Release, Drug Enf't Admin., *DEA Suspends Orlando Branch of Drug Company from Distributing Controlled Substances* (Apr. 24, 2007), available at <https://www.dea.gov/divisions/mia/2007/mia042407p.html>.

³⁶² *Id.*

³⁶³ *Id.*

611. Again in 2012, AmerisourceBergen was implicated for failing to protect against diversion of particular controlled substances into non-medically necessary channels.³⁶⁴

3. H.D. Smith

612. Defendant H.D. Smith breached its duties under federal and state law.

613. As shown by the ARCOS Data, H.D. Smith distributed an extraordinary amount of prescription opioids into Plaintiffs' community. H.D. Smith's excessive distribution was made possible by, and is evidence of, H.D. Smith's failures to comply with its duties under state and federal law.

614. According to ARCOS Data, H.D. Smith was one of the top five distributors of oxycodone and hydrocodone pills in twenty-three Kentucky counties during the eight-year period from 2006 to 2014. In just these twenty-three Kentucky Counties, H.D. Smith distributed 33,313,840 pills during this eight-year period.

a. H.D. Smith's Flawed Written Policies Enable Opioids Diversion

615. Through 2008, H.D. Smith only had two undated policies that were at least nominally in place that covered suspicious order monitoring. These policies were little used. The fact that these policies even existed was not well known by many employees of H.D. Smith.

616. In or around 2008, H.D. Smith began developing a computer based suspicious order monitoring system which H.D. Smith calls CSOMP. The system did not include pattern and frequency as considerations. Another flaw in the program provided for automatic release of all orders by new pharmacies in order for them to "ramp up." Orders which hit CSOMP limits

³⁶⁴ Jeff Overley, *AmerisourceBergen Subpoenaed by DEA Over Drug Diversion*, Law360.com (Aug. 9, 2012), available at <https://www.law360.com/articles/368498/amerisourcebergen-subpoenaed-by-dea-over-drug-diversion>.

were automatically released, allowing the customer to build a high-volume sales “history.” Further, hundreds of people within the company had authority to release a held order.

617. In or around 2014, H.D. Smith hired a new compliance officer and began to create an improved CSOMP program to comply with law requirements. However, in 2016, the new compliance officer was terminated before any enhancements went into effect. H.D. Smith rehired their former Vice President of Compliance, as of May 31, 2016.

b. H.D. Smith’s Failure to Effectively Prevent Diversion in Practice

618. Lori Kirbach worked in the Compliance Department at H.D. Smith until she resigned in February of 2015. When she resigned, she participated in an exit interview, in which she stated that the main reason she wanted to leave H.D. Smith was because she felt that the company, “Is and has been breaking the law for some time.” She did not understand why this was being tolerated. Specifically, Ms. Kirbach stated that CSOMP had not been working correctly since OPUS Go Live and that no one would listen to compliance personnel when the issue was brought up. She confirmed that, “Compliance is releasing orders that they should not be releasing.”³⁶⁵

I. The Distributor Defendants Have Sought to Avoid and Have Misrepresented Their Compliance with Their Legal Duties

619. The Distributor Defendants have repeatedly misrepresented their compliance with their legal duties under state law and have wrongfully and repeatedly disavowed those duties in an effort to mislead regulators and the public regarding the Distributor Defendants’ compliance with their legal duties.

³⁶⁵ See HDS_MDL_00510236.

620. Distributor Defendants have refused to recognize any duty beyond reporting suspicious orders. In *Masters Pharm., Inc. v. Drug Enf't Admin.*, 861 F.3d 206 (D.C. Cir. 2017), the Healthcare Distribution Management Association, n/k/a HDA, a trade association run by the Distributor Defendants, and the National Association of Chain Drug Stores (“NACDS”) submitted amicus briefs regarding the legal duty of wholesale distributors. Denying - inaccurately - the legal duties that the wholesale drug industry has been tragically recalcitrant in performing, they argued as follows:

- a. The Associations complained that the “DEA has required distributors not only to report suspicious orders, but to *investigate* orders (*e.g.*, by interrogating pharmacies and physicians) and take action to *halt* suspicious orders before they are filled.”³⁶⁶
- b. The Associations argued that, “DEA now appears to have changed its position to require that distributors not only *report* suspicious orders, but *investigate* and *halt* suspicious orders. Such a change in agency position must be accompanied by an acknowledgment of the change and a reasoned explanation for it. In other words, an agency must display awareness that it is changing position and show that there are good reasons for the new policy. This is especially important here, because imposing intrusive obligation on distributors threatens to disrupt patient access to needed prescription medications.”³⁶⁷
- c. The Associations alleged (inaccurately) that nothing “requires distributors to investigate the legitimacy of orders, or to halt shipment of any orders deemed to be suspicious.”³⁶⁸
- d. The Associations complained that the purported “practical infeasibility of requiring distributors to investigate and halt suspicious orders (as well as report them) underscores the importance of ensuring that DEA has complied with the APA before attempting to impose such duties.”³⁶⁹

³⁶⁶ Brief for HDMA and NACDS, *supra* n. 293, 2016 WL 1321983, at *4–5.

³⁶⁷ *Id.* at *8 (citations and quotation marks omitted).

³⁶⁸ *Id.* at *14.

³⁶⁹ *Id.* at *22.

- e. The Associations alleged (inaccurately) that “DEA’s regulations [] sensibly impose[] a duty on distributors simply to *report* suspicious orders, but left it to DEA and its agents to investigate and halt suspicious orders.”³⁷⁰
- f. Also inaccurately, the Associations argued that, “[i]mposing a duty on distributors – which lack the patient information and the necessary medical expertise – to investigate and halt orders may force distributors to take a shot-in-the-dark approach to complying with DEA’s demands.”³⁷¹

621. The positions taken by the trade groups is emblematic of the position taken by the Distributor Defendants in a futile attempt to deny their legal obligations to prevent diversion of the dangerous drugs.³⁷²

622. The Court of Appeals for the District of Columbia Circuit recently issued its opinion affirming that a wholesale drug distributor does, in fact, have duties beyond reporting. In *Masters Pharmaceuticals*, the Court upheld the revocation of Masters Pharmaceutical’s license and determined that DEA regulations require that in addition to reporting suspicious orders, distributors must “decline to ship the order, or conduct some ‘due diligence’ and—if it is able to determine that the order is not likely to be diverted into illegal channels—ship the order.” Masters Pharmaceutical was in violation of legal requirements because it failed to conduct necessary investigations and filled suspicious orders. A distributor’s investigation must dispel all the red flags giving rise to suspicious circumstance prior to shipping a suspicious order. The Circuit Court also rejected the argument made by the HDMA and NACDS (quoted above), that, allegedly, the DEA had created or imposed new duties.

³⁷⁰ *Id.* at *24–25

³⁷¹ *Id.* at 26.

³⁷² See Brief of HDMA in Support of Cardinal, *supra* n. 340, 2012 WL 1637016, at *3 (arguing the wholesale distributor industry “does not know the rules of the road because” they claim (inaccurately) that the “DEA has not adequately explained them”).

623. Because of the Distributor Defendants' refusals to abide by their legal obligations, the DEA has repeatedly taken administrative action to attempt to force compliance. For example, in May 2014, the United States Department of Justice, Office of the Inspector General, Evaluation and Inspections Divisions, reported that the DEA issued final decisions in 178 registrant actions between 2008 and 2012.³⁷³ As noted above, the Office of Administrative Law Judges issued a recommended decision in a total of 117 registrant actions before the DEA issued its final decision, including 76 actions involving orders to show cause and 41 actions involving immediate suspension orders.³⁷⁴ These actions include the following:

- a. On April 24, 2007, the DEA issued an *Order to Show Cause and Immediate Suspension Order* against the AmerisourceBergen Orlando, Florida distribution center ("Orlando Facility") alleging failure to maintain effective controls against diversion of controlled substances. On June 22, 2007, AmerisourceBergen entered into a settlement that resulted in the suspension of its DEA registration;
- b. On November 28, 2007, the DEA issued an *Order to Show Cause and Immediate Suspension Order* against the Cardinal Auburn, Washington Distribution Center ("Auburn Facility") for failure to maintain effective controls against diversion of hydrocodone;
- c. On December 5, 2007, the DEA issued an *Order to Show Cause and Immediate Suspension Order* against the Cardinal Lakeland, Florida Distribution Center ("Lakeland Facility") for failure to maintain effective controls against diversion of hydrocodone;
- d. On December 7, 2007, the DEA issued an *Order to Show Cause and Immediate Suspension Order* against the Cardinal Swedesboro, New Jersey Distribution Center ("Swedesboro Facility") for failure to maintain effective controls against diversion of hydrocodone;

³⁷³ *The Drug Enforcement Administration's Adjudication of Registrant Actions*, *supra* n. 313.

³⁷⁴ *Id.*

- e. On January 30, 2008, the DEA issued an *Order to Show Cause and Immediate Suspension Order* against the Cardinal Stafford, Texas Distribution Center (“Stafford Facility”) for failure to maintain effective controls against diversion of hydrocodone;
- f. On September 30, 2008, Cardinal entered into a *Settlement and Release Agreement and Administrative Memorandum of Agreement* with the DEA related to its Auburn Facility, Lakeland Facility, Swedesboro Facility and Stafford Facility. The document also referenced allegations by the DEA that Cardinal failed to maintain effective controls against the diversion of controlled substances at its distribution facilities located in McDonough, Georgia (“McDonough Facility”), Valencia, California (“Valencia Facility”) and Denver, Colorado (“Denver Facility”);
- g. On February 2, 2012, the DEA issued an *Order to Show Cause and Immediate Suspension Order* against the Cardinal Lakeland, Florida Distribution Center (“Lakeland Facility”) for failure to maintain effective controls against diversion of oxycodone; and
- h. On December 23, 2016, Cardinal agreed to pay a \$44 million fine to the DEA to resolve the civil penalty portion of the administrative action taken against its Lakeland, Florida Distribution Center.

624. Rather than abide by their non-delegable duties under public safety laws, the Distributor Defendants, individually and collectively through trade groups in the industry, pressured the U.S. Department of Justice to “halt” prosecutions and lobbied Congress to strip the DEA of its ability to immediately suspend distributor registrations. The result was a “sharp drop in enforcement actions” and the passage of the “Ensuring Patient Access and Effective Drug Enforcement Act” which, ironically, raised the burden for the DEA to revoke a distributor’s license from “imminent harm” to “immediate harm” and provided the industry the right to “cure” any violations of law before a suspension order can be issued.³⁷⁵

³⁷⁵ See Lenny Bernstein & Scott Higham, *Investigation: The DEA Slowed Enforcement While the Opioid Epidemic Grew Out of Control*, WASHINGTON POST (Oct. 22, 2016), https://www.washingtonpost.com/investigations/the-dea-slowed-enforcement-while-the-opioid-epidemic-grew-out-of-control/2016/10/22/aea2bf8e-7f71-11e6-8d13-d7c704ef9fd9_story.html?utm_term=.2f757833e3c4; Lenny Bernstein & Scott Higham,

625. In addition to taking actions to limit regulatory prosecutions and suspensions, the Distributor Defendants undertook to fraudulently convince the public that they were complying with their legal obligations, including those imposed by licensing regulations. Through such statements, the Distributor Defendants attempted to assure the public they were working to curb the opioid epidemic.

626. For example, a Cardinal executive claimed that it uses “advanced analytics” to monitor its supply chain and represented that it was being “as effective and efficient as possible in constantly monitoring, identifying, and eliminating any outside criminal activity.”³⁷⁶ Given the sales volumes and the company’s history of violations, this executive was either not telling the truth, or, if Cardinal had such a system, it ignored the results.

627. By misleading the public about the effectiveness of their controlled substance monitoring programs, the Distributor Defendants successfully concealed the facts sufficient to arouse suspicion of the claims that the Plaintiffs now assert.

628. The Distributor Defendants, pay fines as a cost of doing business in an industry that generates billions of dollars in annual revenue. They hold multiple DEA registration numbers and when one facility is suspended, they simply ship from another facility.

Investigations: U.S. Senator Calls for Investigation of DEA Enforcement Slowdown Amid Opioid Crisis, WASHINGTON POST (Mar. 6, 2017), https://www.washingtonpost.com/investigations/us-senator-calls-for-investigation-of-dea-enforcement-slowdown/2017/03/06/5846ee60-028b-11e7-b1e9-a05d3c21f7cf_story.html?utm_term=.7007bf2b9455; Eric Eyre, *DEA Agent: “We Had No Leadership” in WV Amid Flood of Pain Pills*, CHARLESTON GAZETTE-MAIL (Feb. 18, 2017), https://www.wvgazettemail.com/news/health/dea-agent-we-had-no-leadership-in-wv-amid-flood/article_928e9bcd-e28e-58b1-8e3f-f08288f539fd.html.

³⁷⁶ Lenny Bernstein et al., *How Drugs Intended for Patients Ended Up in the Hands of Illegal Users: “No One Was Doing Their Job,”* WASHINGTON POST (Oct. 22, 2016), available at https://www.washingtonpost.com/investigations/how-drugs-intended-for-patients-ended-up-in-the-hands-of-illegal-users-no-one-was-doing-their-job/2016/10/22/10e79396-30a7-11e6-8ff7-7b6c1998b7a0_story.html?utm_term=.a5f051722a7a.

629. The wrongful actions and omissions of the Distributor Defendants which have caused the diversion of opioids and which have been a substantial contributing factor to and/or proximate cause of the opioid crisis are alleged in greater detail in Plaintiffs' allegations of Defendants' unlawful acts below.

630. The Distributor Defendants have abandoned their duties imposed under Kentucky law, taken advantage of a lack of adequate law enforcement, and abused the privilege of distributing controlled substances.

XIII. THE NATIONAL RETAIL PHARMACIES WERE ON NOTICE OF AND CONTRIBUTED TO ILLEGAL DIVERSION OF OPIOIDS

631. National retail pharmacy chains earned enormous profits by flooding the country with prescription opioids.³⁷⁷ They were keenly aware of the oversupply of prescription opioids through the extensive data and information they developed and maintained as both distributors and dispensaries. Yet, instead of taking any meaningful action to stem the flow of opioids into communities, they continued to participate in the oversupply and profit from it.

632. Each of the National Retail Pharmacies does substantial business throughout the United States and Kentucky. This business includes the distribution of prescription opioids.

633. Data shows that the National Retail Pharmacies distributed substantial quantities of opioids, including fentanyl, hydrocodone, and oxycodone in Kentucky. In addition, they distributed substantial quantities of opioids in other states, and these drugs were diverted from these other states to Kentucky. The National Retail Pharmacies failed to take meaningful action to stop this diversion despite their knowledge of it, and contributed substantially to the diversion problem.

³⁷⁷ Plaintiffs' allegations of wrongdoing are pointing to the National Retail Pharmacies not the pharmacy industry who in general serve a vital healthcare function in the United States.

634. The National Retail Pharmacies developed and maintained extensive data on opioids they distributed. Through this data, National Retail Pharmacies had direct knowledge of patterns and instances of improper distribution, and use of opioids in communities throughout the country, and in Kentucky in particular. They used the data to evaluate their own sales activities and workforce. On information and belief, the National Retail Pharmacies also provided other Defendants with the data in exchange for rebates or other forms of consideration. The National Retail Pharmacies' data is a valuable resource that they could have used to help stop diversion, but failed to do so.

A. The National Retail Pharmacies Have a Duty to Prevent Diversion

635. Each participant in the supply chain of opioid distribution, including the National Retail Pharmacies, is responsible for preventing diversion of opioids into the illegal market by, among other things, monitoring and reporting suspicious activity.

636. The National Retail Pharmacies, like manufacturers and other distributors, are registrants under Kentucky law. Pharmacy registrants are required to ensure that opioid prescriptions filled by them are written for a legitimate patient for a legitimate medical need in the usual course of practice for the prescriber. *See* KRS § 218A.180(3)(a). In addition, “[e]ach pharmacy shall comply with KRS § 218A.202,” which requires that “Every practitioner or pharmacy which dispenses a controlled substance to a person in Kentucky, or to a person at an address in Kentucky, shall report to the Cabinet for Health and Family Services the data required by this section, which includes the reporting of any Schedule II controlled substance dispensed at a facility licensed by the cabinet and a Schedule II through Schedule V controlled substance regardless of dosage when dispensed by the emergency department of a hospital to an emergency department patient.” KRS § 315.035(7); KRS § 218A.202(3). Because pharmacies themselves

are registrants under the CSA, the duty to prevent diversion lies with the pharmacy entity, not the individual pharmacist alone.

637. The DEA, among others, has provided extensive guidance to pharmacies concerning their duties to the public. The guidance advises pharmacies how to identify suspicious orders and other evidence of diversion.

638. Suspicious pharmacy orders include orders unusually large size, orders that are disproportionately large in comparison to the population of a community served by the pharmacy, orders that deviate from a normal pattern and/or orders of unusual frequency and duration, among others.

639. Suspicious pharmacy orders are red flags for if not direct evidence of diversion.

640. Other signs of diversion can be observed through data gathered, consolidated, and analyzed by the National Retail Pharmacies themselves. That data allows them to observe patterns or instances of sales and distribution that are potentially suspicious, of oversupply in particular stores or geographic areas, or of prescribers or facilities that seem to engage in improper conduct.

641. According to industry standards, if a pharmacy finds evidence of prescription diversion, the local Board of Pharmacy and DEA must be contacted.

642. Despite their legal obligations as registrants under state law, the National Retail Pharmacies allowed widespread diversion to occur—and they did so knowingly. They knew that they made money by distributing opioids under suspicious orders.

643. Performance metrics and prescription quotas adopted by the National Retail Pharmacies for their retail stores contributed to their failure. For instance, under CVS's Metrics System, pharmacists are directed to meet high goals that make it difficult, if not impossible, to

comply with applicable laws and regulations. There is no measurement for pharmacy accuracy or customer safety. Moreover, the bonuses for pharmacists are calculated, in part, on how many orders that pharmacist fills within a year. The result is both deeply troubling and entirely predictable: opioids flowed out of National Retail Pharmacies and into communities throughout the country and in Kentucky. The policies remained in place even as the epidemic raged.

644. In consideration of a reasonable opportunity for further investigation and discovery, Plaintiffs allege that this problem was compounded by the National Retail Pharmacies' failure to adequately train their pharmacists and pharmacy technicians on how to properly and adequately handle orders for opioid painkillers, including what constitutes a proper inquiry into whether an order is legitimate, whether an order is likely for a condition with an approved treatment with opioids, and what measures and/or actions to take when suspicious circumstances are present, including when prescriptions are procured and pills supplied for the purpose of illegal diversion and drug trafficking.

645. In consideration of a reasonable opportunity for further investigation and discovery, Plaintiffs allege that the National Retail Pharmacies also failed to adequately use data available to them to identify pill-mills that were ordering suspicious amounts of opioids, or to adequately use data available to them to do statistical analysis to prevent the filling of suspicious orders that have contributed to the opioid crisis.

646. In consideration of a reasonable opportunity for further investigation and discovery, Plaintiffs allege that the National Retail Pharmacies failed to analyze: (a) the number of opioid orders filled by individual pharmacies relative to the population of the pharmacy's community; (b) the increase in opioid sales relative to past years; (c) the number of opioid orders

filled relative to other drugs; and (d) the increase in annual opioid sales relative to the increase in annual sales of other drugs.

647. In consideration of a reasonable opportunity for further investigation and discovery, Plaintiffs allege that the National Retail Pharmacies also failed to conduct adequate internal or external audits of their opioid sales to identify patterns regarding prescriptions that should not have been filled and to create policies accordingly, or if they conducted such audits, they failed to take any meaningful action as a result.

648. In consideration of a reasonable opportunity for further investigation and discovery, Plaintiffs allege that the National Retail Pharmacies also failed to effectively respond to concerns raised by their own employees regarding inadequate policies and procedures regarding the filling of opioid orders.

649. The National Retail Pharmacies were, or should have been, fully aware that the quantity of opioids being distributed by them was untenable, and in many areas patently absurd; yet, they did not take meaningful action to investigate or to ensure that they were complying with their duties and obligations under the law with regard to controlled substances.

B. Multiple Enforcement Actions Against the National Retail Pharmacies Confirm their Compliance Failures.

650. The National Retail Pharmacies have long been on notice of their failure to abide by the law and regulations governing the distribution of prescription opioids. Indeed, several of the National Retail Pharmacies have been repeatedly penalized for their illegal practices. In consideration of a reasonable opportunity for further investigation and discovery, Plaintiffs allege that based upon the widespread nature of these violations, these enforcement actions are the product of, and confirm, national policies and practices of the National Retail Pharmacies.

1. CVS

651. CVS is one of the largest companies in the world, with annual revenue of more than \$150 billion. According to news reports, it manages medications for nearly 90 million customers at 9,700 retail locations. CVS could be a force for good in connection with the opioid crisis, but like other Defendants, CVS sought profits over people.

652. CVS is a repeat offender; the company has paid fines totaling over \$40 million as the result of a series of investigations by the DEA and the DOJ. It nonetheless treated these fines as the cost of doing business and has allowed distribution of opioids in quantities significantly higher than any plausible legitimate need would require, and to continue violating its obligations under the law.

653. As recently as March 2019, CVS entered into a \$535,000 settlement with the U.S. Attorney's Office for the District of Rhode Island regarding allegations that its pharmacies in Rhode Island violated federal law "including by... in 39 instances between September 9, 2015 and June 18, 2017, filling a prescription for a Schedule II drug under circumstances ... that the CVS pharmacist filling the prescription knew or had reason to know that the prescription in question was invalid or unauthorized..."

654. This fine was preceded by numerous others throughout the county.

655. In July 2017, CVS entered into a \$5 million settlement with the U.S. Attorney's Office for the Eastern District of California regarding allegations that its pharmacies failed to keep and maintain accurate records of Schedule II, III, IV, and V controlled substances.³⁷⁸

³⁷⁸ Press Release, U.S. Attorney's Office E. Dist. of Cal., CVS Pharmacy Inc. Pays \$5M to Settle Alleged Violations of the Controlled Substance Act, U.S. Dep't of Just. (July 11, 2017), available at <https://www.justice.gov/usao-edca/pr/cvs-pharmacy-inc-pays-5m-settle-alleged-violationscontrolled-substance-act>.

656. In February 2016, CVS paid \$8 million to settle allegations made by the DEA and the DOJ that from 2008-2012, CVS stores and pharmacists in Maryland violated their duties under the CSA and filling orders with no legitimate medical purpose.³⁷⁹

657. In October 2016, CVS paid \$600,000 to settle allegations by the DOJ that stores in Connecticut failed to maintain proper records in accordance with the CSA.³⁸⁰

658. In September 2016, CVS entered into a \$795,000 settlement with the Massachusetts Attorney General wherein CVS agreed to require pharmacy staff to access the state's prescription monitoring program website and review a patient's drug use history before sales of certain opioid drugs.³⁸¹

659. In June 2016, CVS agreed to pay the DOJ \$3.5 million to resolve allegations that 50 of its stores violated the CSA by filling forged prescriptions for controlled substances—mostly addictive painkillers—more than 500 times between 2011 and 2014.³⁸²

³⁷⁹ Press Release, U.S. Attorney's Office Dist. of Md., United States Reaches \$8 Million Settlement Agreement with CVS for Unlawful Distribution of Controlled Substances, U.S. Dep't of Just. (Feb. 12, 2016), *available at* <https://www.justice.gov/usao-md/pr/united-states-reaches-8-millionsettlement-agreement-cvs-unlawful-distribution-controlled>.

³⁸⁰ Press Release, U.S. Attorney's Office Dist. of Conn., CVS Pharmacy Pays \$600,000 to Settle Controlled Substances Act Allegations, U.S. Dep't of Just. (Oct. 20, 2016), *available at* <https://www.justice.gov/usao-ct/pr/cvs-pharmacy-pays-600000-settle-controlled-substances-actallegations>.

³⁸¹ Dialynn Dwyer, *CVS will pay \$795,000, strengthen policies around dispensing opioids in agreement with state*, Boston.com (Sept. 1, 2016), *available at* <https://www.boston.com/news/localnews/2016/09/01/cvs-will-pay-795000-strengthen-policies-around-dispensing-opioids-inagreement-with-state>.

³⁸² Press Release, U.S. Attorney's Office Dist. of Mass., CVS to Pay \$3.5 Million to Resolve Allegations that Pharmacists Filled Fake Prescriptions, U.S. Dep't of Just. (June 30, 2016), <https://www.justice.gov/usao-ma/pr/cvs-pay-35-million-resolve-allegations-pharmacists-filledfake-prescriptions>.

660. In August 2015, CVS entered into a \$450,000 settlement with the U.S. Attorney's Office for the District of Rhode Island to resolve allegations that several of its Rhode Island stores violated the CSA by filling invalid prescriptions and maintaining deficient records. The United States alleged that CVS retail pharmacies in Rhode Island filled a number of forged prescriptions with invalid DEA numbers, and filled multiple prescriptions written by psychiatric nurse practitioners for hydrocodone, despite the fact that these practitioners were not legally permitted to prescribe that drug. Additionally, the government alleged that CVS had recordkeeping deficiencies.³⁸³

661. In May 2015, CVS agreed to pay a \$22 million penalty following a DEA investigation that found that employees at two pharmacies in Sanford, Florida, had sold opioids, "based on prescriptions that had not been issued for legitimate medical purposes by a health care provider acting in the usual course of professional practice. CVS also acknowledged that its retail pharmacies had a responsibility to dispense only those prescriptions that were issued based on legitimate medical need."³⁸⁴

³⁸³ Press Release, U.S. Attorney's Office Dist. of R.I., Drug Diversion Claims Against CVS Health Corp. Resolved With \$450,000 Civil Settlement, U.S. Dep't of Just. (Aug. 10, 2015), *available at* <https://www.justice.gov/usao-ri/pr/drug-diversion-claims-against-cvs-health-corp-resolved-450000-civil-settlement>.

³⁸⁴ Press Release, U.S. Attorney's Office M. Dist. of Fla., United States Reaches \$22 Million Settlement Agreement with CVS For Unlawful Distribution of Controlled Substances, U.S. Dep't of Just. (May 13, 2015), *available at* <https://www.justice.gov/usao-mdfl/pr/united-states-reaches-22-million-settlement-agreement-cvs-unlawful-distribution>.

662. In September 2014, CVS agreed to pay \$1.9 million in civil penalties to resolve allegations it filled prescriptions written by a doctor whose controlled-substance registration had expired.³⁸⁵

663. In August 2013, CVS was fined \$350,000 by the Oklahoma Pharmacy Board for improperly selling prescription narcotics in at least five locations in the Oklahoma City metropolitan area.³⁸⁶

664. Dating back to 2006, CVS retail pharmacies in Oklahoma and elsewhere intentionally violated the CSA by filling prescriptions signed by prescribers with invalid DEA registration numbers.³⁸⁷

2. Walgreens

665. Walgreens is the second-largest pharmacy store chain in the United States behind CVS, with annual revenue of more than \$118 billion. According to its website, Walgreens operates more than 8,100 retail locations and filled 990 million prescriptions on a 30-day adjusted basis in fiscal 2017.

666. Walgreens also has been penalized for serious and flagrant violations of the CSA. Indeed, Walgreens agreed to the largest settlement in DEA history—\$80 million—to resolve allegations that it committed an unprecedented number of violations of the CSA, including

³⁸⁵ Patrick Danner, H-E-B, CVS Fined Over Prescriptions, San Antonio Express-News (Sept. 5, 2014), *available at* <http://www.expressnews.com/business/local/article/H-E-B-CVSfined-over-prescriptions-5736554.php>.

³⁸⁶ Andrew Knittle, *Oklahoma pharmacy board stays busy, hands out massive fines at times*, NEWSOK (May 3, 2015), *available at* <http://newsok.com/article/5415840>.

³⁸⁷ Press Release, U.S. Attorney's Office W. Dist. of Okla., CVS to Pay \$11 Million To Settle Civil Penalty Claims Involving Violations of Controlled Substances Act, U.S. Dep't of Just. (Apr. 3, 2013), *available at* <https://www.justice.gov/usao-wdok/pr/cvs-pay-11-million-settle-civil-penaltyclaims-involving-violations-controlled>.

negligently allowing controlled substances such as oxycodone and other prescription painkillers to be diverted for abuse and illegal black-market sales.³⁸⁸

667. As part of the settlement, Walgreens admitted that it failed to uphold its obligations as a DEA registrant regarding the above-described conduct.³⁸⁹

668. The settlement resolved investigations into and allegations of CSA violations in Florida, New York, Michigan, and Colorado that resulted in the diversion of millions of opioids into illicit channels.

669. Walgreens' Florida operations at issue in this settlement highlight its egregious conduct regarding diversion of prescription opioids. Walgreens' Florida pharmacies each allegedly ordered more than one million dosage units of oxycodone in 2011—more than ten times the average amount.³⁹⁰

670. They increased their orders over time, in some cases as much as 600% in the space of just two years, including, for example, supplying a town of 3,000 with 285,800 orders of oxycodone in a one-month period. Yet Walgreens' corporate officers not only turned a blind eye, but provided pharmacists with incentives through a bonus program that compensated them based on the number of prescriptions filled at the pharmacy. In fact, corporate attorneys at Walgreens suggested, in reviewing the legitimacy of prescriptions coming from pain clinics, that “if these are legitimate indicators of inappropriate prescriptions perhaps we should consider not

³⁸⁸ Press Release, U.S. Attorney's Office S. Dist. of Fla., Walgreens Agrees to Pay a Record Settlement of \$80 Million for Civil Penalties Under the Controlled Substances Act, U.S. Dep't of Just. (June 11, 2013), *available at* <https://www.justice.gov/usao-sdfl/pr/walgreens-agrees-pay-recordsettlement-80-million-civil-penalties-under-controlled>.

³⁸⁹ *Id.*

³⁹⁰ Order to Show Cause and Immediate Suspension of Registration, *In the Matter of Walgreens Co.* (Drug Enf't Admin. Sept. 13, 2012).

documenting our own potential noncompliance,” underscoring Walgreens’ attitude that profit outweighed compliance with the law or the health of communities.³⁹¹

671. Defendant Walgreens’ settlement with the DEA stemmed from the DEA’s investigation into Walgreens’ distribution center in Jupiter, Florida, which was responsible for significant opioid diversion in Florida. According to the Order to Show Cause, Defendant Walgreens’ corporate headquarters pushed to increase the number of oxycodone sales to Walgreens’ Florida pharmacies, and provided bonuses for pharmacy employees based on number of prescriptions filled at the pharmacy in an effort to increase oxycodone sales. In July 2010, Defendant Walgreens ranked all of its Florida stores by number of oxycodone prescriptions dispensed in June of that year, and found that the highest-ranking store in oxycodone sales sold almost 18 oxycodone prescriptions per day. All of these prescriptions were filled by the Jupiter Center.³⁹²

672. The six retail pharmacies in Florida that received the suspicious drug shipments from the Jupiter Distribution Center, in turn, filled customer prescriptions that they knew or should have known were not for legitimate medical use.³⁹³

673. Walgreens has also settled with a number of state attorneys general, including West Virginia (\$575,000) and Massachusetts (\$200,000).³⁹⁴

³⁹¹ *Id.*

³⁹² *Id.*

³⁹³ *Id.*

³⁹⁴ *Walgreens to pay \$200,000 settlement for lapses with opioids*, APhA (Jan. 25, 2017) available at <https://www.pharmacist.com/article/walgreens-pay-200000-settlement-lapses-opioids>. .

674. The Massachusetts Attorney General's Medicaid Fraud Division found that, from 2010 through most of 2015, multiple Walgreens stores across the state failed to monitor the opioid use of some Medicaid patients who were considered high-risk.

675. In January 2017, an investigation by the Massachusetts Attorney General found that some Walgreens pharmacies failed to monitor patients' drug use patterns and didn't use sound professional judgment when distributing opioids and other controlled substances—despite the context of soaring overdose deaths in Massachusetts. Walgreens agreed to pay \$200,000 and follow certain procedures for dispensing opioids.³⁹⁵

3. Rite Aid

676. With approximately 4,600 stores in 31 states and the District of Columbia, Rite Aid is the largest drugstore chain on the East Coast and the third-largest in the United States, with annual revenue of more than \$21 billion.

677. In 2009, as a result of a multi-jurisdictional investigation by the DOJ, Rite Aid and nine of its subsidiaries in eight states were fined \$5 million in civil penalties for its violations of the CSA.³⁹⁶

678. The investigation revealed that from 2004 onwards, Rite Aid pharmacies across the country had a pattern of non-compliance with the requirements of the CSA and regulations that lead to the diversion of prescription opioids in and around the communities of the Rite Aid

³⁹⁵ *Id.*

³⁹⁶ Press Release, Dep't of Justice, Rite Aid Corporation and Subsidiaries Agree to Pay \$5 Million in Civil Penalties to Resolve Violations in Eight States of the Controlled Substances Act, U.S. Dep't of Just. (Jan. 12, 2009), <https://www.justice.gov/opa/pr/rite-aid-corporation-andsubsidiaries-agree-pay-5-million-civil-penalties-resolve-violations>.

pharmacies investigated. Rite Aid also failed to notify the DEA of losses of controlled substances in violation of 21 U.S.C. § 842(a)(5) and 21 C.F.R 1301.76(b).³⁹⁷

679. Numerous state and federal drug diversion prosecutions have occurred in which prescription opioid pills were procured from National Retail Pharmacies. The allegations in this Complaint do not attempt to identify all these prosecutions, and the information above is merely by way of example.

680. The litany of state and federal actions against the National Retail Pharmacies demonstrate that they routinely, and as a matter of standard operation procedure, violated their legal obligations under the CSA and other laws and regulations that govern the distribution and dispensing of prescription opioids.

681. Throughout the country and in Kentucky in particular, the National Retail Pharmacies were or should have been aware of numerous red flags of potential suspicious activity and diversion.

682. On information and belief, from the catbird seat of their retail pharmacy operations, the National Retail Pharmacies knew or reasonably should have known about the disproportionate flow of opioids into Kentucky and the operation of “pill mills” that generated opioid prescriptions that, by their quantity or nature, were red flags for if not direct evidence of illicit supply and diversion. Additional information was provided by news reports, and state and federal regulatory actions, including prosecutions of pill mills in the area.

683. On information and belief, the National Retail Pharmacies knew or reasonably should have known about the devastating consequences of the oversupply and diversion of prescription opioids, including spiking opioid overdose rates in the community.

³⁹⁷ *Id.*

684. On information and belief, because of (among others sources of information) regulatory and other actions taken against the National Retail Pharmacies directly, actions taken against others pertaining to prescription opioids obtained from their retail stores, complaints and information from employees and other agents, and the massive volume of opioid prescription drug sale data that they developed and monitored, the National Retail Pharmacies were well aware that their distribution and dispensing activities fell far short of legal requirements.

685. The National Retail Pharmacies' actions and omissions in failing to effectively prevent diversion and failing to monitor, report, and prevent suspicious orders have contributed significantly to the opioid crisis by enabling, and failing to prevent, the diversion of opioids.

XIV. DEFENDANTS' UNLAWFUL CONDUCT AND BREACHES OF LEGAL DUTIES CAUSED THE HARM AND SUBSTANTIAL DAMAGE ALLEGED HEREIN

686. As the Marketing Defendants' and Purdue's efforts to expand the market for opioids increased so have the rates of prescription and sale of their products — and the rates of opioid-related substance abuse, hospitalization, and death among the people of the United States. The Supply Chain Defendants have continued to unlawfully ship these massive quantities of opioids.

687. There is a “parallel relationship between the availability of prescription opioid analgesics through legitimate pharmacy channels and the diversion and abuse of these drugs and associated adverse outcomes.”³⁹⁸

688. Opioid analgesics are widely diverted and improperly used, and the widespread use of the drugs has resulted in a national epidemic of opioid overdose deaths and addictions.³⁹⁹

³⁹⁸ See Richard C. Dart et al, *Trends in Opioid Analgesic Abuse and Mortality in the United States*, 372 N. Eng. J. Med. 241-248 (2015), doi: 10.1056/NEJMsa1406143, available at <http://www.nejm.org/doi/full/10.1056/NEJMsa1406143>.

689. The epidemic is “directly related to the increasingly widespread misuse of powerful opioid pain medications.”⁴⁰⁰

690. The increased abuse of prescription painkillers along with growing sales has contributed to a large number of overdoses and deaths.⁴⁰¹

691. As shown above, the opioid epidemic has escalated with devastating effects: substantial opiate-related substance abuse, hospitalization, and death that goes hand in hand with Defendants’ increased distribution of opioids.

692. Because of the well-established relationship between the use of prescription opioids and the use of non-prescription opioids, like heroin, the massive distribution of opioids by Defendants has caused the opioid epidemic to include heroin addiction, abuse, and death.

693. Defendants repeatedly and purposefully breached their duties under federal and Kentucky law, and such breaches are direct and proximate causes of, and/or substantial factors leading to, the widespread diversion of prescription opioids for nonmedical purposes and the foreseeable, inevitable financial burdens imposed on and incurred by hospitals and other health care providers.

694. Hospitals are integral to the solution to the opioid epidemic, because they can “aid in the proper treatment of postoperative pain while also helping to combat a nationwide epidemic.”⁴⁰² Indeed, “[h]ospital pharmacists...are in an ideal position to help address the

³⁹⁹ See Volkow & McLellan, *supra* n. 99.

⁴⁰⁰ See Califf, *et al.*, *supra* n. 30.

⁴⁰¹ See Press Release, Centers for Disease Control and Prevention, U.S. Dep’t of Health and Human Servs., *supra* n. 25.

⁴⁰² Opioid Exit Plan, *supra* n. 181.

opioid epidemic and make sure these agents are used appropriately.”⁴⁰³ But Defendants’ wrongful conduct has jeopardized the ability of Plaintiffs and other hospital purchasers to properly limit their purchasing and dispensing of opioids, particularly at the key junctures of patient admission and discharge. Indeed, by creating and fueling the opioid epidemic, Defendants have impaired the hospitals’ ability to perform their integral responsibilities to patients.

695. During admission, hospital professionals routinely consult with the patient to assess which medications the patient is taking at home. But, due to Defendants’ conduct, hospitals can no longer trust patients to self-report their prescriptions. Hospital pharmacists may also check available databases to ensure that patients are not stockpiling prescription opioids, but such databases often do not record the actual flow of opioids.⁴⁰⁴ Hospital pharmacies’ inability to rely on their patients’ self-reporting, and having to take additional steps to independently verify their patients’ purchases from other sources, imposes additional burdens on hospitals.

696. Then, before discharge, hospital professionals “obtain a list of planned outpatient prescriptions and perform a counseling session on how to safely and effectively control postoperative pain.”⁴⁰⁵ The hospitals’ efforts to provide meaningful counseling is subverted by Defendants’ sales practices described in the Complaint, pursuant to which Defendants have disseminated misinformation throughout all levels of the marketplace and fostered increased demand for their products.

⁴⁰³ Joey Sweeney, *Hospital Pharmacists Can Help Reduce Opioid Prescriptions*, PHARMACY TODAY (July 2016) (emphasis added), available at [https://www.pharmacytoday.org/article/S1042-0991\(16\)30505-9/fulltext](https://www.pharmacytoday.org/article/S1042-0991(16)30505-9/fulltext).

⁴⁰⁴ *Id.* at ¶ 32.

⁴⁰⁵ Opioid Exit Plan, *supra* n. 181.

697. Hospitals must admit opioid users who present in need of intensive care or who display symptoms of mental illness. Defendants knew that federal and state law require hospitals to admit and treat opioid-dependent patients. Similarly, if a pregnant opioid-dependent patient presents for treatment, the hospital must provide care for both the opioid-addicted mother and the opioid-dependent baby. Defendants relied on Plaintiffs to provide a safety net to prevent overdose deaths and treat health consequences arising from opioid dependence and depended on hospitals themselves to mitigate the health consequences of their illegal activities.⁴⁰⁶ In 2011, it is “estimated that [there were] greater than 420[,000 emergency room] visits related to the misuse of abuse of narcotic pain relievers” in the United States.⁴⁰⁷ Hospitals bear an enormous burden in providing care, as insurance covers only a portion of the cost.

698. The increased financial burdens on hospitals include, but are not limited to the following:

- a. Unreimbursed, uncompensated, and/or undercompensated costs for providing healthcare and medical care, additional diagnostic, therapeutic and other treatments for patients suffering from opioid-related addiction or disease, including physical and mental disabilities, overdoses and deaths.;
- b. Costs associated with patient counseling with respect to pain management, necessitated by overprescription to the general population and dissemination of false and misleading information to prospective patients and others; as hospitals and other providers question their patients’ self-reporting, it necessitates further steps to be taken in all phases of treatment and counseling;
- c. Unreimbursed, uncompensated, and/or undercompensated costs of opioids purchased by hospitals themselves, which were direct targets of the

⁴⁰⁶ *Id.* at ¶ 19.

⁴⁰⁷ Cindy Williams, Vice President and Chief Pharmacy Officer, Riverside Health System, *Establishment of an Opioid Stewardship Program*, available at http://www.vshp.org/uploads/6/3/6/0/6360223/williams-opioid_1_per_page.pdf (“Va. Hospital Pharmacists Paper”).

Defendants' marketing campaigns;

- d. Unreimbursed, uncompensated, and/or undercompensated costs of prescription drugs used to treat addiction;
- e. Costs of training additional personnel in the proper treatment of drug overdoses;
- f. Costs associated with obtaining and training staff in the application of naloxone—an opioid antagonist used to block the deadly effects of opioids in the context of overdose;
- g. Additional unreimbursed, uncompensated, and/or undercompensated costs for providing mental-health services, treatment, counseling, rehabilitation services, and social services to victims of the opioid epidemic and their families;
- h. Unreimbursed, uncompensated, and/or undercompensated costs for providing treatment of infants born with opioid-related medical conditions, or born dependent on opioids due to drug use by mother during pregnancy; and
- i. Substantial reimbursement shortages for patients treated with opioid-related conditions or comorbidities and patients for whom opioid dependence is a condition.

699. The unlawful diversion of prescription opioids is a direct and proximate cause of, and/or substantial factor leading to, the opioid epidemic, prescription opioid abuse, dependence, morbidity, and mortality in the United States. This diversion and the epidemic are direct causes of foreseeable harm to Plaintiffs.

700. Defendants' unlawful conduct resulted in direct and foreseeable, past and continuing, economic damages for which Plaintiffs seek relief.

A. Conspiracy Allegations

701. The Defendants conspired with each other and with Purdue (not named in this Complaint as a Defendant), to engage in the wrongful conduct complained of herein and intended to benefit both independently and jointly from their wrongful conduct.

1. Conspiracy Among the Marketing Defendants and Purdue

702. The Marketing Defendants and Purdue agreed among themselves to set up, develop, and fund an unbranded promotion and marketing network to promote the use of opioids for the management of pain. The promotion and marketing network was intended and designed to mislead physicians, patients, health care providers such as hospitals, and health care payors through misrepresentations and omissions regarding the appropriate uses, risks, and safety of opioids in order to increase sales, revenue, and profit from their opioid products.

703. This interconnected and interrelated network relied on the Marketing Defendants' and Purdue's collective use of unbranded marketing materials, such as KOLs, scientific literature, CMEs, patient education materials, and Front Groups developed and funded collectively by the Marketing Defendants and Purdue intended to mislead consumers and medical providers, such as hospitals, of the appropriate uses, risks, and safety of opioids.

704. The Marketing Defendants' and Purdue's collective marketing scheme to increase opioid prescriptions, sales, revenues and profits centered around the development, dissemination, and reinforcement of nine false propositions: (1) that addiction is rare among patients taking opioids for pain; (2) that addiction risk can be effectively managed; (3) that symptoms of addiction exhibited by opioid patients are actually symptoms of an invented condition dubbed "pseudoaddiction"; (4) that withdrawal is easily managed; (5) that increased dosing presents no significant risks; (6) that long-term use of opioids improves function; (7) that the risks of alternative forms of pain treatment are greater than the adverse effects of opioids; (8) that use of time-released dosing prevents addiction; and (9) that abuse-deterrent formulations provide a solution to opioid abuse.

705. The Marketing Defendants and Purdue knew that none of these propositions are true.

706. Each Marketing Defendant and Purdue worked individually and collectively to develop and actively promulgate these nine false propositions in order to mislead physicians, patients, and health care providers, such as hospitals and healthcare payors regarding the appropriate uses, risks, and safety of opioids.

707. What is particularly remarkable about the Marketing Defendants' and Purdue's efforts is the seamless method in which the Marketing Defendants and Purdue joined forces to achieve their collective goal: to persuade consumers and medical providers, such as hospitals, of the safety of opioids, and to hide their actual risks and dangers. In doing so, the Marketing Defendants and Purdue effectively built a new – and extremely lucrative – opioid marketplace for their select group of industry players.

708. The Marketing Defendants' and Purdue's unbranded promotion and marketing network was a wildly successful marketing tool that achieved marketing goals that would have been impossible to have been met by a single or even a handful of the network's distinct corporate members.

709. For example, the network members pooled their vast marketing funds and dedicated them to expansive and normally cost-prohibitive marketing ventures, such as the creation of Front Groups. These collaborative networking tactics allowed each Marketing Defendant and Purdue to diversify its marketing efforts, all the while sharing any risk and exposure, financial and/or legal, with other Marketing Defendants and Purdue.

710. The most unnerving tactic utilized by the Marketing Defendants' and Purdue's network was their unabashed mimicry of the scientific method of citing “references” in their materials. In the scientific community, cited materials and references are rigorously vetted by

objective unbiased and disinterested experts in the field, and an unfounded theory or proposition would, or should, never gain traction.

711. Marketing Defendants and Purdue put their own twist on the scientific method: they worked together to manufacture wide support for their unfounded theories and propositions involving opioids. Due to their sheer numbers and resources, the Marketing Defendants and Purdue were able to create a false consensus through their materials and references.

712. An illustrative example of the Marketing Defendants' and Purdue's utilization of this tactic is the wide promulgation of the Porter & Jick Letter, which declared the incidence of addiction "rare" for patients treated with opioids. The authors had analyzed a database of hospitalized patients who were given opioids in a controlled setting to ease suffering from acute pain. These patients were not given long-term opioid prescriptions or provided opioids to administer to themselves at home, nor was it known how frequently or infrequently and in what doses the patients were given their narcotics. Rather, it appears the patients were treated with opioids for short periods of time under in-hospital doctor supervision.

713. Nonetheless, Marketing Defendants and Purdue widely and repeatedly cited this letter as proof of the low addiction risk in connection with taking opioids despite the letter's obvious shortcomings. Marketing Defendants' and Purdue's egregious misrepresentations based on this letter included claims that less than one percent of opioid users became addicted.

714. Marketing Defendants' and Purdue's collective misuse of the Porter & Jick Letter helped the opioid manufacturers convince patients and healthcare providers, such as hospitals that opioids were not a concern. The enormous impact of Marketing Defendants' and Purdue's misleading amplification of this letter was well documented in another letter published in the NEJM on June, 1, 2017, describing the way the one-paragraph 1980 letter had been irresponsibly

cited and, in some cases, “grossly misrepresented.” In particular, the authors of this letter explained:

[W]e found that a five-sentence letter published in the Journal in 1980 was heavily and uncritically cited as evidence that addiction was rare with long-term opioid therapy. We believe that this citation pattern contributed to the North American opioid crises by helping to shape a narrative that allayed prescribers’ concerns about the risk of addiction associated with long-term opioid therapy...

715. By knowingly misrepresenting the appropriate uses, risks, and safety of opioids, the Marketing Defendants committed overt acts in furtherance of their conspiracy.

2. **Conspiracy Among the Marketing Defendants, Purdue, and the Supply Chain Defendants**

716. In addition, and on an even broader level, all the Marketing Defendants and Purdue and Supply Chain Defendants took advantage of the industry structure, including end-running its internal checks and balances, to their collective advantage. The Marketing Defendants and Purdue and Supply Chain Defendants agreed among themselves to increase the supply of opioids and fraudulently increase the quotas that governed the manufacture and supply of prescription opioids. The Marketing Defendants and Purdue and Supply Chain Defendants did so to increase sales, revenue, and profit from their opioid products.

717. The interaction and length of the relationships between and among the Marketing Defendants and Supply Chain Defendants reflects a deep level of interaction and cooperation between the Marketing Defendants and Purdue and Supply Chain Defendants in a tightly knit industry. The Marketing Defendants and Purdue and Supply Chain Defendants were not separate groups operating in isolation or forced to work together in a closed system. The Marketing Defendants and Purdue and Supply Chain Defendants operated together as a united entity, working together on multiple fronts, to engage in the unlawful sale of prescription opioids.

718. The Marketing Defendants and Purdue and Supply Chain Defendants collaborated to expand the opioid market in an interconnected and interrelated network in the following ways, as set forth more fully below including, for example, membership in the Healthcare Distribution Alliance.

719. The Marketing Defendants and Purdue and Distributor Defendants utilized their membership in the HDA and other forms of collaboration to form agreements about their approach to their duties under the CSA, as well as under Kentucky and other laws to report suspicious orders. The Marketing Defendants and Purdue and Supply Chain Defendants overwhelmingly agreed on the same approach – to fail to identify, report, or halt suspicious opioid orders, and fail to prevent diversion. The Marketing Defendants and Purdue and Supply Chain Defendants’ understanding to restrict reporting provided an added layer of insulation from DEA scrutiny for the entire industry as the Marketing Defendants and Purdue and Supply Chain Defendants were thus collectively responsible for each other’s compliance with their reporting obligations. The Marketing Defendants and Purdue and Supply Chain Defendants were aware, both individually and collectively, of the suspicious orders that flowed directly from the Marketing Defendants and Purdue and Supply Chain Defendants’ facilities.

720. The Marketing Defendants and Purdue and Supply Chain Defendants knew that their own conduct could be reported by other Defendants and that their failure to report suspicious orders they filled could be brought to the government’s attention. As a result, the Marketing Defendants and Purdue and Supply Chain Defendants had an incentive to communicate with each other about the reporting or suspicious orders to ensure consistency in their dealings with the authorities.

721. The desired consistency, and collective end goal were achieved. The Marketing Defendants and Purdue and Supply Chain Defendants achieved blockbuster profits through higher opioid sales by orchestrating the unimpeded flow of opioids.

722. By their participation in this Conspiracy, all of the Defendants are responsible for the actions of the other Conspirators taken in furtherance of the conspiracy, and share liability for the claims for which they are charged as having liability as Conspirators.

723. The countless acts of the Manufacturing Defendants and Purdue in deceptively marketing opioids each constitutes an overt act in furtherance of a conspiracy.

724. The countless acts of the Supply Chain Defendants in filling suspicious orders, in the face of overwhelming evidence of drug diversions, including the acts and practices for which some of the Supply Chain Defendants have been administratively sanctioned, each constitutes acts in furtherance of a conspiracy.

725. The acts of coordination of the Manufacturing Defendants and Purdue, and Supply Chain Defendants, through trade associations such as HAD and through other means, designed to avoid regulatory scrutiny while they attempted to create and supply an ever-expanding market for opioids by creating and supplying an ever-increasing number of opioid-dependent individuals, constitute acts in furtherance of a conspiracy.

726. Through the operation of this Conspiracy, the Defendants are liable for the actions of each other in using unlawful and fraudulent means to pursue the goals, and are liable with each other for the Claims set forth in this Complaint

XV. ADDITIONAL FACTS PERTAINING TO PUNITIVE DAMAGES

727. As set forth above, Defendants acted deliberately to increase sales of, and profits from, opioid drugs. The Marketing Defendants and Purdue knew there was no support for their

claims that addiction was rare, that addiction risk could be effectively managed, that signs of addiction were merely “pseudoaddiction,” that withdrawal is easily managed, that higher doses pose no significant additional risks, that long-term use of opioids improves function, or that time-release or abuse-deterrent formulations would prevent addiction or abuse. Nonetheless, they knowingly promoted these falsehoods in order to increase the market for their addictive drugs.

728. All of the Defendants, moreover, knew that large and suspicious quantities of opioids were being poured into communities throughout the United States. Despite this knowledge, Defendants took no steps to report suspicious orders, control the supply of opioids, or otherwise prevent diversion. Indeed, as described above, Defendants acted in concert together to maintain high levels of quotas for their products and to ensure that suspicious orders would not be reported to regulators.

729. Defendants’ conduct was so willful and deliberate that it continued in the face of numerous enforcement actions, fines, and other warnings from state and local governments and regulatory agencies. Defendants paid their fines, made promises to do better, and continued on with their marketing and supply schemes. This ongoing course of conduct knowingly, deliberately and repeatedly threatened and accomplished harm and risk of harm to public health and safety, and large-scale economic loss to communities, governments, families, communities, hospitals and health care providers, across the country.

730. As all of the governmental actions against all of the Defendants show, Defendants knew that their actions were unlawful, and yet deliberately refused to change their practices because compliance with their legal obligations would have decreased their sales and their profits.

731. Defendants, acting in concert, knew or should have known, in light of the surrounding circumstances, that their conduct would naturally and probably result in injury or damage to Plaintiffs, and Defendants continued the conduct with malice or in reckless disregard of the consequences from which malice may be inferred. Defendants intentionally pursued the course of conduct described herein for the purpose of causing injury and damages to Plaintiffs.

A. The Marketing Defendants and Purdue Persisted in Their Fraudulent Scheme Despite Repeated Admonitions, Warnings, and Even Prosecutions

732. So determined were the Marketing Defendants and Purdue to sell more opioids that they simply ignored multiple admonitions, warnings and prosecutions, as described more fully below.

1. FDA Warnings to Janssen Failed to Deter Janssen's Misleading Promotion of Duragesic

733. On February 15, 2000, the FDA sent Janssen a letter concerning the dissemination of “homemade” promotional pieces that promoted the Janssen drug Duragesic in violation of the Federal Food, Drug, and Cosmetic Act. In a subsequent letter, dated March 30, 2000, the FDA explained that the “homemade” promotional pieces were “false or misleading because they contain misrepresentations of safety information, broaden Duragesic’s indication, contain unsubstantiated claims, and lack fair balance.” The March 30, 2000 letter detailed numerous ways in which Janssen’s marketing was misleading.

734. The letter did not stop Janssen. On September 2, 2004, the U.S. Department of Health and Human Services (“HHS”) sent Janssen a warning letter concerning Duragesic due to “false or misleading claims about the abuse potential and other risks of the drug, and . . . unsubstantiated effectiveness claims for Duragesic,” including, specifically, “suggesting that Duragesic has a lower potential for abuse compared to other opioid products.” The September 2, 2004 letter detailed a series of unsubstantiated, false or misleading claims.

735. One year later, Janssen was still at it. On July 15, 2005, the FDA issued a public health advisory warning doctors of deaths resulting from the use of Duragesic and its generic competitor, manufactured by Mylan N.V. The advisory noted that the FDA had been “examining the circumstances of product use to determine if the reported adverse events may be related to inappropriate use of the patch” and noted the possibility “that patients and physicians might be unaware of the risks” of using the fentanyl transdermal patch, which is a potent opioid analgesic approved only for chronic pain in opioid-tolerant patients that could not be treated by other drugs.

2. **Governmental Action, Including Large Monetary Fines, Failed to Stop Cephalon From Falsely Marketing Actiq For Off-label Uses**

736. On September 29, 2008, Cephalon finalized and entered into a corporate integrity agreement with the Office of the Inspector General of HHS and agreed to pay \$425 million in civil and criminal penalties for its off-label marketing of Actiq and two other drugs (Gabitril and Provigil). According to a DOJ press release, Cephalon had trained sales representatives to disregard restrictions of the FDA-approved label, employed sales representatives and healthcare professionals to speak to physicians about off-label uses of the three drugs and funded CMEs to promote off-label uses.

737. Notwithstanding letters, an FDA safety alert, DOJ and state investigations, and the massive settlement, Cephalon has continued its deceptive marketing strategy.

3. **FDA Warnings Did Not Prevent Cephalon from Continuing False and Off-Label Marketing of Fentora**

738. On September 27, 2007, the FDA issued a public health advisory to address numerous reports that patients who did not have cancer or were not opioid tolerant had been prescribed Fentora, and death or life-threatening side effects had resulted. The FDA warned: “Fentora should not be used to treat any type of short-term pain.” Indeed, FDA specifically

denied Cephalon's application, in 2008, to broaden the indication of Fentora to include treatment of non-cancer breakthrough pain and use in patients who were not already opioid-tolerant.

739. Flagrantly disregarding the FDA's refusal to broaden the indication for Fentora, Cephalon nonetheless marketed Fentora beyond its approved indications. On March 26, 2009, the FDA warned Cephalon against its misleading advertising of Fentora ("Warning Letter"). The Warning Letter described a Fentora Internet advertisement as misleading because it purported to broaden "the indication for Fentora by implying that any patient with cancer who requires treatment for breakthrough pain is a candidate for Fentora . . . when this is not the case." It further criticized Cephalon's other direct Fentora advertisements because they did not disclose the risks associated with the drug.

740. Despite this warning, Cephalon continued to use the same sales tactics to push Fentora as it did with Actiq. For example, on January 13, 2012, Cephalon published an insert in Pharmacy Times titled "An Integrated Risk Evaluation and Mitigation Strategy (REMS) for FENTORA (Fentanyl Buccal Tablet) and ACTIQ (Oral Transmucosal Fentanyl Citrate)." Despite the repeated warnings of the dangers associated with the use of the drugs beyond their limited indication, as detailed above, the first sentence of the insert states: "It is well recognized that the judicious use of opioids can facilitate effective and safe management of chronic pain."

4. **A Guilty Plea and a Large Fine did not Deter Co-Conspirator Purdue from Continuing its Fraudulent Marketing of OxyContin**

741. In May 2007, Purdue and three of its executives pled guilty to federal charges of misbranding OxyContin in what the company acknowledged was an attempt to mislead doctors about the risk of addiction. Purdue was ordered to pay nearly \$635 million in fines and fees. In its plea, Purdue admitted that its promotion of OxyContin was misleading and inaccurate, misrepresented the risk of addiction and was unsupported by science. At the time, this was one

of the largest settlements with a drug company for marketing misconduct.⁴⁰⁸ Additionally, Michael Friedman the company's president, pled guilty to a misbranding charge and agreed to pay \$19 million in fines; Howard R. Udell, Purdue's top lawyer, also pled guilty and agreed to pay \$8 million in fines; and Paul D. Goldenheim, its former medical director, pled guilty as well and agreed to pay \$7.5 million in fines.

742. Nevertheless, even after the settlement, Purdue continued to pay doctors on speakers' bureaus to promote the liberal prescribing of OxyContin for chronic pain and to fund seemingly neutral organizations to disseminate the message that opioids were non-addictive as well as other misrepresentations. At least until early 2018, Purdue continued deceptively marketing the benefits of opioids for chronic pain while diminishing the associated dangers of addiction. After Purdue made its guilty plea in 2007, it assembled an army of lobbyists to fight any legislative actions that might encroach on its business. Between 2006 and 2015, Purdue and other painkiller producers, along with their associated nonprofits, spent nearly \$900 million dollars on lobbying and political contributions - eight times what the gun lobby spent during that period.

743. Since at least 2002, Purdue has maintained a database of health care providers suspected of inappropriately prescribing OxyContin or other opioids. Physicians could be added to this database based on observed indicators of illicit prescribing such as excessive numbers of patients, cash transactions, patient overdoses, and unusual prescribing of the highest-strength pills (80 mg OxyContin pills or "80s," as they were known on the street, were a prime target for diversion). Purdue claims that health care providers added to the database no longer were

⁴⁰⁸ Barry Meier, *In Guilty Plea, OxyContin Maker to Pay \$600 Million*, N.Y. TIMES (May 10, 2007), available at <http://www.nytimes.com/2007/05/10/business/11drug-web.html>.

detailed, and that sales representatives received no compensation tied to these providers' prescriptions.

744. Yet, Purdue failed to cut off these providers' opioid supply at the pharmacy level—meaning Purdue continued to generate sales revenue from their prescriptions—and failed to report these providers to state medical boards or law enforcement. Purdue's former senior compliance officer acknowledged in an interview with the Los Angeles Times that in five years of investigating suspicious pharmacies, the company never stopped the supply of its opioids to a pharmacy, even where Purdue employees personally witnessed the diversion of its drugs.

745. The same was true of prescribers. For example, as discussed above, despite Purdue's knowledge of illicit prescribing from one Los Angeles clinic which its district manager called an "organized drug ring" in 2009, Purdue did not report its suspicions until long after law enforcement shut it down and not until the ring prescribed more than 1.1 million OxyContin tablets.

746. Indeed, the New York Attorney General found that Purdue placed 103 New York health care providers on its "No-Call" List between January 1, 2008 and March 7, 2015, and that Purdue's sales representatives had detailed approximately two-thirds of these providers, some quite extensively, making more than a total of 1,800 sales calls to their offices over a six-year period.

5. **Endo Continued to Aggressively Promote Opana After Becoming Aware of Its Widespread Abuse**

747. The New York Attorney General found that Endo knew, as early as 2011, that Opana ER was being abused in New York, but certain sales representatives who detailed New York health care providers testified that they did not know about any policy or duty to report problematic conduct. The New York Attorney General further determined that Endo detailed

health care providers who were subsequently arrested or convicted for illegal prescribing of opioids a total of 326 times, and these prescribers collectively wrote 1,370 prescriptions for Opana ER (although the subsequent criminal charges at issue did not involve Opana ER).

748. Even after the Indiana Department of Public Health determined that an HIV outbreak in Southeastern Indiana was linked to injection of the prescription painkiller Opana and requested removal from the market, in 2015, “based on its concern that the benefits of the drug may no longer outweigh its risks,” Endo continued to market the drug until 2017.

6. Repeated Admonishments and Fines Did Not Stop the Supply Chain Defendants from Ignoring Their Obligations to Control the Supply Chain and Prevent Diversion

749. Defendants were repeatedly admonished and even fined by regulatory authorities, but continued to disregard their obligations to control the supply chain of dangerous opioids and to institute controls to prevent diversion.

750. In a *60 Minutes* interview, former DEA agent Joe Rannazzisi described Defendants’ industry as “out of control,” stating that “[w]hat they wanna do, is do what they wanna do, and not worry about what the law is. And if they don’t follow the law in drug supply, people die. That’s just it. People die.” The interview continued:

JOE RANNAZZISI: The three largest distributors are Cardinal Health, McKesson, and AmerisourceBergen. They control probably 85 or 90 percent of the drugs going downstream.

[INTERVIEWER]: You know the implication of what you’re saying, that these big companies knew that they were pumping drugs into American communities that were killing people.

JOE RANNAZZISI: That’s not an implication, that’s a fact. That’s exactly what they did.

751. Another DEA veteran similarly stated that these companies failed to make even a “good faith effort” to “do the right thing.” He explained that “I can tell you with 100 percent

accuracy that we were in there on multiple occasions trying to get them to change their behavior.

And they just flat out ignored us.”⁴⁰⁹

752. Government actions against the Distributor Defendants with respect to their obligations to control the supply chain and prevent diversion include:

- a. On April 24, 2007, the DEA issued an Order to Show Cause and Immediate Suspension Order against the AmerisourceBergen Orlando, Florida distribution center (“Orlando Facility”) alleging failure to maintain effective controls against diversion of controlled substances. On June 22, 2007, AmerisourceBergen entered into a settlement that resulted in the suspension of its DEA registration;
- b. On November 28, 2007, the DEA issued an Order to Show Cause and Immediate Suspension Order against the Cardinal Auburn, Washington Distribution Center (“Auburn Facility”) for failure to maintain effective controls against diversion of hydrocodone;
- c. On December 5, 2007, the DEA issued an Order to Show Cause and Immediate Suspension Order against the Cardinal Lakeland, Florida Distribution Center (“Lakeland Facility”) for failure to maintain effective controls against diversion of hydrocodone;
- d. On December 7, 2007, the DEA issued an Order to Show Cause and Immediate Suspension Order against the Cardinal Swedesboro, New Jersey Distribution Center (“Swedesboro Facility”) for failure to maintain effective controls against diversion of hydrocodone;
- e. On January 30, 2008, the DEA issued an Order to Show Cause against the Cardinal Stafford, Texas Distribution Center (“Stafford Facility”) for failure to maintain effective controls against diversion of hydrocodone;
- f. On September 30, 2008, Cardinal entered into a Settlement and Release Agreement and Administrative Memorandum of Agreement with the DEA related to its Auburn, Lakeland, Swedesboro and Stafford Facilities. The document also referenced allegations by the DEA that Cardinal failed to maintain effective controls against the diversion of controlled substances at its distribution facilities located in McDonough, Georgia (“McDonough Facility”), Valencia, California (“Valencia Facility”) and Denver, Colorado (“Denver Facility”);

⁴⁰⁹ *Id.*

- g. On February 2, 2012, the DEA issued an Order to Show Cause and Immediate Suspension Order against the Cardinal's Lakeland Facility for failure to maintain effective controls against diversion of oxycodone; and
- h. On December 23, 2016, Cardinal agreed to pay a \$44 million fine to the DEA to resolve the civil penalty portion of the administrative action taken against its Lakeland Facility.
- i. In January 2017, an investigation by the Massachusetts Attorney General found that some Walgreens pharmacies failed to monitor patients' drug use patterns and did not use sound professional judgment when dispensing opioids and other controlled substances—despite the context of soaring overdose deaths in Massachusetts. Walgreens agreed to pay \$200,000 and follow certain procedures for dispensing opioids.
- j. In March 2019, CVS entered into a \$535,000 settlement with the U.S. Attorney's Office for the District of Rhode Island regarding allegations that its pharmacies in Rhode Island violated federal law “including by... in 39 instances between September 9, 2015 and June 18, 2017, filling a prescription for a Schedule II drug under circumstances ... that the CVS pharmacist filling the prescription knew or had reason to know that the prescription in question was invalid or unauthorized...” This fine was preceded by numerous others throughout the county.

XVI. JOINT ENTERPRISE ALLEGATIONS

753. Defendants entered into an agreement with respect to the unlawful marketing of opioids and/or distribution of opioids in Kentucky and Plaintiffs' communities.

754. The agreement had a common purpose: to promote the sale and distribution of opioids through the marketing of opioids and/or distribution of opioids into Kentucky and Plaintiffs' community, in violation of the KCPA and the common law of fraud and nuisance, and regulations of Kentucky.

755. The Defendants had a community of pecuniary interest in that common purpose, as all of the Defendants profited from sales of opioids in Kentucky and elsewhere.

756. The Defendants had an equal right to a voice in the direction of the enterprise.

XVII. TOLLING AND FRAUDULENT CONCEALMENT

757. Plaintiffs' claims are equitably tolled because Defendants knowingly and fraudulently concealed from the Plaintiffs the facts and their wrongful acts, and the material information pertinent to their discovery. Plaintiffs did not know, or could not have known through the exercise of reasonable diligence, of their claims, as a result of Defendants' conduct.

758. The fraudulent concealment consists of numerous acts forth throughout this Complaint.

759. The Defendants invented the term "pseudoaddiction" and promoted it to the medical community, including Plaintiffs. Defendants provided the medical community, including Plaintiffs, with false and misleading information about ineffectual medical strategies to avoid or control opioid addiction. Marketing Defendants recommended to the medical community that dosages be increased, without disclosing the risks. Defendants spent millions of dollars over a period of years on a misinformation campaign aimed at highlighting opioids' alleged benefits, disguising the risks, and promoting sales.

760. Defendants overstated the benefits of and evidence for the use of opioids for chronic pain and understated their very serious risks, including the risk of addiction and death. Defendants falsely promoted abuse-deterrent formulations as reducing abuse, and falsely claimed that OxyContin provides 12 hours of relief. Defendants falsely portrayed their efforts or commitment to rein in the supply and diversion of opioids when, in truth and in fact, they behaved recklessly in disregard of their duties and adopted practices and policies that caused nearly an unchecked supply of opioids. By word and deed, Defendants have engaged in intentional, fraudulent misrepresentations and concealment of material facts.

761. Plaintiffs had no reason to suspect that the Marketing Defendants were perpetrating what was, in essence, a massive fraud on the public. Plaintiffs had no reason to

suspect that the Supply Chain Defendants – including large publicly traded companies – were routinely violating legal and commonsense duties of not distributing addictive drugs in ways that they knew were facilitating and promoting widespread opioid dependence.

762. So long as the Defendants' worked in coordination with each other in pursuit of the common goal of expanding opioid consumption, so that the false statements to create demand went hand in hand with the negligent and unlawful distribution activities to create abundant supply, Plaintiffs were kept unaware of the existence of the facts supporting the causes of actions set forth in this Complaint, and those facts supporting the causes of action could not have been discoverable by reasonable diligence.

763. Defendants continually and secretly engaged in their scheme to avoid compliance with their legal obligations. Only Defendants and their agents knew or could have known about Defendants' unlawful statements and actions because Defendants made deliberate efforts to conceal their conduct. As a result of the above, Plaintiffs were unable to obtain vital information bearing on their claims absent any fault or lack of diligence on their part.

764. The tortious and unlawful conduct by the Defendants is not limited to a single transgression, but constitutes an ongoing and continuous series of acts causing an ongoing and continuous series of injuries to Plaintiffs. The tortious conduct and injury to Plaintiffs occurs each time an individual presents himself or herself to Plaintiffs' hospitals as a result of an opioid-related condition. The damages have not occurred all at once but have continued to occur and have increased as time progresses. The harm is not completed nor have all the damages been incurred until the wrongdoing ceases. The wrongdoing and unlawful activity by Defendants have not ceased. The nuisance created by Defendants remains unabated.

XVIII. WAIVER OF CERTAIN CLAIMS FOR RELIEF

765. Plaintiffs expressly disclaim and waive any and all right to recovery, whether financial, injunctive, or equitable, relating to or arising out of the distribution by any person of any product, or the provision of any service, pursuant to McKesson Corporation's Pharmaceutical Prime Vendor Contract with the United States Department of Veteran Affairs ("PPV Contract"). Plaintiffs further commit that they will not, in any forum, rely on or raise the PPV Contract in connection with their allegations and/or prosecution in this matter.

766. Plaintiffs agree that should Defendants present evidence sufficient for the trier of fact to determine that Plaintiffs' injuries were caused, in whole or in part, by the distribution of products or provision of services through the PPV, Defendants are entitled to a reduction of their liability proportionately by the extent to which the trier of fact determines that any injury to Plaintiffs was caused by goods or products distributed and/or services provided through the PPV.

XIX. CLAIMS FOR RELIEF**FIRST CLAIM FOR RELIEF****Violation of Kentucky's Consumer Protection Act (K.R.S 367.120)
(Against All Defendants)**

767. Plaintiffs repeat, reallege, and incorporate by reference all other paragraphs of this Complaint, as if fully set forth herein. This Claim is brought against all Defendants as principals and as conspirators with each other.

768. This cause of action is brought pursuant to Section 367.120, Kentucky Revised Statutes, which is known as the Consumer Protection Act (the "KCPA").

769. Kentucky has enacted a Consumer Protection Act to ensure that citizens are protected against predatory or inappropriate actions by sellers of goods. "The General Assembly finds that the public health, welfare and interest require a strong consumer protection program to

protect the public interest and the well-being of both the consumer public and the ethical sellers of goods and services...” KRS § 367.120.

770. KRS § 367.170 (1) states that “[u]nfair, false, misleading, or deceptive acts or practices in the conduct of any trade or commerce are hereby declared unlawful.” Where such practices occur in the course of “trade” and “commerce”, as those terms are defined in KRS § 367.170(1) and KRS § 367.110(2), that being: “the advertising, offering for sale, or distribution of any services and any property, tangible or intangible, real, personal or mixed, and any other article, commodity, or thing of value, and shall include any trade or commerce directly or indirectly affecting the people of this Commonwealth”, the KCPA applies to penalize the seller and to protect the consumer.

771. Specifically, those penalties are monetary and may be enforced per willful violation of KRS § 367.170.

772. As provided under KRS § 367.200, “[t]he court may make such additional orders or judgments as may be necessary to restore to any person in interest any moneys or property, real or personal, which may have been paid out as a result of any practice declared to be unlawful by KRS §§ 367.130 to 367.300.”

773. Plaintiffs are “persons” for purposes of this statute.

774. As alleged herein, and upon information and belief, Defendants committed unfair, false, misleading, and/or deceptive acts with regard to the sale and distribution of opioids within the Commonwealth.

775. Defendants engaged in deception, deceptive or unfair acts or practices, fraud, false pretense, false promise, misrepresentation, or concealment, suppression or omission of material facts with the intent that others rely upon such concealment, suppression or omission, in

connection with the sale or advertisement of prescription drugs in violation of the KCPA, KRS § 367.170(1).

776. During the relevant period and as detailed further herein, the Marketing Defendants have each engaged in unfair and deceptive acts or practices in commerce in violation of the Kentucky Consumer Protection statute by actively promoting and marketing the use of opioids for indications not federally approved, circulating false and misleading information concerning opioids' safety and efficacy, and downplaying or omitting the risk of addiction arising from their use.

777. Each of the Defendants have engaged in unfair and/or deceptive trade practices by omitting the material fact of its failure to design and operate a system to disclose suspicious orders of controlled substances, as well as by failing to actually disclose such suspicious orders, as required of "registrants" by the federal CSA, 21 C.F.R. § 1301.74(b). The CSA defines "registrant" as any person who is registered pursuant to 21 U.S.C § 823. 21 C.F.R. § 1300.02(b). Section 823(a)-(b) requires manufacturers and distributors of controlled substances Schedule II to register.

778. Defendants' unfair or deceptive acts or practices in violation of the Kentucky KCPA offend Kentucky's public policy, are immoral, unethical, oppressive and unscrupulous, as well as malicious, wanton and manifesting of ill will, and they caused substantial injury to Plaintiffs. Plaintiffs risk irreparable injury as a result of the Marketing and Distributor Defendants', and their agents', acts, misrepresentations and omissions in violation of the KCPA, and these violations present a continuing risk to Plaintiffs, as well as to the general public.

779. As a direct and proximate result of Defendants' violations of the KCPA, Plaintiffs have suffered and continue to suffer injury-in-fact and actual damages.

780. Defendants violated the KCPA because they engaged in false or misleading statements about the efficacy and safety of opioid pharmaceuticals.

781. Defendants, individually and acting through their employees and agents, and in concert with each other, knowingly made material misrepresentations and omissions of facts to Plaintiffs to induce them to purchase and administer opioids as set forth in detail above.

782. Defendants knew at the time that they made their misrepresentations and omissions that they were false.

783. Defendants intended that Plaintiffs, physicians, patients, and/or others would rely on their misrepresentations and omissions.

784. Plaintiffs, physicians, patients, and/or others reasonably relied upon Defendants' misrepresentations and omissions.

785. In the alternate, the Defendants recklessly disregarded the falsity of their representations regarding opioids.

786. By reason of their reliance on Defendants' misrepresentations and omissions of material fact, Plaintiffs, physicians, patients, and/or others suffered actual pecuniary damage.

787. Defendants' conduct was willful, wanton, and malicious and was directed at the public generally.

788. Plaintiffs have suffered an ascertainable loss of money or property and/or other things of value as a result of the use or employment by Defendants of an unfair or deceptive act or practices described in the KCPA.

789. Plaintiffs are entitled to recover damages caused by Defendants' fraud in an amount to be determined at trial.

SECOND CLAIM FOR RELIEF**Negligence
(Against All Defendants)**

790. Plaintiffs repeat, reallege, and incorporate by reference all other paragraphs of this Complaint, as if fully set forth herein. All Defendants are charged in this claim, as principals and as conspirators with each other.

791. This claim is brought under the common law of negligence.

1. Defendants Owed a Duty of Care

792. To establish actionable negligence, one must show in addition to the existence of a duty, a breach of that duty, and loss or damage caused by the breach, and actual loss or damage to another. All such essential elements exist here.

793. Kentucky law has adopted a “universal duty of care,” which requires every person to exercise ordinary care in his activities to prevent foreseeable injury.

794. Each Defendant had a duty to exercise reasonable care in the manufacturing, marketing, selling, and distributing of highly dangerous opioid drugs. These Defendants knew or should have known that opioids were unreasonably dangerous and were likely to cause opioid dependence. These Defendants owed their aforesaid duties to Plaintiffs because the injuries alleged herein were foreseeable by the Defendants.

795. A reasonable person could foresee the probability of occurrence of injury to Plaintiffs. Reasonably prudent wholesale drug manufactures, marketers and distributors of opioids would have anticipated the scourge of opioid dependence, especially when being warned and prosecuted by law enforcement repeatedly. These Marketing and Supply Chain Defendants are required to exercise a high degree of care and diligence to prevent injury to the public from the diversion of highly dangerous opioid drugs during manufacture and distribution.

2. Defendants Breached Their Duty of Care

a. Defendants' Conduct, in Violation of Applicable Statutes, Constitutes Negligence Per Se

796. The marketing and Supply Chain Defendants' conduct, in violation of Kentucky statutes and regulations (including KRS § 315.005, KRS § 218A.200, and KRS § 218A.1404(3)) in failing to maintain effective controls against the diversion of opioids into other than legitimate medical channels. Defendants also violated state law, including KRS § 218A.202, in failing to operate a system to stop orders which is flagged or should have been flagged as suspicious.

797. A manufacturer or wholesaler/distributor of prescription drugs must obtain a license from Kentucky Board of Pharmacy and "shall keep records of all controlled substances compounded, mixed, cultivated, grown, or by any other process produced or prepared drugs, and of all controlled substances received and disposed of by them," among other requirements by the Board. KRS § 218A.200(2). Kentucky state law also requires that a "manufacturer, distributor, or wholesaler" must comply with "KRS § 218A.200 and the federal controlled substances laws." KRS § 218A.170. "No person shall dispense, prescribe, distribute, or administer any controlled substance except as authorized by law." KRS § 218A.1404(2). Defendants have a duty to comply with the law.

798. Each Defendant's actions were in violation of Chapter 218A of the Kentucky Revised Statutes, as set out above, and also including KRS § 218A.1404(3), which forbids unlawful distribution of controlled substances; § 218A.1404(1), which forbids the trafficking of controlled substances; and, KRS § 506.040 and § 218A.1402, which forbid criminal drug conspiracies; and KRS § 218A.1405, which forbids receipt of income from trafficking and utilizing that income to operate a commercial enterprise.

799. Defendants violated both State and Federal Controlled Substances act in failing to report suspicious orders of opioid pain medications in Kentucky. Defendants violated state law in failing to maintain effective controls against the diversion of opioids into other than legitimate medical channels. Defendants also violated state law in failing to operate a system to stop orders which is flagged or should have been flagged as suspicious.

800. Defendants' failure to comply with Kentucky law, and the CSA constitutes negligence *per se*.

801. The KCPA and the CSA require that the Defendants know their customers, which includes, an awareness of the customer base, knowledge of the average prescriptions filled each day, the percentage of controlled substances compared to overall purchases, a description of how the dispenser fulfills its responsibility to ensure that prescriptions filled are for legitimate medical purposes, and identification of physicians and bogus centers for the alleged treatment of pain that are the dispenser's most frequent prescribers.

802. The Marketing and Supply Chain Defendants violated Kentucky laws in failing to report suspicious orders of opioid pain medications, in failing to maintain effective controls against the diversion of opioids into other than legitimate medical channels, and in failing to operate a system to stop or at least diligently respond to orders which are flagged or should have been flagged as suspicious. The Marketing and Supply Chain Defendants negligently acted with others by dispensing controlled substances for illegitimate medical purposes, operating bogus pain clinics which do little more than provide prescriptions controlled substances, thereby creating and continuing opioid dependence on prescription medications.

803. Defendants have willfully turned a blind eye towards the actual facts by regularly distributing large quantities of controlled substances to retailers and dispensers who are serving a

customer base substantially comprised of individuals who are abusing and/or diverting prescription medications, many of whom are addicted and all of whom can reasonably be expected to become addicted. Defendants negligently acted with others by dispensing controlled substances for illegitimate medical purposes, operating bogus pain clinics which do little more than provide prescriptions for controlled substances, thereby creating and continuing addictions to prescription medications in this state.

804. Defendants have, by their acts and omissions, proximately caused and substantially contributed to damages to Plaintiffs by violating Kentucky law, by creating conditions which contribute to violations of Kentucky laws by others, and by their negligent and/or reckless disregard of the customs, standards, and practices within their own industry.

805. Plaintiffs have suffered and will continue to suffer enormous damages as the proximate result of the failure by Defendants to comply with Kentucky law.

806. Defendants' acts and omissions imposed an unreasonable risk of harm to others separately and/or combined with the negligent and/or criminal acts of third parties. Plaintiffs are within the class of persons the KCPA and the CSA were intended to protect. The harm that has occurred is the type of harm that the KCPA and the CSA was intended to guard against.

807. Defendants' violations constitute negligence *per se*.

b. Defendants Breached Their Duty of Reasonable Care

808. Alternatively, to the extent that Marketing and Supply Chain Defendants' statutory violations do not obviate the need to show breaches of the duty of care, each Defendant breached its aforesaid duties of care.

i. Negligent Marketing

809. The Marketing Defendants marketed opioids in a negligent and improper manner by:

- a. Overstating the benefits of chronic opioid therapy, promising improvement in patients' function and quality of life, and failing to disclose the lack of evidence supporting long-term use;
- b. Trivializing or obscuring opioids' serious risks and adverse outcomes, including the risk of addiction, overdose and death;
- c. Overstating opioids' superiority compared with other treatments, such as other non-opioid analgesics, physical therapy, and other alternatives;
- d. Mischaracterizing the difficulty of withdrawal from opioids and the prevalence of withdrawal symptoms; and
- e. Marketing opioids for indications and benefits that were outside of the opioids' labels and not supported by substantial evidence.

810. It was Defendants' marketing – and not any medical breakthrough – that rationalized prescribing opioids for chronic pain and opened the floodgates of opioid use and abuse. The result has been catastrophic.

811. The Marketing Defendants disseminated many of their false, misleading, imbalanced, and unsupported statements indirectly, through KOLs and Front Groups, and in unbranded marketing materials. These KOLs and Front Groups were important elements of Defendants' marketing plans, which specifically contemplated their use, because they seemed independent and therefore outside FDA oversight. Through unbranded materials, Marketing Defendants, with their own knowledge of the risks, benefits and advantages of opioids, presented information and instructions concerning opioids generally that were contrary to, or at best, inconsistent with information and instructions listed on Marketing Defendants' branded marketing materials and drug labels. Marketing Defendants did so knowing that unbranded materials typically are not submitted to or reviewed by the FDA.

812. The Marketing Defendants also marketed opioids through the following vehicles: (a) KOLs, who could be counted upon to write favorable journal articles and deliver supportive CMEs; (b) a body of biased and unsupported scientific literature; (c) treatment guidelines; (d) CMEs; (e) unbranded patient education materials; and (f) Front Group patient-advocacy and professional organizations, which exercised their influence both directly and through Defendant-controlled KOLs who served in leadership roles in those organizations.

ii. Negligent Distribution

813. The Marketing and Supply Chain Defendants distributed opioids in an improper manner by:

- a. Distributing and selling opioids in ways that facilitated and encouraged their flow into the illegal, secondary market;
- b. Distributing and selling opioids without maintaining effective controls against diversion;
- c. Choosing not to or failing to effectively monitor for suspicious orders;
- d. Choosing not to or failing to report suspicious orders;
- e. Choosing not to or failing to stop or suspend shipments of suspicious orders; and
- f. Distributing and selling opioids prescribed by “pill mills” when Marketing and Supply Chain Defendants knew or should have known the opioids were being prescribed by “pill mills.”

iii. The Marketing and Supply Chain Defendants’ Breaches of Care Were Intentional, Willful, Wanton and/or Reckless

814. Marketing and Supply Chain Defendants’ breaches of care were intentional, willful, wanton and/or reckless. Marketing and Supply Chain Defendants purposely overstated the benefits of chronic opioid therapy and opioids’ superiority compared with other treatments, such as other non-opioid analgesics, physical therapy, and other alternatives; actively and

continuously promoted the use of opioids for improvement in patients' function and quality of life but failed to disclose the lack of evidence supporting the long-term use, as well as mischaracterized the difficulty of withdrawal from opioids and the prevalence of withdrawal symptoms; intentionally trivialized or obscured opioids' serious risks and adverse outcomes, including the risk of addiction, overdose, and death; continuously marketed opioids for indications and benefits that were outside of the opioids' labels and not supported by substantial evidence.

815. Marketing and Supply Chain Defendants willfully turned a blind eye towards the actual facts by regularly distributing large quantities of controlled substances to retailers and dispensers who are serving a customer base substantially comprised of individuals who are abusing and/or diverting prescription medications, many of whom are opioid-dependent addicted and all of whom can reasonably be expected to become opioid dependent. Marketing and Supply Chain Defendants conducted themselves with wanton and conscious disregard for the rights and safety of others. Notwithstanding their conscious and timely knowledge that their conduct posed unusual danger and of common probability of injury to others, including the Plaintiffs.

3. Injury, Causation and Damages

816. As a proximate result of Marketing and Supply Chain Defendants' conduct, Marketing and Supply Chain Defendants have caused Plaintiffs' injury related to the diagnosis and treatment of opioid-related conditions. Plaintiffs have incurred massive costs by providing unreimbursed, uncompensated, and/or undercompensated care as a result of opioid-related conditions.

817. The injuries to Plaintiffs would not have happened in the ordinary course of events had Marketing and Supply Chain Defendants exercise the degree of care, prudence,

watchfulness, and vigilance commensurate to the dangers involved in the transaction of its business in the manufacture, marketing, sale and distribution of opioids.

818. Plaintiffs are entitled to recover compensatory damages as a result of Marketing and Supply Chain Defendants' negligence, in an amount to be determined at trial.

819. The Purdue Individual Co-Conspirators directed and participated in the tortious conduct of Purdue and are individually liable.

820. As a result of Marketing and Supply Chain Defendants' intentional, willful, wanton and/or reckless conduct described herein, Plaintiffs are entitled to treble, punitive, exemplary and/or otherwise enhanced damages to the full extent available under state law, in an amount to be determined at trial.

THIRD CLAIM FOR RELIEF

Nuisance (Against All Defendants)

821. Plaintiffs repeat, reallege, and incorporate by reference all other paragraphs of this Complaint, as if fully set forth herein.

822. All Defendants are charged in this claim, as principals and as conspirators with each other.

823. The Defendants' conduct set forth in this Complaint, consisting of thousands of purposeful and intentional acts directed at vastly expanding the use of opioids, created a nuisance. The conduct caused widespread opioid dependence and related individual and social harms. The conduct injured public health and interfered with the comfortable enjoyment of life and property of thousands of citizens throughout Kentucky and the regions served by Plaintiffs, and, as discussed below, inflicted special pecuniary injury on Plaintiffs.

824. Defendants' nuisance-causing activities include selling or facilitating the sale of prescription opioids to the patients of Plaintiffs, as well as to unintended users, including children, people at risk of overdose or suicide, and criminals.

825. Defendants' nuisance-causing activities also include failing to implement effective controls and procedures in their supply chains to guard against theft, diversion and misuse of controlled substances, and their failure to adequately design and operate a system to detect, halt and report suspicious orders of controlled substances.

826. Defendants' activities unreasonably interfere with and injured the economic rights of Plaintiffs.

827. The Defendants' interference with these rights of Plaintiffs is unreasonable because it:

- a. Has harmed and will continue to harm the public health services of and public peace of Plaintiffs;
- b. Has harmed and will continue to harm the communities and neighborhoods which Plaintiffs serve;
- c. Is proscribed by statutes and regulation, including the CSA and KCPA;
- d. Is of a continuing nature and it has produced long-lasting effects;
- e. Was the result of conduct that the Defendants knew, or had reason to know, would inflict a significant effect upon Plaintiffs; and
- f. Has inflicted substantial costs on Plaintiffs.

828. The nuisance undermines public health, quality of life, and safety. It has resulted in high rates of opioid dependence, overdoses, dysfunction, and despair within families and entire communities. It has created a public health crisis.

829. The resources of Plaintiffs are being unreasonably consumed in efforts to address the prescription drug abuse epidemic, thereby eliminating available resources needed in other health care areas.

830. Defendants' nuisance-causing activities are not outweighed by the utility of Defendants' behavior. In fact, their behavior is illegal and has no social utility whatsoever. There is no legitimately recognized societal interest in facilitating widespread opioid dependence and failing to identify, halt, and report suspicious opioid transactions.

831. At all times, all Defendants possessed the right and ability to control the nuisance causing outflow of opioids from pharmacy locations or other points of sale. Distributor Defendants had the power to shut off the supply of illicit opioids to Plaintiffs and in the geographic area served by Plaintiffs.

832. As a direct and proximate result of the nuisance, Plaintiffs have sustained economic harm by spending a substantial amount of money trying to remedy the harms caused by Defendants' nuisance-causing activity, including, but not limited to, costs of hospital services and healthcare. In short, the Defendants created a mess, leaving to the Plaintiffs and other hospitals the costs of cleaning it up. This is a classic nuisance.

833. As a result of Defendants' actions, Plaintiffs have suffered a special injury, different from that suffered by the general public at large by individual users and by governmental entities, namely that Plaintiffs have incurred costs by providing unreimbursed, uncompensated, and/or undercompensated care for patients suffering from opioid-related conditions.

834. The effects of the nuisance can be abated, and the further occurrence of such harm and inconvenience can be prevented. All Defendants share in the responsibility for doing so.

835. Defendants should be required to pay the expenses Plaintiffs have incurred or will incur in the future to fully abate the nuisance.

FOURTH CLAIM FOR RELIEF

**Unjust Enrichment
(Against All Defendants)**

836. Plaintiffs repeat, reallege, and incorporate by reference all other paragraphs of this Complaint, as if fully set forth herein. All Defendants are charged in this claim, as principals and as conspirators with each other.

837. This claim is brought under the common law of unjust enrichment.

838. Plaintiffs provided unreimbursed, uncompensated, and/or undercompensated healthcare treatment to patients with opioid related conditions that Defendants are responsible for creating. Plaintiffs thereby conferred a benefit on Defendants because Defendants should bear the expense of treating these patients' opioid conditions. This is because Defendants created the opioid epidemic and the patients' opioid conditions, as described above.

839. Defendants appreciated and knew of this benefit because they knew their opioid promotional and marketing policies would cause, and in fact caused, hospitals throughout the United States and Kentucky to provide unreimbursed, uncompensated, and/or undercompensated healthcare treatment to patients with opioid related conditions that Defendants were responsible for creating.

840. The circumstances under which Defendants accepted or retained the benefit, described throughout this Complaint, were such as to make it inequitable for Defendants to retain the benefit without payment of its value.

841. Defendants have therefore been unjustly enriched.

842. By reason of the foregoing, Defendants must disgorge their unjustly acquired profits and other monetary benefits resulting from their unlawful conduct and provide restitution to the Plaintiffs.

FIFTH CLAIM FOR RELIEF
Fraud and Deceit
(Against All Defendants)

843. Plaintiffs repeat, reallege, and incorporate by reference all other paragraphs of this Complaint, as if fully set forth herein.

844. This claim is brought under the common law of fraud and deceit. All Defendants are charged in this Claim as principals and as conspirators with each other.

845. As alleged herein, Defendants violated their duty not to actively deceive by intentionally and unlawfully making knowingly false representations, intending that the representations be relied upon, and by intentionally and unlawfully omitting and/or concealing information.

846. Defendants made misrepresentations and failed to disclose material facts to physicians and consumers throughout Kentucky and the United States, to induce the physicians to prescribe and administer, and consumers to purchase and consume, opioids as set forth herein.

847. Specifically, the Marketing Defendants' knowing deceptions during the relevant period, which were intended to induce reliance, include but are not limited to:

- a. Marketing Defendants' misrepresentations overstating the benefits of, and evidence for, the use of opioids in chronic pain;
- b. Marketing Defendants' misrepresentations that the risks of long-term opioid use, especially the risk of addiction, were overblown;
- c. Marketing Defendants' misrepresentations that opioid doses can be safely and effectively increased until pain relief is achieved;

- d. Marketing Defendants' misrepresentations that signs of addiction were "pseudoaddiction" and thus reflected undertreated pain, which should be responded to with more opioids;
- e. Marketing Defendants' misrepresentations that screening tools effectively prevent addiction;
- f. Marketing Defendants' misrepresentations concerning the comparative risks of NSAIDs and opioids;
- g. Marketing Defendants' misrepresentations that opioids differ from NSAIDs in that opioids have no ceiling dose;
- h. Marketing Defendants' misrepresentations that evidence supports the long-term use of opioids for chronic pain;
- i. Marketing Defendants' misrepresentations that chronic opioid therapy would improve patients' function and quality of life;
- j. Marketing Defendants' false portrayal of their efforts and/or commitment to rein in the diversion and abuse of opioids;
- k. Marketing Defendants' misrepresentations that withdrawal is easily managed;
- l. Endo's and Co-Conspirator Purdue's misrepresentations that alleged abuse-deterrent opioids reduce tampering and abuse;
- m. Co-Conspirator Purdue's misrepresentations that OxyContin provides a full 12 hours of pain relief;
- n. Co-Conspirator Purdue's misrepresentations that it cooperates with and supports efforts to prevent opioid abuse and diversion;
- o. Mallinckrodt's misrepresentations that it meets or exceeds legal requirements for controlling against diversion of controlled substances it has been entrusted to handle;
- p. Teva's misrepresentations that Actiq and Fentora were appropriate for treatment of non-cancer pain and its failure to disclose that Actiq and Fentora were not approved for such use;
- q. Cephalon's unsubstantiated claims that Actiq and Fentora were appropriate for treatment of non-cancer pain;

- r. Marketing Defendants' use of front groups to misrepresent that the deceptive statements from the sources described in this Complaint came from objective, independent sources;
- s. Marketing Defendants' creation of a body of deceptive, misleading and unsupported medical and popular literature, advertisements, training materials, and speaker presentations about opioids that (1i) understated the risks and overstated the benefits of long-term use; (ii) appeared to be the result of independent, objective research; and (iii) was thus more likely to be relied upon by physicians, patients, and payors; and,
- t. Such other misrepresentations and deceptions outlined above.

848. By engaging in the acts and practices alleged herein, Marketing Defendants, in the relevant time period; and with the intent that others rely on their omissions or suppression of information, omitted material facts that Marketing Defendants had a duty to disclose by virtue of these Defendants' other representations, including, but not limited to, the fact that:

- a. Opioids are highly addictive and may result in overdose or death;
- b. No credible scientific evidence supports the use of screening tools as a strategy for reducing abuse or diversion;
- c. High dose opioids subject the user to greater risks of opioid dependence, other injury, and/or death;
- d. Opioids present the risks of hyperalgesia, hormonal dysfunction, decline in immune function, mental clouding, confusion, dizziness, increased falls and fractures in the elderly, NAS, and potentially fatal interactions with alcohol or benzodiazepines; these omissions were made while Defendants exaggerated the risks of competing products such as NSAIDs;
- e. Claims regarding the benefits of chronic opioid therapy lacked scientific support or were contrary to the scientific evidence;
- f. Co-Conspirator Purdue's 12-hour OxyContin fails to last a full twelve hours in many patients;
- g. Co-Conspirator Purdue and Defendant Endo's abuse-deterrent formulations are not designed to address, and have no effect on, the common route of abuse (oral), can be defeated with relative ease, and may increase overall abuse;

- h. Marketing Defendants were systematically failing to report suspicious prescribers and/or orders;
- i. Cephalon's products Actiq and Fentora were not approved for non-cancer pain;
- j. Marketing Defendants had substantial financial ties to and a substantial role in connection with KOLs, front groups, and their creation and the contents of deceptive literature and related materials, and their promotion and contents of CME programs, as more fully described above; and
- k. Such other omissions and concealments as described above in this Complaint.

849. In each of the circumstances described *inter alia* the foregoing paragraph, Marketing Defendants knew that their failure to disclose rendered their prior representations untrue or misleading, or would be material to the targets of their false representations.

850. In addition, and independently, Marketing Defendants had a duty not to deceive Plaintiffs because Marketing Defendants had in their possession unique material knowledge that was unknown, and not knowable, to Plaintiffs, their agents, their community, physicians, and the public.

851. Marketing Defendants intended and had reason to expect under the operative circumstances that Plaintiffs, their agents, their community, physicians, and persons on whom Plaintiffs and their agents relied would be deceived by Defendants' statements, concealments, and conduct as alleged herein and that Plaintiffs would act or fail to act in reasonable reliance thereon.

852. Marketing Defendants intended that Plaintiffs, their agents, their communities, physicians, and persons on whom Plaintiffs and their agents relied would rely on these Defendants' misrepresentations and omissions; Defendants intended and knew that this reasonable and rightful reliance would be induced by these Defendants' misrepresentations and

omissions; and, Defendants intended and knew that such reliance would cause Plaintiffs to suffer loss.

853. The Marketing Defendants were not alone in this. The Supply Chain Defendants were also knowingly deceptive during the relevant period, and their deception was intended to induce reliance. The Supply Chain Defendants repeatedly made statements acknowledging their roles and responsibilities to guard against diversion, and claiming that they were carrying out those functions. Such statements included but are not limited to:

- a. Acknowledgment of the Distributor Defendants by and through their front group, the HDMA, that distributors are at the center of a sophisticated supply chain and therefore, are uniquely situated to perform due diligence in order to help support the security of the controlled substances they deliver to their customers;
- b. Acknowledgment of the Distributor Defendants that because of their unique position within the “closed” system, they were to act as the first line of defense in the movement of legal pharmaceutical controlled substances from legitimate channels into the illicit market;
- c. Cardinal Health claims to “lead [its] industry in anti-diversion strategies to help prevent opioids from being diverted for misuse or abuse;”
- d. AmerisourceBergen took a same position as its counterpart within the industry and stated that it was “work[ing] diligently to combat diversion and [is] working closely with regulatory agencies and other partners in pharmaceutical and healthcare to help find solutions that will support appropriate access while limiting misuse of controlled substances;”
- e. More holistically, Distributor Defendants misrepresented that not only do its members (Distributor Defendants) have statutory and regulatory responsibilities to guard against diversion of controlled prescription drugs, but undertake such efforts as responsible members of society; and
- f. Such other omissions or concealments as described above in this Complaint.

854. In truth and in fact, despite having induced reliance on their purported good faith efforts to protect against diversion, Supply Chain Defendants, in the relevant time period, and with the intent that others rely on their omissions or suppression of information, omitted material

facts that Supply Chain Defendants had a duty to disclose by virtue of the above representations, so as to make those statements true and accurate and complete, including but not limited to:

- a. There being no legitimate medical purpose for the copious amounts of opioids shipped into and distributed around Plaintiffs' communities;
- b. That they failed to report to the DEA suspicious orders;
- c. That they failed to maintain effective controls against diversion of particular controlled substances into other than legitimate medical scientific and industrial channels by sales to certain customers;
- d. That they failed to prevent against diversion from legitimate to non-legitimate channels;
- e. That they failed to conduct meaningful due diligence to ensure that controlled substances were not diverted into other than legitimate channels;
- f. That they failed to keep and maintain accurate records of Schedule II – V controlled substances;
- g. That they maintained they were entitled to ship opioids to locations where diversion was obvious so long as the DEA did not actually tell them not to; and
- h. Such other omissions or concealments as alleged above in this Complaint.

855. Supply Chain Defendants intended and had reason to expect under the operative circumstances that Plaintiffs, their agents, community, physicians, and persons on whom Plaintiffs relied would be deceived by their statements, concealments, and conduct as alleged herein and that Plaintiffs would act or fail to act in reasonable reliance thereon.

856. Supply Chain Defendants intended that Plaintiffs, their agents, communities, physicians, and persons on whom Plaintiffs and their agents relied would rely on these Defendants' misrepresentations and omissions; Defendants intended and knew that this reasonable and rightful reliance would be induced by these Defendants' misrepresentations and omissions; and, Defendants intended and knew that such reliance would cause Plaintiffs to suffer loss.

857. Plaintiffs rightfully, reasonably, and justifiably relied on Defendants' and their Co-Conspirators' representations and/or concealments, both directly and indirectly. As the Defendants and their Co-Conspirators knew or should have known Plaintiffs were directly and proximately injured as a result of this reliance, Plaintiffs' injuries were directly and proximately caused by this reliance.

858. As a result of these representations and/or omissions, Plaintiffs proceeded under the misapprehension that the opioid crisis was simply a result of conduct by persons other than Defendants and their Co-Conspirators. As a consequence, Defendants prevented Plaintiffs from a timelier and effective response to the opioid epidemic.

859. Defendants' false representations and omissions were material and were made and omitted intentionally and recklessly.

860. Defendants' misconduct alleged in this case is ongoing and persistent.

861. Defendants' misconduct alleged in this case does not concern a discrete event or discrete emergency of the sort Plaintiffs would reasonably expect to occur and is not part of the normal and expected costs of a hospital's healthcare services. Plaintiffs allege wrongful acts which are neither discrete nor of the sort a hospital can reasonably expect.

862. Plaintiffs have incurred expenditures for special programs over and above ordinary hospital healthcare services.

863. Defendants' conduct was accompanied by wanton and willful disregard of person who foreseeably might be harmed by their acts and omissions.

864. Defendants acted with actual malice because Defendants acted with a conscious disregard for the rights and safety of other persons, and said actions had a great probability of causing substantial harm.

865. Plaintiffs have suffered monetary damages as aforesaid. As such Plaintiffs seek all legal and equitable relief as allowed by law, including *inter alia* injunctive relief, restitution, disgorgement of profits, compensatory and punitive damages, and all damages allowed by law to be paid by the Defendants, including attorney fees and costs, and pre- and post-judgment interest.

SIXTH CLAIM FOR RELIEF

Civil Conspiracy to Violate the KCPA, Commit Fraud and Maintain a Nuisance (Against All Defendants)

866. Plaintiffs repeat, reallege, and incorporate by reference all other paragraphs of this Complaint, as if fully set forth herein.

867. Plaintiffs bring this claim under the common law providing for the civil liability of persons who conspire to commit one or more unlawful acts.

868. Defendants engaged in a common design between two or more persons to accomplish by concerted action an unlawful purpose, or a lawful purpose by unlawful means, an overt act in furtherance of the conspiracy, and resulting injury to Plaintiffs.

869. Defendants engaged in a combination and an agreement to act in concert in their tortious and/or otherwise unlawful marketing of opioids and/or distribution of opioids in Kentucky and Plaintiffs' communities.

870. Defendants engaged in one or more unlawful activities to further the conspiracy. The objects of the conspiracy were nuisance, negligence, fraud, misrepresentation, violation of the KCPA, and other unlawful conduct as described above in this Complaint. Defendants knew that these objects were unlawful and would be accomplished by unlawful means such as fraud, misrepresentations, and omissions.

871. Defendants each conspired with various KOLs and Front Groups to commit unlawful or lawful acts in an unlawful manner. Defendants and the various KOLs and Front Groups with which each of them was allied, knowingly and voluntarily agreed to engage in unfair and deceptive practices to promote and distribute opioids for the treatment of chronic pain by making and disseminating false, unsubstantiated, and misleading statements and misrepresentations to prescribers and consumers. Defendants enlisted various KOLs and Front Groups to make and disseminate these statements in furtherance of their common strategy to increase the sale and distribution of opioids, and Defendants—along with the KOLs and Front Groups with whom each of them conspired—knew that the statements they made and disseminated served this purpose.

872. By engaging in the conduct described in this Complaint, Defendant Cephalon agreed with Front Groups FSMB and APF that they would deceptively promote the risks, benefits and superiority of opioid therapy. As part of its agreements with FSMB and APF, Cephalon provided support for FSMB's and APF's deceptive statements promoting opioids and FSMB and APF used that support to more broadly disseminate deceptive messaging promoting opioids, which would benefit Cephalon's drugs. *Responsible Opioid Prescribing* (Cephalon and FSMB) and *Treatment Options: A Guide for People Living with Pain* (Cephalon and APF) are publications that contained a number of deceptive statements about opioids as outlined *supra*. They are products of these conspiracies, and the collaboration between Cephalon and each of these entities in creating and disseminating these publications is further evidence of each conspiracy's existence.

873. By engaging in the conduct described in this Complaint, Defendant Endo agreed with Front Groups APF, NICP, AGS and FSMB that they would deceptively promote the risks,

benefits, and superiority of opioid therapy. As part of its agreements with APF, NIPC, AGS and FSMB, Endo provided support for APF, NIPC, AGS and FSMB's deceptive statements promoting opioids and APF, NIPC, AGS and FSMB used that support to more broadly disseminate deceptive messaging promoting opioids, which would benefit Endo's drugs. *Persistent Pain in the Older Adult* (Endo, APF, and NIPC), *Persistent Pain in the Older Patient* (Endo, APF, and NIPC), *Painknowledge.com* (Endo, APF, and NIPC), *Exit Wounds* (Endo and APF), *Pharmacological Management of Persistent Pain in Older Persons* (Endo and AGS), and *Responsible Opioid Prescribing* (Endo and FSMB) are publications, CMEs, and websites that contained a number of deceptive statements about opioids as outlined *supra*. They are products of these conspiracies, and the collaboration between Endo and each of these entities in creating and disseminating these publication, CMEs, and websites is further evidence of each conspiracy's existence.

874. By engaging in the conduct described in this Complaint, Defendant Janssen agreed with Front Groups AAPM, AGS and APF that they would deceptively promote the risks, benefits, and superiority of opioid therapy. As part of its agreements with AAPM, AGS, and APF, Janssen provided support for AAPM, AGS, and APF's deceptive statements promoting opioids and Conrad & Associates LLC, Medical Writer X, AAPM, AGS, and APF used that support to more broadly disseminate deceptive messaging promoting opioids, which would benefit Janssen's drugs. *Finding Relief: Pain Management for Older Adults* (Janssen, AAPM, and AGS), a CME promoting the *Pharmacological Management of Persistent Pain in Older Persons* (Janssen and APF), the *Let's Talk Pain* website (Janssen and APF), and *Exit Wounds* (Janssen and APF) are publications, CMEs, and websites that contained a number of deceptive statements about opioids as outlined *supra*. They are products of these conspiracies and the

collaboration between Janssen and each of these entities in creating and disseminating these publications is further evidence of each conspiracy's existence.

875. By engaging in the conduct described in this Complaint, Purdue agreed with Front Groups APF, FDMB, and AGS that they would deceptively promote the risks, benefits, and superiority of opioid therapy. As part of its agreements with APF, FSMB, and AGS, Purdue provided support for APF, FSMB, and AGS's deceptive statements promoting opioids and APF, FSMB, and AGS used that support to more broadly disseminate deceptive messaging promoting opioids, which would benefit Purdue's drugs. The *Partners Against Pain* website (Purdue and APF), *A Policymaker's Guide to Understanding Pain & Its Management* (Purdue and APF), *Treatment Options: A Guide for People Living with Pain* (Purdue and APF), *Exit Wounds* (Purdue and APF),⁴¹⁰ *Responsible Opioid Prescribing* (Purdue and FSMB), and a CME promoting the *Pharmacological Management of Persistent Pain in Older Persons* (Purdue and AGS) are publications, CMEs, and websites that contained a number of deceptive statements about opioids as outlined *supra*. They are products of these conspiracies, and the collaboration between Purdue and each of these entities in creating and disseminating these publications, CME's and websites is further evidence of each conspiracy's existence.

876. Each of the participants to the conspiracies outlined above was aware of the misleading nature of the statements they planned to issue and of the role they played in each scheme to deceptively promote opioids as appropriate for the treatment of chronic pain. These Defendants and third parties nevertheless agreed to misrepresent the risks, benefits, and

⁴¹⁰ Purdue's collaboration with APF through APF's "Corporate Roundtable" and Purdue and APF's active collaboration in running PCF constitute additional evidence of the conspiracy between Purdue and APF to deceptively promote opioids.

superiority of using opioids to Plaintiffs in return for increased pharmaceutical sales, financial contributions, reputational enhancements, and other benefits.

877. Each of the participants to the conspiracies outlined above was aware of the nuisance resulting from their conduct, and agreed to continue the practices described above that resulted in the maintenance of that nuisance.

878. Supply Chain Defendants utilized their membership in the HDA and other forms of collaboration to form agreements about their approach to their duties under the CSA to report suspicious orders. The Defendants overwhelmingly agreed on the same approach – to fail to identify, report or halt suspicious opioid orders, and fail to prevent diversion. Defendants' agreement to restrict reporting provided an added layer of insulation from DEA scrutiny for the entire industry as Defendants were thus collectively responsible for each other's compliance with their reporting obligations. Defendants were aware, both individually and collectively aware of the suspicious orders that flowed directly from Defendants' facilities.

879. Defendants knew that their own conduct could be reported by other Defendants and that their failure to report suspicious orders they filled could be brought to the DEA's attention. As a result, Defendants had an incentive to communicate with each other about the reporting or suspicious orders to ensure consistency in their dealings with DEA.

880. The Defendants also worked together to ensure that the opioid quotas allowed by the DEA remained artificially high and ensured that suspicious orders were not reported to the DEA in order to ensure that the DEA had no basis for refusing to increase or decrease production quotas due to diversion.

881. The Defendants further worked together in their unlawful failure to act to prevent diversion and failure to monitor for, report, and prevent suspicious order of opioids.

882. The desired consistency, and collective end goal was achieved. Defendants achieved blockbuster profits through higher opioid sales by orchestrating the unimpeded flow of opioids.

883. By reason of Defendants' unlawful acts, Plaintiffs have been damaged and continue to be damaged by paying the costs of Defendants' externalities have suffered additional damages for the costs of providing and using opioids long-term to treat chronic pain.

884. Defendants acted with a common understanding or design to commit unlawful acts, as alleged herein, acted purposely, without a reasonable or lawful excuse, which directly caused the injuries alleged herein.

885. Defendants acted with malice, purposely, intentionally, unlawfully, and without a reasonable or lawful excuse.

886. Defendants acted with actual malice because Defendants acted with a conscious disregard for the rights and safety of other persons, and said actions had a great probability of causing substantial harm.

887. As outlined above, Defendants played an active role in determining the substance of the misleading messages issued by KOLs and Front Groups, including by providing content themselves, editing and approving content developed by their co-conspirators, and providing slide decks for speaking engagements. Defendants further ensured that these misstatements were widely disseminated, by both distributing the misstatements themselves and providing their co-conspirators with funding and other assistance with distribution. The result was and unrelenting stream of misleading information about compliance with state and federal legislation as related to opioid distribution, and the risks, benefits, and superiority of using opioids to treat chronic pain from sources Defendants knew were trusted by prescribers and consumers. Defendants

exercised direct editorial control over most of these statements. However, even if Defendants did not directly disseminate or control the content of these misleading statements, they are liable for conspiring with the third parties who did.

888. Defendants conduct in furtherance of the conspiracy described herein was not mere parallel conduct because each Defendant acted directly against their commercial interests in not reporting the unlawful distribution practices of their competitors to the authorities, which they had a legal duty to do. Each Defendant acted against their commercial interests in this regard due to an actual or tacit agreement between the Defendants that they would not report each other to the authorities so they could all continue to engage in their unlawful conduct.

889. Defendants had a meeting of the minds on the object of or course of action for this conspiracy. Defendants knew and agreed upon the unlawful object or course of action for this conspiracy. Defendants also knew that their wrongful actions would inflict injury upon the targets of the conspiracy, including Plaintiffs.

890. Defendants' conspiracy, and Defendants' actions and omissions in furtherance thereof, caused the direct and foreseeable losses alleged herein.

891. Defendants' misconduct alleged in this case is ongoing and persistent.

892. Defendants' misconduct alleged in this case does not concern a discrete event or discrete emergent of the sort a hospital would reasonably expect to occur and is not part of the normal and expected costs of a hospital's healthcare services. Plaintiffs allege wrongful acts which are neither discrete nor of the sort a hospital can reasonably expect.

893. Plaintiffs have incurred expenditures for special programs over and above ordinary healthcare services.

894. Because of Defendants dissemination of false information and misleading information of opioid risks, benefits, and sustainability for chronic pain, and false and misleading statements regarding compliance with Kentucky law concerning the distribution of opioids, Defendants are responsible for the costs.

895. Defendants conspired to create a public nuisance and to commit tortious conduct and are therefore jointly and severally liable for the damages flowing from the conspiracy.

896. Plaintiffs therefore request this Court to enter an order awarding judgment in their favor against Defendants, compelling Defendants to pay the direct and consequential damages, and awarding Plaintiffs such other, further, and different relief as this Court may deem just and proper.

SEVENTH CLAIM FOR RELIEF

Fraudulent Concealment (Against All Defendants)

897. Plaintiffs repeat, reallege, and incorporate by reference all other paragraphs of this Complaint, as if fully set forth herein.

898. “One party to a transaction who by concealment or other action intentionally prevents the other from acquiring material information is subject to the same liability to the other, for pecuniary loss as though he had stated the nonexistence of the matter that the other was thus prevented from discovering.” Restatement (Second) of Torts § 550 (1977).

899. Defendants, individually and acting through their employees and agents, knowingly and intentionally concealed material fact and knowledge to Plaintiffs to induce it to purchase and administer opioids as set forth in detail above.

900. In overstating the benefits of and evidence for the use of opioids for chronic pain and understating their very serious risks, including the risk of addiction and death; in falsely

promoting abuse-deterrent formulations as reducing abuse; in falsely claiming that OxyContin provides 12 hours of relief; in falsely portraying their efforts or commitment to rein in the supply and diversion of opioids; and doing all of this while knowing full well that their statements were misrepresentations of facts material, Defendants have engaged in intentional, fraudulent misrepresentations and concealment of the material fact, as detailed herein.

901. Defendants intended that Plaintiffs would rely on their misrepresentations, omissions, and concealment, knew that Plaintiffs would rely on their misrepresentations, and that such reliance would cause harm to Plaintiffs.

902. Plaintiffs reasonably relied on Defendants' misrepresentations and omissions in writing and filling prescriptions for Defendants' opioids. The use of Defendants' opioid medicines became widespread and continuous as a result.

903. Plaintiffs seek economic losses (direct, incidental, or consequential pecuniary losses) resulting from the negligence of Defendants. They do not seek damages which may have been suffered by individual citizens for wrongful death, physical personal injury, serious emotional distress, or any physical damage to property caused by the actions of Defendants.

904. Plaintiffs suffered actual pecuniary damages proximately caused by Defendants concealment of material fact, which include but are not limited to, expending funds on emergency services, emergency response, additional training, additional security, and other services Plaintiffs would not have incurred.

905. Plaintiffs have incurred expenditures for special programs over and above their ordinary hospital services.

906. Defendants' misconduct alleged in this case does not concern a discrete event or discrete emergency of the sort a hospital would reasonably expect to occur and is not part of the

normal and expected costs of a hospital's existence. Plaintiffs allege wrongful acts which were neither discrete nor of the sort a hospital can reasonable expect.

907. Plaintiffs therefore demand judgment in their favor against Defendants for compensatory, exemplary, and punitive damages in an amount to be determined by a jury, together with all the costs of this action, including prejudgment interest, post-judgment interest, costs and expenses, attorney fees, and such other relief as this Court deems just and equitable.

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs ask that the Court:

- A. Enter judgment against Defendants, jointly and severally, and in favor of Plaintiffs;
- B. Award compensatory damages in an amount sufficient to fairly and completely compensate Plaintiffs for all damages; treble damages; punitive damages; pre-judgment and post-judgment interest as provided by law, and that such interest be awarded at the highest legal rate; and such equitable relief against Defendants as the Court should find appropriate;
- C. Award Plaintiffs their cost of suit, including reasonable attorneys' fees as provided by law; and
- D. Award such further and additional relief as the Court may deem just and proper under the circumstances.

JURY DEMAND

Plaintiffs demand a trial by jury on all issues so triable.

Dated: _____

Respectfully Submitted,

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