MAYOR & CITY COUNCIL OF BALTIMORE	*	IN THE
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	*	
Plaintiff,	*	
	*	CIRCUIT COURT
v.	*	
	*	
PURDUE PHARMA L.P., Corporate Service Co. 80 State Street Albany, NY 12207	*	
	*	OF MARYLAND
	*	
	*	
and	*	
	*	FOR BALTIMORE CITY
PURDUE PHARMA INC., Corporate Service Co. 80 State Street Albany, NY 12207	*	
	*	
	*	
	*	
and	*	
	*	
The Purdue Frederick Company, Inc. Corporate Service Co. 80 State Street Albany, NY 12207	*	CASE No.:
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	*	
and	*	
	*	
TEVA PHARMACEUTICALS USA, Inc. Corporate Creations Network 15 North Mill Street Nyack, NY 10960	*	
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and	*	
	*	
CEPHALON, Inc. Corporate Creations Network 15 North Mill Street Nyack, NY 10960	*	
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	*	
and	*	
	*	
JOHNSON & JOHNSON One Johnson & Johnson Plaza New Brunswick, NJ 08933	*	
	*	
	*	

and

JANSSEN PHARMACEUTICA, Inc.
n/k/a JANSSEN PHARMACEUTICALS, Inc.
CT Corporation System
600 North 2nd Street, Suite 401
Harrisburg, PA 17101

and

ORTHO-MCNEIL-JANSSEN
PHARMACEUTICALS, Inc.
n/k/a JANSSEN PHARMACEUTICALS, Inc.
CT Corporation System
600 North 2nd Street, Suite 401
Harrisburg, PA 17101

and

ALLERGAN Plc f/k/a ACTAVIS Plc
The Corporation Trust Company
Corporation Trust Center
1209 Orange Street
Wilmington, DE 19801

and

ACTAVIS, Inc.
f/k/a WATSON PHARMACEUTICALS, Inc.
The Corporation Trust Company
Corporation Trust Center
1209 Orange Street
Wilmington, DE 19801

and

WATSON LABORATORIES, Inc.
Corporate Creations Network, Inc.
3411 Silverside Road
Tatnall Building, Suite 104
Wilmington, DE 19810

and

ACTAVIS, LLC *
Corporate Creations Network, Inc. *
3411 Silverside Road *
Tatnall Building, Suite 104 *
Wilmington, DE 19810 *
*
and *
*
ACTAVIS PHARMA, Inc. *
f/k/a WATSON PHARMA, Inc. *
Corporate Creations Network, Inc. *
3411 Silverside Road *
Tatnall Building, Suite 104 *
Wilmington, DE 19810 *
*
and *
*
ENDO HEALTH SOLUTIONS, Inc. *
CT Corporation System *
111 Eighth Avenue *
New York, NY 10011 *
*
and *
*
ENDO PHARMACEUTICALS, Inc. *
CT Corporation System *
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New York, NY 10011 *
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and *
*
MCKESSON CORPORATION *
Corporation Service Company *
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Wilmington, DE 19808 *
*
and *
*
CARDINAL HEALTH, Inc. *
CT Corporation System *
4400 Easton Commons Way, Suite 125 *
Columbus, OH 43219 *
*
and *
*
*

AMERISOURCEBERGEN DRUG CORP. *
The Corporation Trust Company *
Corporation Trust Center *
1209 Orange Street *
Wilmington, DE 19801 *
*
and *
*
ROSEN-HOFFBERG REHABILITATION AND *
PAIN MANAGEMENT ASSOCIATES, P.A. *
8415 Bellona Lane *
Towson, MD 21204 *
*
and *
*
NORMAN B. ROSEN *
129 Beech Bark Lane *
Towson, MD 21286 *
*
and *
*
HOWARD J. HOFFBERG *
18 Norris Run Court *
Reisterstown, MD 21136 *
*
Defendants. *
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*

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MAYOR & CITY COUNCIL OF BALTIMORE'S COMPLAINT FOR DAMAGES & INJUNCTIVE RELIEF

TABLE OF CONTENTS

Plaintiff the Mayor & City Council of Baltimore ("the City of Baltimore" or "the City"), by its attorney, Andre M. Davis, City Solicitor, alleges as follows:

Defendants in this case—who are manufacturers, wholesalers, and prescribers of prescription opioid painkillers—bear significant responsibility for the epidemic of substance abuse and death that has devastated much of the country. Cities and towns throughout the United States now face a full-scale public health crisis, and Baltimore is no exception: its citizens are more likely to die of a drug overdose than those of nearly any city in the country, and over 90% of those deaths involve opioids. The City now seeks to hold Defendants responsible for their roles in the epidemic, including by demanding contribution to the expensive solutions necessary to abate the ongoing crisis. The City pursues these remedies in its sovereign capacity for the benefit of the general public.

I. PRELIMINARY STATEMENT

1. The bulk of the Defendants in this case are manufacturers of powerful and addictive prescription opioid painkillers (the "Manufacturing Defendants").[1] Before the mid- to late-1990s, opioid painkillers were generally prescribed for short-term use—for example, to treat acute pain following surgery or caused by cancer treatment—or to treat severe pain during end-of-life care. Restricting prescription opioid use to those relatively narrow classes of patients made good sense: Prescription opioids are either derived naturally from or produced through chemical synthesis to possess properties similar to opium and heroin. Like heroin, prescription

[1] The Manufacturing Defendants include Purdue Pharma L.P.; Purdue Pharma, Inc.; The Purdue Frederick Company, Inc.; Teva Pharmaceuticals USA, Inc.; Cephalon, Inc.; Ortho-McNeil-Janssen Pharmaceuticals, Inc. now known as ("n/k/a") Janssen Pharmaceuticals, Inc.; Janssen Pharmaceutica Inc. n/k/a Janssen Pharmaceuticals, Inc.; Endo Health Solutions Inc.; Endo Pharmaceuticals, Inc.; Allergan PLC formerly known as ("f/k/a") Actavis PLC; Watson Pharmaceuticals, Inc. n/k/a Actavis, Inc.; Watson Laboratories, Inc.; Actavis LLC; and Actavis Pharma, Inc. f/k/a Watson Pharma, Inc.

opioids dull the perception of pain by acting on opioid receptors in the brain and spinal cord. Because they can produce a euphoric high, prescription opioids are addictive, and because they cause respiratory depression at higher doses, they can be fatal. For those reasons, prescription opioids are regulated by the Federal Drug Administration ("FDA") as Schedule II Controlled Substances—drugs with "a high potential for abuse" that "may lead to severe psychological or physical dependence." 21 U.S.C. § 812(b)(2). Prescription opioids include both brand name drugs such as OxyContin and Percocet and generic drugs such as oxycodone (the active ingredient in OxyContin) and hydrocodone. Generic prescription opioids are often made by more than one manufacturer.[2]

2. When patients use prescription opioids continuously over time, they develop analgesic[3] tolerance—in other words, their nervous system no longer reacts the same way to the drug and they require higher doses to achieve the same numbing effect. Moreover, prescription opioid use lasting more than a few weeks results in physical dependence, meaning that if the patient stops or delays use of the drug, she will experience symptoms of physical withdrawal. Withdrawal symptoms can include severe anxiety, headaches and muscle pain, increased heart rate, sweating, chills, nausea, and vomiting, among others.

3. The combination of these characteristics makes long-term prescription opioid use fraught with serious risks of withdrawal, addiction, and overdose. Thus, until the late 1990s, prescription of opioid painkillers remained largely limited to short-term use (to treat severe pain following surgery or during chemotherapy) and end-of-life care (when the consequences of

[2] For example, oxycodone is manufactured by Purdue (in the form of OxyContin) and in its generic form by Actavis, Endo, and Teva.

[3] "Analgesia" refers to relief from pain. Painkillers are often referred to alternatively as analgesics.

tolerance and physical dependence are less significant). Long-term use of opioids to treat chronic pain—meaning non-cancer pain lasting more than three months—remained rare.

4. Beginning in the mid to late 1990s, those prescribing patterns began to change. Realizing that they could make more money if they sold more pills to more patients, Manufacturing Defendants, led by Purdue Pharma ("Purdue"), developed and pursued a sophisticated and long-running campaign to expand the market for their addictive drugs. The goal of the campaign was simple: Convince prescribers and patients that pain—and chronic pain in particular—was being routinely ignored and undertreated, and that long-term use of Manufacturing Defendants' prescription opioids was the safe and effective solution.

5. To achieve this goal, Manufacturing Defendants spent hundreds of millions of dollars on a vast array of promotional activities and materials that minimized or misrepresented the risks posed by opioid use and overstated the benefits of opioids to treat a wide variety of ailments, including back pain, headaches, and arthritis. Much of that money was spent on materials and activities that were not obviously produced by Manufacturing Defendants, but were sponsored or financed by them, making it easier for Manufacturing Defendants to affect the way prescription opioids were perceived and prescribed without appearing publicly to have had a thumb on the scales. The nationwide campaign included:

a. directly marketing opioid painkillers to prescribers through advertising and in-person sales calls, which misrepresented the risks and benefits of prescribing opioids for chronic pain;

b. financing biased and scientifically unreliable research regarding the efficacy and risk of opioids to support the long-term use of opioids to treat chronic pain; and

c. indirectly marketing opioid painkillers to prescribers and consumers through unbranded marketing websites and through "front groups" and "key opinion leaders"—pain advocacy groups, professional societies, and

individual physicians whose lectures and publications had the appearance of independence but were in fact funded by Manufacturing Defendants.

6. The Manufacturing Defendants' campaign was a massive success. Prescribers began writing more prescriptions, for more conditions, for more days per prescription, and at higher doses. In just over a decade, overall sales of prescription opioid painkillers more than quadrupled due in large part to the increasing prevalence of prescribing opioid painkillers on a long-term basis to treat chronic pain—so-called "chronic opioid therapy." By 2014, 80% of all prescription opioid users were using the drugs on a long-term basis, in other words, for twelve weeks or longer. The number of opioids prescribed in 2015 alone was sufficient to medicate every American citizen twenty-four hours a day for three weeks. By minimizing the serious risks of addiction of prescription opioids and overstating their effectiveness at treating chronic pain—and by spending hundreds of millions of dollars to disseminate and promote those misleading claims—Manufacturing Defendants successfully revolutionized the way prescription opioid painkillers were viewed and prescribed.

7. In particular, Manufacturing Defendants have (1) downplayed the serious risks of addiction associated with opioid use; (2) overstated the reliability of "screening tools" to accurately assess the risk that particular patients would develop an opioid use disorder, causing unwarranted confidence in prescribers that they could safely prescribe opioids to patients not identified as "high risk"; (3) denied, obscured, or omitted the dangers associated with opioids administered at high doses, which can cause respiratory depression and death; and (4) exaggerated the effectiveness of "abuse-deterrent" formulations to prevent opioid misuse and addiction. At the same time, they have offered up an unjustifiably rosy picture of the benefits of prescription opioids, including by falsely representing that long-term use of opioids to treat chronic pain appropriately and effectively improves patients' function and quality of life.

8. In fact, no reliable clinical trial has ever been conducted to examine the safety and efficacy of using prescription opioids for more than twelve weeks to treat chronic pain. Both the FDA and the Centers for Disease Control (CDC) have recognized the Manufacturing Defendants' false and misleading representations about the relative risks and benefits of long-term opioid use,[4] and indeed, many of the claims made in the course of their campaign to expand the market for opioid painkillers were directly contradicted by required FDA-approved labeling. The Manufacturing Defendants knew the representations made in the course of their campaign to expand the market for their drugs—representations that were made both to prescribers and consumers, both directly and through seemingly independent third parties funded by the Manufacturing Defendants, on a nationwide basis including in Baltimore—were either unsupported or directly contradicted by reliable scientific evidence.

9. Purdue and three of its now-former executives pleaded guilty in 2007 to federal criminal charges associated with the deceptive sales and marketing of its most popular drug, OxyContin. Purdue paid some $600 million to resolve civil and criminal charges. But by then, prescription opioid sales had already more than tripled in just seven years, and the sea change in prescribing—whereby drugs that were once seen as a last resort or temporary necessity came to be viewed as commonplace long-term treatment options—was complete.

10. That sea change proved staggeringly profitable for the Manufacturing Defendants. Purdue alone generated over $3 billion in revenue in a single year, largely from the sale of

[4] *See* Letter to Dr. Andrew Kolodny from Dr. Janet Woodcock dated September 10, 2013, *available at* http://paindr.com/wp-content/uploads/2013/09/FDA_CDER_Response_to_Physicians_for_Responsible_Opioid_Prescribing_Partial_Petition_Approval_and_Denial.pdf ("Dr. Woodcock Letter"); *CDC Guideline for Prescribing Opioids for Chronic Pain—United States, 2016*, Centers for Disease Control and Prevention, *available at* https://www.cdc.gov/mmwr/volumes/65/rr/rr6501e1.htm.

OxyContin. The costs imposed on patients and their families, and on cities and states across the country, have also been staggering. As depicted below, the surge in sales of prescription opioids brought on by Manufacturing Defendants' deceptive marketing correlates directly with skyrocketing rates of opioid use disorders, overdose, and death.

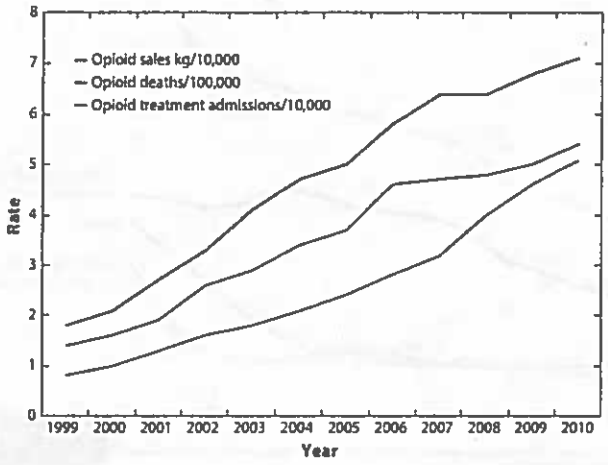


Figure 1

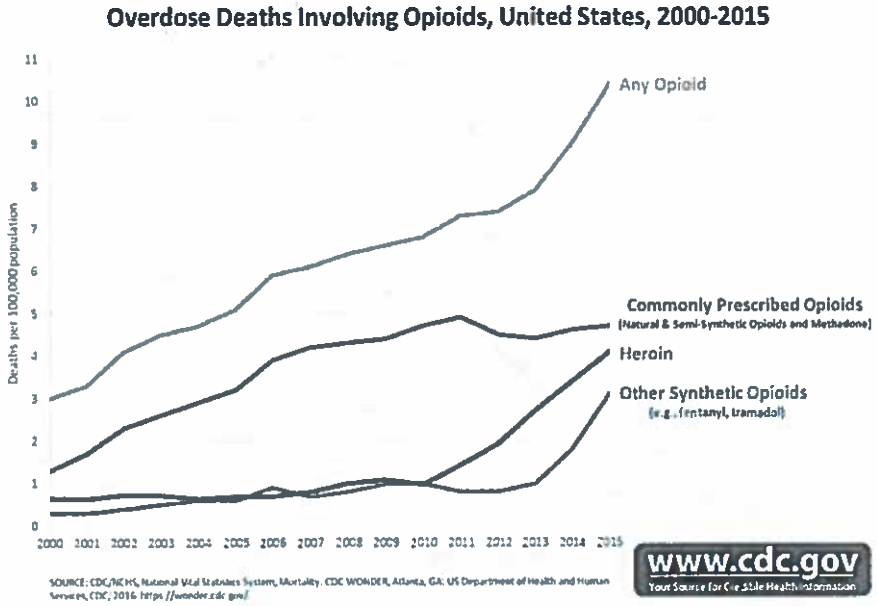
Rates of OPR sales, OPR-related unintentional overdose deaths, and OPR addiction treatment admissions, 1999–2010. Abbreviation: OPR, opioid pain reliever. Source: 10.

[5]

11. Between 1999 and 2010, overdose deaths involving prescription opioids nearly quadrupled. More than 183,000 people died in the United States from overdoses related to prescription opioids between 1999 and 2015. Surging sales of prescription opioids also spawned booming secondary markets for illegally diverted prescription pills and heroin—the drug of choice for many individuals with an opioid use disorder who can no longer afford or access prescription drugs. Nearly 80% of new heroin users report prior abuse of prescription opioids. Even more recently, overdoses related to fentanyl—a synthetic opioid fifty to one hundred times

[5] Andrew Kolodny et al., *The Prescription Opioid and Heroin Crisis: A Public Health Approach to an Epidemic of Addiction*, Annu. Rev. Public Health 36, 559-74 (2015), *available at* http://www.annualreviews.org/doi/pdf/10.1146/annurev-publhealth-031914-122957 (using CDC data).

more powerful than heroin—have soared as drug dealers have begun "cutting" heroin with fentanyl.



12. Opioids as a whole—a category encompassing prescription opioids as well as illicit drugs including heroin—are the main driver of all drug overdose deaths, the rate of which more than quintupled between the mid-1990s and 2015. The rate of drug overdose deaths continues to rise faster than ever.

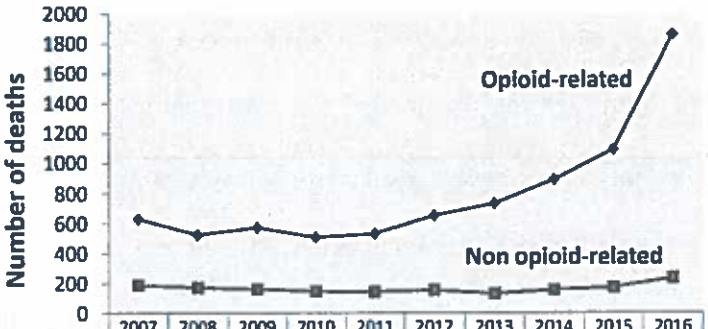
13. As prescription opioids flooded into communities throughout the country and fueled the current epidemic, both the Manufacturing Defendants and the major distributors of prescription drugs that act as middlemen between manufacturers and pharmacies were keenly aware of the increasing rates of addiction and abuse associated with the surge in sales of prescription opioids. McKesson Corporation ("McKesson"), Cardinal Health, Inc. ("Cardinal Health"), and AmerisourceBergen Corporation ("AmerisourceBergen") ("the Wholesaler Defendants")—along with the Manufacturing Defendants—each knew the precise quantities of opioids being distributed and the frequency with which those distributions were made to

individual pharmacies throughout the country, including in Baltimore. Yet the Manufacturing Defendants and Wholesaler Defendants each consistently failed to report suspicious orders of opioids as required under both state and federal law. As a result, more prescription opioids than could possibly be used legitimately flooded into communities including Baltimore, where they were dispensed by "pill mills," illegally diverted, and sold on the streets. One such pill mill is the Rosen-Hoffberg Rehabilitation Pain Management Associates ("Rosen-Hoffberg").

14. The Manufacturing Defendants and Wholesaler Defendants disregarded their legal duties to report suspicious orders of opioids to law enforcement, and instead sought to ensure that the quotas—which are set by the United States Drug Enforcement Agency ("DEA") and cap the number of opioids allowed to be produced in a given year—continued to increase. They did so in spite of their knowledge that a substantial portion of the drugs produced and distributed would be illegally diverted or otherwise misused. Each of the Wholesaler Defendants has already paid tens of millions of dollars to settle allegations regarding their failure to report.

15. As described in Section IV.G, the costs of the opioid epidemic—an epidemic precipitated by the Manufacturing Defendants and allowed to flourish by the Manufacturing Defendants, the Wholesaler Defendants, and the Pill Mill Defendants—have been overwhelming for the City of Baltimore. Between 2007, already years into the opioid epidemic, and 2016, the number of opioid-related deaths in Maryland more than tripled while non-opioid related deaths remained entirely stable.

Figure 6. Total Number of Opioid* and Non-Opioid-Related Deaths Occurring in Maryland, 2007-2016.



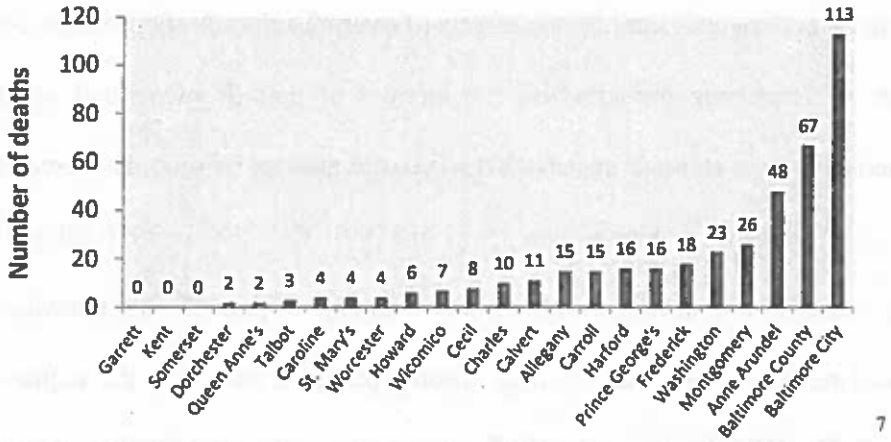
	2007	2008	2009	2010	2011	2012	2013	2014	2015	2016
Opioid-related	628	523	570	504	529	648	729	888	1089	1856
Non opioid-related	187	171	161	145	142	151	128	153	170	233

[6]

16. Between 2015 and 2016 alone the number of opioid-related deaths spiked 70%, and preliminary data indicates that the number continued to rise in 2017. The State ranks first in the country in the rate of opioid-related in-patient hospital stays, and second in opioid-related emergency department visits. The number of babies born with neonatal abstinence syndrome—in other words, babies born addicted to opioids—increased 57% in Maryland between 2007 and 2015. And the epicenter of the epidemic in Maryland is in Baltimore: approximately one third of the total number of opioid-related deaths in the state occurs in Baltimore, which is home to only 11% of the state's citizens. The City also suffers by far the highest number of prescription opioid overdoses of anywhere in the state:

[6] Maryland Department of Health and Mental Hygiene, *Drug- and Alcohol-Related Intoxication Deaths in Maryland, 2016*, at 14, *available at* https://bha.health.maryland.gov/OVERDOSE_PREVENTION/Documents/Maryland%202016%20Overdose%20Annual%20report.pdf.

Figure 14. Number of Prescription Opioid-Related Deaths Occurring in Maryland by Place of Occurrence, 2016.



[7]

Eighty-nine percent of all overdose deaths in the City of Baltimore involve opioids. Two people die of an overdose every single day.

17. Those numbers cannot convey the extent of the harm suffered by the City and its citizens. Baltimore is a city of vibrant neighborhoods. It has a rich history and diverse culture. Yet the flood of opioids into Baltimore has disrupted the lives of its citizens, damaged its communities, and imposed overwhelming financial and logistical costs on its government. Individuals with opioid use disorders not only face the risk of overdose and death, but may also struggle to hold jobs, maintain homes, and be stable parents. They are likely to suffer additional health problems, and may turn to crime to finance their addictions. A steady stream of individuals with opioid use disorders in turn fuels the illegal and brutally violent heroin trade in the City. Combatting organized crime syndicates (*i.e.*, gangs) that control the heroin trade is a major focus of the Baltimore City Police Department and the law enforcement entities with which it partners. The opioid epidemic therefore permeates all aspects of life in Baltimore, and threatens the physical and financial health and future of the City.

[7] *Id.*

18. The City has, in conjunction with the State of Maryland and the nation as a whole, expended extraordinary time, effort, and funds to combat the opioid epidemic in Baltimore, including by curbing and limiting the effects of overprescription of opioid painkillers. After over a decade of increasing opioid sales, the amount of opioids prescribed peaked in 2010 and decreased each year through at least 2015 (yet the amount of opioids prescribed per person in 2015 was still three times higher than it was in 1999). The CDC in 2016 acknowledged based on existing available literature that "for the vast majority of patients, the known, serious, and too-often-fatal risks [of opioid use to treat chronic pain] far outweigh the unproven and transient benefits."[8] The DEA beginning in 2017 ordered cuts to the total number of prescription opioids allowed to be produced, and will continue to make further cuts for 2018.

19. In Maryland, hospitals throughout the state have begun imposing stricter limits on the duration of prescriptions and the number of pills provided. In March 2017 Governor Larry Hogan declared a State of Emergency in response to the opioid crisis and announced $50 million in funding. Years earlier, in October 2014, then-Mayor of Baltimore Stephanie Rawlings-Blake convened a Heroin Treatment and Prevention Task Force, which was spearheaded by the City's Health Commissioner, Dr. Leana Wen, and which developed a multi-faceted plan to stem the crisis of opioid addiction. Efforts undertaken so far include:

a. implementation of a city-wide opioid overdose plan, including distribution and training for tens of thousands of kits of naloxone—the life-saving medication that reverses the effects of an opioid overdose;

b. development of a 24/7 on-demand "Stabilization Center" for addiction including a full capacity for treatment in both intensive inpatient and low-intensity outpatient settings;

[8] Thomas R. Frieden & Debra Houry, *Reducing the Risks of Relief—The CDC Opioid-Prescribing Guideline*, 374 New England Journal of Medicine 1501, 1503 (2016) ("CDC Opioid-Prescribing Guideline").

c. coordination of city-wide programs uniting law enforcement and public health, including programs encouraging residents to anonymously dispose of unused prescription opioids; overdose education and naloxone training programs within the City's Drug Treatment Court Program; and law-enforcement assisted diversion; and

d. partnership with physicians and substance use disorder treatment providers in the City to expand access to medication-assisted treatment for opioid use disorders.

20. Still, there is more to be done, and funding remains a consistent barrier in effectively responding to the epidemic in Baltimore. For example, Health Commissioner Dr. Wen has been forced to begin rationing naloxone due to lack of resources. The City's Task Force concluded that misuse of opioids generates crime and strains the healthcare system, and that as a result, devoting further resources to law enforcement, diversion programs, and short- and long-term drug treatment programs is necessary to address the crisis. All of this is in addition to the millions of dollars the City has spent directly paying for opioid painkillers through its City-funded employee and retiree health insurance and workers' compensation programs. In other words, the City must expend significant and specific additional resources to combat the various problems caused by the opioid epidemic generated by the Manufacturing Defendants and encouraged by the Wholesaler Defendants.

21. The Manufacturing Defendants have violated and continue to violate the Maryland Consumer Protection Act, Md. Com. L. § 13-301 *et seq.* and the Maryland false claims statute, Md. Gen. L. § 7-101 *et seq.* Each of the Defendants is also liable for the creation of a public nuisance and negligence.

II. PARTIES

A. Plaintiff

22. Plaintiff is the Mayor & City Council of Baltimore, a municipal corporation organized and existing under the laws of the State of Maryland. The City Solicitor has the "sole

charge and direction of the preparation and trial of all suits, actions and proceedings of every kind to which the City . . . shall be a party." Baltimore City Charter Art. VII § 24(b).

B. Defendants

23. Defendant Purdue Pharma L.P. is a privately held limited partnership organized under the laws of Delaware. Defendant The Purdue Frederick Company is a corporation organized under the laws of New York with its principal place of business in Stamford, Connecticut. Defendant Purdue Pharma Inc. is a corporation organized under the laws of New York with its principal place of business in Stamford, Connecticut (collectively, "Purdue" or "Purdue Pharma"). The number, names, and citizenship of the limited partners of Purdue Pharma L.P. are unknown to the City. It is therefore not possible at this time for the City to identify the states in which Purdue Pharma L.P. is a citizen.

24. Purdue manufactures, promotes, sells, and distributes opioids including OxyContin, MS Contin, Dilaudid, Dilaudid HP, Butrans, and Hysingla ER in the United States and in Baltimore. OxyContin, Purdue's most popular drug, was first approved for use by the FDA in 1995. OxyContin is oxycodone hydrochloride tablet in an "extended release" formula, meaning that the drug is delivered over a sustained period of time, though not at a constant rate. OxyContin was initially indicated for the "management of moderate to severe pain when a continuous, around-the-clock opioid analgesic is needed for an extended period of time." By 2012, OxyContin made up approximately 30 percent of the market for opioid painkillers. Beginning in April 2014—in response to a citizens' petition by doctors—the FDA-approved labeling was amended to reflect that OxyContin is indicated for the "management of pain severe enough to require daily, around-the-clock, long-term opioid treatment and for which alternative

treatment options are inadequate."[9] Purdue has generated sales around more than $35 billion—mostly from the sale of OxyContin—since the release of the drug. In 2007, Purdue pleaded guilty to misbranding charges and paid criminal and civil penalties to the United States of over $600 million.

25. Defendant Cephalon, Inc. is a corporation organized under the laws of Delaware with its principal place of business in Frazer, Pennsylvania. Teva Pharmaceutical Industries, Ltd. ("Teva Ltd.") is an Israeli corporation with its principal place of business in Petah Tikva, Israel. Teva Ltd. acquired Cephalon, Inc. in 2011. Defendant Teva Pharmaceuticals USA, Inc. ("Teva USA") is a wholly-owned subsidiary of Teva Ltd. Teva USA is a corporation organized under the laws of Delaware with its principle place of business in Pennsylvania. Teva USA acquired Cephalon in October 2011.

26. Teva USA and Cephalon, Inc. work together closely to market and sell Cephalon products in the United States. Teva USA conducts all sales and marketing activities of Teva Ltd. for Cephalon in the United States and has done so since the acquisition of Cephalon by Teva Ltd. in October 2011. Teva USA holds out Actiq and Fentora as Teva products to the public. Teva USA sells all former Cephalon branded products through its "specialty medicines" division. The FDA approved prescribing information and medication guide, which is distributed with Cephalon opioids marketing and sold in Baltimore, discloses that the guide was submitted by Teva USA, and directs physicians to contact Teva USA to report adverse events. Teva USA and Cephalon, Inc. are referred to herein as "Cephalon."

[9] The labeling was also revised—from "[m]onitor for signs of misuse, abuse, and addiction," to "[drug name] exposes users to risks of addiction, abuse, and misuse, which can lead to overdose and death"—to more accurately reflect the risks associated with prescription of OxyContin.

27. Cephalon manufactures, promotes, sells, and distributes opioids including generic versions of OxyContin as well as Fentora and Actiq—both Schedule II opioids indicated for the management of breakthrough pain[10] in cancer patients—in the United States and in Baltimore. Fentora is a fentanyl tablet that is placed inside a patient's mouth in a manner similar to chewing tobacco and then allowed to dissolve. Actiq is a fentanyl citrate lozenge resembling a lollipop. Actiq was granted restricted marketing approval by the FDA in 1998 and was to be promoted only for the "management of breakthrough cancer pain in patients 16 years of age and older who are already receiving and who are tolerant to opioid therapy for their underlying persistent cancer pain."

28. Cephalon pleaded guilty in 2008 to criminal violation of the Federal Food, Drug and Cosmetic Act for the misleading promotion of Actiq and two other drugs for "off-label" uses—in other words, uses not indicated in the FDA-approved label. Cephalon paid $425 million to resolve the charges. It also entered into a Corporate Integrity Agreement with the Office of Inspector General of the Department of Health and Human Services, under which it agreed to notify doctors of the settlement terms and give doctors a means by which to report questionable conduct of Cephalon sales representatives. Cephalon was also required to disclose payments to doctors on its website, and to regularly certify that it has an effective compliance program.

29. Defendant Janssen Pharmaceuticals, Inc. is a corporation organized under the laws of Delaware with its principal place of business in Titusville, New Jersey, and is a wholly-owned subsidiary of Defendant Johnson & Johnson, a corporation organized under the laws of New Jersey with its principal place of business in New Brunswick, New Jersey. Janssen Pharmaceuticals, Inc. was formerly known as Ortho-McNeil-Janssen Pharmaceuticals, Inc.,

[10] "Breakthrough pain" refers to severe pain that erupts while a patient—usually a cancer patient—is already being medicated with a long-acting painkiller.

which in turn was formerly known as Janssen Pharmaceutica Inc. Ortho-McNeil-Janssen Pharmaceuticals, Inc. and Janssen Pharmaceutica, Inc. (both now known as Janssen Pharmaceuticals, Inc.) are each a corporation organized under the laws of Pennsylvania with its principal place of business in Titusville, New Jersey. Johnson & Johnson is the sole company that owns more than 10% of the stock of Janssen Pharmaceuticals, Inc., and corresponds with the FDA regarding products made by Janssen. Upon information and belief, Johnson & Johnson controls the sale and development of drugs made by Janssen Pharmaceutical, and the profits of Janssen inure to the benefit of Johnson & Johnson. Janssen Pharmaceuticals, Inc., Ortho-McNeil-Janssen Pharmaceuticals, Inc., Janssen Pharmaceutica, Inc., and Johnson & Johnson are collectively referred to herein as "Janssen."

30. Janssen manufactures, promotes, sells, and distributes drugs and medical devices in the United States and Baltimore. Those drugs include Duragesic, a Schedule II opioid fentanyl patch first approved by the FDA in 1990 which is indicated for the "management of pain in opioid-tolerant patients, severe enough to require daily, around-the-clock, long-term opioid treatment and for which alternative treatment options are inadequate." Annual sales of Duragesic frequently hit at least $1 billion before 2009. Until January 2015, Janssen was the manufacturer of the tapentadol tablets Nucynta and Nucynta ER (extended release). Together, Nucynta and Nucynta ER accounted for $172 million in sales in 2014.

31. Defendant Endo Health Solutions, Inc. is a corporation organized under the laws of Delaware with its principal place of business in Malvern, Pennsylvania. Endo Pharmaceuticals, Inc. is a wholly-owned subsidiary of Defendant Endo Health Solutions, Inc. and is organized under the laws of Delaware with its principal place of business in Malvern,

Pennsylvania. Endo Health Solutions, Inc. and Endo Pharmaceuticals, Inc. are collectively referred to herein as "Endo."

32. Endo develops, markets, and sells prescription drugs, including the opioids Opana and Opana ER, Percodan, Percocet, and Zydone in the United States and in Baltimore. Opana and Opana ER are Schedule II oxymorphone hydrochloride tablets. Opana ER (extended release) is indicated for the "management of pain severe enough to require daily, around-the-clock, long-term opioid treatment and for which alternative treatment options are inadequate." Before April 2014, Opana ER was indicated for the "relief of moderate to severe pain in patients requiring continuous, around-the-clock opioid treatment for an extended period of time."

33. The sale of opioids accounted for approximately $403 million—over 10%—of overall revenues for Endo in 2012. Opana ER along accounted for revenue of approximately $1.14 billion between 2010 and 2013—including accounting for 10% of overall Endo revenue in 2012. Endo also manufactures and sells generic opioids nationally and in Baltimore both itself and through its subsidiary Qualitest Pharmaceuticals, Inc. Those generic opioids include oxycodone, oxymorphone, hydromorphone, and hydrocodone products.

34. Defendant Allergan plc is a public limited company incorporated in Ireland with its principal place of business in Dublin, Ireland. Defendant Actavis plc acquired Allergan plc in March 2015 and changed the combined company name to Allergan plc. Before that acquisition, in October 2012, Defendant Watson Pharmaceuticals, Inc. acquired Actavis, Inc., and changed the name of the combined company to Actavis Inc. and then, in October 2013, to Actavis plc. Defendant Watson Laboratories, Inc. is a corporation organized under the laws of Nevada with its principal place of business in Corona, California, and is a wholly-owned subsidiary of Allergan plc (f/k/a Actavis, Inc., f/k/a Watson Pharmaceuticals, Inc.). Actavis Pharma, Inc. (f/k/a

Actavis, Inc.) is a corporation organized under the law of Delaware with its principal place of business in New Jersey, and was formerly known as Watson Pharma, Inc. Actavis LLC is a limited liability company organized under the law of Delaware with its principal place of business in Parsippany, New Jersey. Each of these Defendants is owned by Allergan plc, which uses them to market and sell its drugs in the United States. Upon information and belief, Allergan plc exercises control over these marketing and sales efforts, and profits from the sale of Allergan/Actavis products ultimately inure to the benefit of Allergan plc. Allergan plc, Actavis plc, Actavis, Inc., Actavis LLC, Actavis Pharma, Inc., Watson Pharmaceuticals, Inc., Watson Pharma, Inc., and Watson Laboratories, Inc. are collectively referred to herein as "Actavis."

35. Actavis markets and sells opioids including Kadian and Norco and the generic versions of Kadian, Duragesic, and Opana, in the United States and in Baltimore. Actavis acquired the rights to Kadian—an extended release morphine tablet—from King Pharmaceuticals, Inc. on December 30, 2008 and began marketing it in 2009.

36. Each of the Manufacturing Defendants—including Purdue, Cephalon, Janssen, Endo, and Actavis—are currently being investigated by a coalition of state attorneys general, including Maryland Attorney General Brian Frosh, to determine whether they engaged in unlawful practices in the marketing of their prescription opioids.

37. Defendant McKesson is a corporation organized under the laws of Delaware with its principal place of business in San Francisco, California. McKesson is the largest drug distributor and the fifth largest company in the United States. With revenues over $192 billion, McKesson ranked fifth on the 2017 Fortune 500. McKesson supplies hospitals, pharmacies, and other healthcare providers with both generic and branded prescription opioid painkillers, including the Manufacturing Defendants' opioids.

38. McKesson paid over $13 million in civil penalties in 2008 to resolve charges that it violated the Controlled Substances Act ("CSA") by failing to detect and report "suspicious orders" of controlled substances supplied by McKesson to certain pharmacies. In January 2017 McKesson agreed to pay $150 million in civil penalties to settle charges alleging precisely the same kind of misconduct.

39. Defendant Cardinal Health is a corporation organized under the laws of Delaware with its principal place of business in Dublin, Ohio. The pharmaceutical segment of Cardinal Health distributes generic and branded prescription opioid painkillers, including the Manufacturing Defendants' opioids, and had revenues of $109.1 billion in fiscal year 2016.

40. Cardinal Health agreed to pay $34 million in civil penalties in 2016 to resolve charges that it violated the CSA by failing to detect and report suspicious orders of prescription opioids sent to pharmacies in Florida and Maryland.

41. AmerisourceBergen is a corporation organized under the laws of Delaware with its principal place of business in Chesterbook, Pennsylvania. AmerisourceBergen accounts for approximately one fifth of all pharmaceuticals sold and distributed in the United States, with revenue in 2017 of over $146 billion. AmerisourceBergen distributes generic and branded prescription opioid painkillers, including the Manufacturing Defendants' opioids. Together with Cardinal Health, AmerisourceBergen agreed to pay $36 million—$20 million to be paid by Cardinal Health and $16 million to be paid by AmerisourceBergen—to settle a lawsuit brought by the State of West Virginia alleging of the state's consumer protection and other laws.

42. Each of the Wholesaler Defendants is being investigated by the multi-state coalition of attorneys general, including Maryland Attorney General Brian Frosh, to determine whether they engaged in unlawful practices in the distribution of prescription opioids.

43. Defendant Rosen-Hoffberg Rehabilitation and Pain Management Associates, P.A. ("Rosen-Hoffberg") is an active professional corporation organized under the laws of Maryland and with its principal place of business at 8415 Bellona Lane in Towson, Maryland.

44. Defendant Norman B. Rosen is the medical director and registered agent of Rosen-Hoffberg. He is licensed to practiced medicine in the state of Maryland. Dr. Rosen is a citizen of Maryland and, on information and belief, maintains a residence at 129 Beech Bark Lane, Towson, Maryland.

45. Defendant Howard J. Hoffberg is the associate medical director of Rosen-Hoffberg. He is licensed to practice medicine in the state of Maryland. Dr. Hoffberg is a citizen of Maryland and, on information and belief, maintains a residence at 18 Norris Run Court, Reistertown, Maryland. Collectively, Rosen-Hoffberg, Dr. Rosen, and Dr. Hoffberg are referred to as the "Pill Mill Defendants."

III. JURISDICTION AND VENUE

46. This Court has subject matter jurisdiction by grant of authority under the Constitution of the State of Maryland.

47. This Court has personal jurisdiction over Defendants under the long-arm statute of the State of Maryland, Md. Code Ann. § 6-103, and the United States Constitution, because they have regularly transacted business in Maryland; have purposefully directed business activities to Maryland; and have engaged in unlawful practices and caused injury in Maryland. Each Defendant has promoted, marketed, sold, and/or distributed or prescribed opioid painkillers in the State of Maryland or directed to the State of Maryland.

48. The Manufacturing and Wholesaler Defendants are each registered to do business in Maryland. The Manufacturing and Wholesaler Defendants have generated substantial sums through the sale of prescription opioids in Maryland. The Manufacturing Defendants have also

unlawfully promoted their opioids in Maryland, through conduct within the State and through other business activities directed into Maryland. The Pill Mill Defendants each reside in Maryland and do business in Maryland.

49. Venue in this Court is proper because the City's claims arise in part in the City of Baltimore and the Defendants each conduct business there.

IV. FACTUAL ALLEGATIONS

A. The Science of Pain Medicine

1. Prescribers Need Accurate Information Regarding the Risks and Benefits of Prescription Opioids in Order to Treat Pain Safely and Effectively.

50. The choice whether and how to prescribe opioid painkillers—like all treatment decisions—requires prescribers to use their knowledge and judgment to weigh the potential risks and benefits of all available treatment options, as well as the risks and benefits of non-treatment. The safe and effective treatment of chronic pain—pain lasting more than three months—thus requires that prescribers be able to accurately weigh the relative risks associated with prescribing opioid painkillers against the benefits likely to result from treatment with opioids and to compare those risks and benefits against the risks and benefits of alternative courses of treatment.

51. Full disclosure of accurate information regarding risks and benefits is particularly essential in the context of prescription opioids—especially when used long-term to treat chronic pain—because of the risks of physical and psychological dependence.

52. The FDA approves and mandates drug labels on each of the opioids made by the Manufacturing Defendants. Although those labels offer essential information to prescribers regarding, for example, potential adverse reactions and dangerous drug interactions, they do not and cannot inform the prescriber how to weigh the risks and benefits of a particular course of treatment. FDA labels do not contain dosing caps to limit the total amount of a drug that can

safely be prescribed, nor do they identify durational limits beyond which continued use of a drug may result in greater risks to a patient. Prescribers therefore rely more heavily on materials not produced or reviewed by the FDA—including professional educational materials, such as treatment guidelines and continuing medical education programs ("CMEs"), and scientific and patient-oriented publications and websites—to inform their treatment decisions.

2. Prescription Opioids are Dangerous and Potentially Deadly.

53. Opioids—both prescription and illicit—relieve pain by interfering with receptors in the brain and spinal cord. They also cause physical dependence and, at high doses, result in respiratory depression and death. For thousands of years people have used opioids as pain relievers and for thousands of years people have become addicted to them. In the United States, an outbreak of opioid addiction occurred after the Civil War—during which soldiers and others became addicted to morphine that had been used liberally on the battlefield to relieve pain and anxiety—and continued into the early twentieth century. By around 1920, the development of more sophisticated understandings of public health, alternatives to morphine (such as aspirin), and warnings regarding morphine in the relevant medical literature had stemmed the tide of opioid addiction.

54. Governments—federal, state, and local—have therefore consistently prioritized policies to reduce and minimize addiction. Opioids have been regulated as controlled substances by the DEA since 1970. The FDA-required labeling on scheduled opioid painkillers include "black box" warnings regarding potential addiction and "[s]erious, life-threatening, or fatal respiratory depression" resulting from excessive doses.

55. Opioids trigger the release of dopamine, which causes feelings of euphoria by stimulating parts of the brain that control pleasure. A patient using prescription opioids continuously for more than a few weeks will experience tolerance—meaning that higher doses of

the drug will be required to achieve the same painkilling effect—and physical dependence—meaning that delay or discontinuance of the opioid will cause symptoms of withdrawal. Withdrawal symptoms can include severe anxiety, insomnia, hallucinations, headaches and muscle pain, increased heart rate, sweating, chills, nausea, vomiting, and more. The higher a patient's tolerance—in other words, the higher the dose of opioids—the more severe the symptoms of withdrawal will be in the event of delay or discontinued use. Symptoms may persist for months after complete withdrawal from opioids.

56. Unsurprisingly, a patient who is physically dependent on prescription opioids will attempt to avoid the effects of withdrawal. The euphoric effect of opioid use combined with the unpleasant symptoms of discontinuing use can drive patients to seek further opioid treatment—even if continued use is ineffective at treating pain or interferes with the patient's quality of life—in order to avoid withdrawal. Continuous opioid use over just a few weeks can alter the brain's reward system, as well as other systems in the brain—which drive judgment, planning, and organization—driving patients to engage in opioid-seeking behavior even when that behavior is irrational or detrimental to the patient's health. Thus, although the concepts of dependence and addiction are distinct—dependence refers to physical dependence on a drug and is characterized by withdrawal in the event of discontinued use, whereas addiction generally refers to dependence characterized by continued or compulsive use of a drug in spite of negative physical, mental, or social consequences—in practice the two are inextricably linked. The combination of physical dependence and addiction is a medical condition often referred to as an "opioid use disorder."

57. Drug-seeking behaviors can occur and emerge when opioids suddenly become unavailable, or when the patient has become tolerant such that the dosage is no longer effective,

or when doses are tapered too quickly. Thus, *all* patients who continuously use prescription opioids are at risk of dependence and addiction—not just patients who "misuse" the drugs. In short, "correct use and abuse of [prescription opioids] are not polar opposites—they are complex, inter-related phenomena."[11]

58. Similarly, the risk of overdose and death is present even for patients who take opioids exactly as prescribed. Patients taking opioids on a long-term basis will develop a tolerance to the painkilling effects of the drug and require higher and higher doses to achieve the same effect. But scholars suggest that tolerance to the respiratory depressive effects of prescription opioids develop at a slower rate, meaning that the dose necessary to achieve effective pain relief may also kill the patient. Indeed, patients receiving high doses of opioids are between three and nine times more likely to overdose than those taking low doses. The FDA has acknowledged that available data suggest a relationship between increasing doses—a common pattern in the context of prescribing opioids for long-term use—and the risk of adverse events including addiction and overdose.

59. In all, studies have shown that between 30 and 40 percent of individuals who use prescription opioids on a long-term basis will develop an opioid use disorder.[12] Moreover, one of those studies concluded that the lifetime prevalence of physical opioid dependence was nearly identical—within one percentage point—to the lifetime prevalence of an opioid use disorder.

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[11] Wilson M. Compton & Nora D. Volkow, *Major Increases in Opioid Analgesic Abuse in the United States: Concerns and Strategies*, 81(2) Drug & Alcohol Dependence 103, 106 (2006).

[12] Joseph A. Boscarino et al., *Risk factors for drug dependence among out-patients on opioid therapy in a large US health-care system*, 105 Addiction 10, 1776-82 (October 2010); 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 J. Addict Dis. 3, 195-94 (July 2011).

60. The FDA-approved label for each of the Manufacturing Defendants' drugs discloses the risks described above, including the risks of dependence, tolerance, addiction, and overdose. Before the Manufacturing Defendants' comprehensive deceptive marketing campaign—which misrepresented or ignored those risks entirely—the medical community recognized the significant dangers associated with long-term use of opioids and therefore generally considered such treatment as a last resort.

61. Prescription opioids include long-acting drugs taken once or twice daily which are purported generally to provide continuous opioid therapy for twelve hours. These long-acting opioids include OxyContin and MS Contin (Purdue), Nucynta ER and Duragesic (Janssen), Opana ER (Endo), and Kadian (Actavis). Long-acting opioids are generally also "extended release" (ER) drugs, meaning that the drug is delivered over a sustained period of time. Short-acting formulations include Actiq and Fentora (Cephalon) and release immediately to provide 4-6 hours of treatment to address "episodic" or "breakthrough" pain. Part of the Manufacturing Defendants' marketing campaign included promoting the use of short-acting opioids to be layered on top of and in conjunction with a continuous course of long-acting opioids.

62. Both kinds of opioids are extremely addictive. The FDA has therefore required all extended release, long-acting opioids to adopt Risk Evaluation and Mitigation Strategies ("REMS") to address "the risks of serious adverse outcomes including addiction, unintentional overdose, and death,"[13] and all labels of Schedule II long-acting opioids warn that the drug "exposes users to risk of addiction, abuse, and misuses, which can lead to overdose and death." In 2013, the FDA recognized—based on already-available scientific evidence—that "[e]ven

[13] *Introduction for the FDA Blueprint for Prescriber Education for Extended-Release and Long-Acting Opioid Analgesics*, updated May 5, 2017, *available at* https://www.fda.gov/downloads/Drugs/DrugSafety/InformationbyDrugClass/UCM515636.pdf.

proper use of opioids under medical supervision can result in life-threatening respiratory depression, coma, and death."[14] The FDA therefore required manufacturers of long-acting opioids to clearly communicate these risks on the drugs' labels and in promotional materials distributed by or on behalf of the manufacturers. Those warnings reflected the same view that had been accepted practice in the treatment of pain prior to the Manufacturing Defendants' deceptive campaign: that all opioid use involves the risks of "addiction, unintentional overdose, and death," and that because of those serious risks, continued use of long-acting opioids should be limited to instances in which "*alternative treatments are inadequate.*"[15]

3. Reliable Scientific Evidence Supporting the Safety and Efficacy of Long-Term Opioid Use to Treat Chronic Pain Does Not and Has Never Existed.

63. There is no reliable scientific support for the Manufacturing Defendants' claims that long-term use of opioids can safely and effectively treat chronic pain. Manufacturing Defendants knew this but persisted in promoting their drugs as safe, appropriate, and effective treatment options for chronic pain and failed to disclose evidence that long-term use of opioids actually makes patients sicker.

64. No reliable clinical trial has ever been conducted to examine the safety and efficacy of using prescription opioids for more than twelve weeks to treat chronic pain. Both the FDA and the Centers for Disease Control (CDC) have recognized that fact.[16] Random, controlled trials have produced evidence for the short-term efficacy of opioids to treat certain kinds of pain, but systematic reviews of studies analyzing the efficacy of long-term use conclude that any evidence of long-term efficacy is poor or otherwise unreliable. Studies of long-term use of

[14] Dr. Woodcock Letter, *supra.*

[15] *Id.* p. 7.

[16] *See* Dr. Woodcock Letter, *supra*; CDC Opioid-Prescribing Guideline, *supra.*

opioids to treat chronic pain have also routinely failed to attempt to assess the likelihood of dependence and addiction.

65. Available evidence in fact casts doubt on the efficacy of opioids to treat chronic pain. Part of the reason that reliable data regarding the efficacy of long-term opioid use is so scarce is precisely because many patients in clinical trials treated with opioids on a long-term basis drop out because of ineffective pain relief or unpleasant side effects. A full third of patients included in a meta-analysis of forty-one trials regarding opioid treatment for chronic pain dropped out before the trials were over. The same study concluded that, although some studies provided evidence that strong opioids (including oxycodone and morphine) were more effective than non-opioid analgesics at relieving pain, for "functional outcomes"—meaning the patient's recovery in areas such as vocational and social functioning rather than symptom resolution—non-opioid pain relievers were more effective than opioids.[17] Data regarding the use of opioids by individuals with workers' compensation claims establishes that claims involving opioids—and long-acting opioids in particular—are nearly four times as likely to result in costs of over $100,000 than claims that do not involve opioid use, because individuals who take opioids suffer greater side effects and are slower to return to work. Most importantly, the analysis found that longer-term use of opioids increased the chances that a patient would still be on work disability one year later even *after* controlling for the severity of the injury and the patient's self-reported pain score.[18] Studies assessing the efficacy of long-term opioid use to treat more specific

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[17] Andrea D. Furlan et al., *Opioids for chronic noncancer pain: a meta-analysis of effectiveness and side effects*, 174(11) Can. Med. Ass'n J. 1589 (2006).

[18] Jeffrey A. White et al., *The Effect of Opioid Use on Workers' Compensation Claim Cost in the State of Michigan*, 54 Journal of Occupational and Environmental Medicine Issue 8, 948-953 (August 2012), *available at* http://journals.lww.com/joem/Abstract/2012/08000/The_Effect_of_Opioid_Use_on_Workers__Compensation.8.aspx.

conditions—including migraines, back pain, and osteoarthritis—have each failed to provide support for such use.

66. In sum, although prescription opioids may effectively treat pain on a short-term basis, long-term use leads to tolerance, physical dependence, higher dosing, and increased risks of addiction and overdose. No reliable evidence supports the safety or efficacy of continued use of opioids for more than twelve weeks to treat chronic pain. As a pain specialist noted in an article summarizing and assessing the results of multiple studies, scientific data "confirm a common experience for patients with chronic pain: 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."[19]

4. Generally Accepted Standards Regarding Prescription of Opioids Prior to Manufacturing Defendants' Deceptive Marketing Campaign

67. For all of the reasons described above, prior to the Manufacturing Defendants' marketing campaign, the generally accepted view in the medical community was that opioids should be prescribed only on a short-term basis to treat acute pain or for cancer pain or during end-of-life care—in other words, under circumstances in which the risks of tolerance, dependence, and addiction are low or have little significance.

68. Throughout the 1970s and 1980s prescribers continued to avoid the long-term use of opioids to treat chronic pain. Scientists around that time observed negative outcomes from such opioid use, including mixed reactions regarding the long-term pain relief and function;

[19] Andrea Rubinstein, *Are we making pain patients worse?*, Sonoma Medicine, *available at* http://www.nbcms.org/about-us/sonoma-county-medical-association/magazine/sonoma-medicine-are-we-making-pain-patients-worse.aspx?pageid=144&tabid=747.

inability to take advantage of complementary treatments including physical therapy because of the side effects of opioids; and misuse or addiction. Even in the context in which the use of opioids was considered appropriate—to treat cancer pain—the generally-accepted view was to prescribe opioids only after exhausting other options. This generally-accepted view was exemplified by the "analgesic ladder" published by the World Health Organization ("WHO") in 1986. The ladder recommended that cancer pain first be treated with acetaminophen (Tylenol) or non-steroidal anti-inflammatory drugs ("NSAIDs") (aspirin, ibuprofen, or naproxen), and then with unscheduled or combination opioids (weak opioids like codeine or tramadol), and only then with stronger opioids (Schedule II or III drugs like morphine and oxycodone) if pain persisted. The guidelines did not contemplate the use of opioid painkillers for long-term use to treat chronic pain.

69. In 1994, Dr. Russell Portenoy—who later became Charmain of the Department of Pain Medicine and Palliative Care at Beth Israel Medical Center, as well as a primary paid spokesperson for drug manufacturers—described prevailing attitudes toward long-term use of opioids this way:

> The traditional approach to chronic nonmalignant pain does not accept the long-term administration of opioid drugs. . . . 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.[20]

Thus, at the same time as Purdue was about to release its powerful long-acting opioid OxyContin, it was faced with a market of prescribers and consumers who saw such drugs as

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[20] Russell K. Portenoy, *Opioid Therapy for Chronic Nonmalignant Pain: Current Status*, 1 Progress in Pain Res. & Mgmt. 247 (1994).

appropriate in only an extraordinarily narrow class of cases. Manufacturing Defendants sought to change those perceptions.

B. Manufacturing Defendants Spread False and Misleading Statements to Create and Sustain a Market for Its Prescription Opioids

1. Manufacturing Defendants Spread False and Misleading Statements Through Direct Marketing to Prescribers and Consumers

70. Manufacturing Defendants' direct marketing of opioids generally proceeded on two tracks. First, each Manufacturing Defendant conducted and continues to conduct advertising campaigns touting the purported benefits of their branded drugs. For example, Manufacturing Defendants spent more than $14 million on medical journal advertising in 2011.

71. A number of Manufacturing Defendants' branded advertisements deceptively portrayed the risks and benefits of opioids for chronic pain. For example, Endo distributed a pamphlet and posted on its public website (www.opana.com) photographs of purported Opana ER patients that misleadingly implied that the drug would provide long-term pain relief and functional improvement. The photos depict individuals with physically demanding jobs (construction worker, chef, and teacher), and portray seemingly healthy, unimpaired people. Endo also distributed pamphlets that Opana ER was "designed to be" crush resistant,[21] despite the fact that internal Endo studies showed that the pill could be crushed and ground. Indeed, the State of New York found that Endo falsely marketed Opana ER.

72. As another example of misleading direct advertising, Purdue marketed OxyContin as effective for 12 hours. Purdue knew that these claims were misleading because, for many patients, pain relief lasted for as little as eight hours, which led to "end-of-dose failure" and withdrawal symptoms and prompted doctors to prescribe or patients to take higher or more frequent doses of opioids, all of which increased the risk of abuse and addiction. Upon

[21] "Crush resistant" pills are designed to make it more difficult for users to crush the pills and snort the drug in its powder form, which provides an immediate high.

information and belief, Purdue ran advertisements in the *Journal of Pain* and the *Clinical Journal of Pain* reinforcing the message that Purdue provided pain relief for a full 12 hours.

73. Further, Actavis distributed a product advertisement that falsely claimed that the use of Kadian to treat chronic non-cancer pain would allow patients to return to work, relieve "stress on your body and mental health," and help patients enjoy their lives. The FDA subsequently warned Actavis that such claims were misleading.

74. Second, the Manufacturer Defendants also promoted the use of opioids for chronic pain through "detailers"—sales representatives who visited individual doctors and medical staff in their offices, as well as through small-group speaker programs. Manufacturing Defendants then tracked prescribing data in order the monitor the effectiveness of their detailing. A 2015 survey of more than 1,000 opioid patients found that 4 out of 10 were not told the drugs were potentially addictive.[22]

75. The claims Manufacturer Defendants made through their detailers have been deceptive. As one example, on information and belief, in 2010 the FDA mandated Actavis to acknowledge to the doctors to whom it marketed its drugs that "[b]etween June 2009 and February 2010, Actavis sales representatives omitted and minimized serious risks associated with [Kadian]," including the risk of "[m]isuse, [a]buse, and [d]iversion of [o]pioids," and specifically, the risk that "[o]piod[s] have the potential for being abused and are sought by drug abusers and people with addiction disorders and are subject to criminal diversion."

76. Further, on information and belief, a sales education module created by Actavis for its sales representatives titled "Kadian Learning System" instructed Actavis sales

[22] Hazelden Betty Ford Foundation, *Missed Questions, Missed Opportunities*, January 27, 2016, *available at* http://www.hazeldenbettyford.org/about-us/news-media/press-release/2016-doctors-missing-questions-that-could-prevent-opioid-addiction.

representatives that "most chronic benign pain patients do have markedly improved ability to function when maintained on chronic opioid therapy," that "[a]lthough tolerance and dependence do occur with long-term use of opioids, many studies have shown that tolerance is limited in most patients with [chronic pain]," that "no ceiling dose can be given as to the recommended maximal dose," that "there is no evidence that simply taking opioids for a period of time will cause substance abuse or addiction," and "that most substance-abusing patients in pain management practices had an abuse problem before entering the practice." On information and belief, the module also directed sales representatives to instruct doctors to be on the lookout for signs of "pseudoaddiction," which were defined as "[b]ehaviors (that mimic addictive behaviors) exhibited by patients with inadequately treated pain." In other words, Actavis representatives told doctors that signs of opioid abuse and addiction should be treated as signs that the patient needed more—not fewer—addictive drugs.

77. Moreover, Endo instructed its sales representatives to describe Opana ER as "crush resistant," despite the fact that its own internal studies indicated that the drug could still be ground and chewed. Endo also trained its sales representatives to state to physicians that "symptoms of withdrawal do not indicate addiction," and to distinguish addiction from "pseudoaddiction." The "pseudoaddiction" concept has never been empirically validated and Endo's own Vice President for Pharmacovigliance and Risk Management testified that he was not aware of any research validating the concept of pseudoaddiction.

78. Janssen trained its detailers to trivialize the risk of addiction. On information and belief, a training module created by Janssen states that physicians' reluctance to prescribe controlled substances like its drug Nucynta is unfounded because "the risks . . . are [actually] much smaller than commonly believed." Further, on information and belief, a sales training

PowerPoint created by Janssen titled "Selling Nucynta ER and Nucynta" indicates that a "core message" of its sales force is the "low incidence of opioid withdrawal symptoms."

79. Purdue also trained its detailers to spread false and misleading messages about OxyContin. As reported by the *Los Angeles Times*, "[w]hen many doctors began prescribing OxyContin at shorter intervals in the late 1990s, Purdue executives mobilized hundreds of sales reps to 'refocus' physicians on 12-hour dosing. Anything shorter 'needs to be nipped in the bud. NOW!!' one manager wrote to her staff."[23] Purdue knew, however, that these claims were misleading because, for many patients, the pain relief lasted for as little as eight hours.

80. Purdue also trained its sales representatives to carry the message that the risk of addiction was "less than one percent," even though the studies purportedly supporting this statistic did not evaluate the risk of addiction when opioids are used daily for a prolonged time to treat chronic pain. Studies that do evaluate the risk of addiction in treatment of chronic non-cancer pain establish that there is a high incidence of prescription drug abuse.[24]

2. Manufacturing Defendants Spread False and Misleading Statements by Funding Unreliable and Biased Research Regarding the Efficacy and Risks of Opioids

81. Manufacturing Defendants created scientific support for their marketing claims by sponsoring studies that were methodologically flawed, biased, and drew inappropriate conclusions from prior evidence. They published and promoted studies with outcomes favoring the use of opioids to treat chronic pain, and suppressed those with unfavorable outcomes. The result of this behavior was the creation of a body of literature whose primary purpose was to

[23] Harriet Ryan, et al., *"You Want A Description of Hell?" OxyContin's 12-Hour Problem*, L.A. Times, May 5, 2016, *available at* http://www.latimes.com/projects/oxycontin-part1 ("Ryan et al. Part One").

[24] Art Van Zee, *The Promotion and Marketing of OxyContin: Commercial Triumph, Public Health Tragedy*, 99(2) American Journal of Public Health 221-227 (February 2009).

support the use of opioids for chronic pain, but which was passed off as legitimate scientific research.

82. The "evidence" at the root of Manufacturing Defendants' scheme is a 100-word letter to the editor published in the *New England Journal of Medicine* in 1980 (the "Porter-Jick Letter"). That letter, *Addiction Rare in Patients Treated with Narcotics*, is reproduced in full below:

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 patients[1] 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.

JANE PORTER
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1. Jick H, Miettinen OS, Shapiro S, Lewis GP, Siskind V, 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.

83. Notably, the Porter-Jick Letter does not reflect any study, but simply describes a review of the charts of hospitalized patients who had received opioids. Although it notes that the review found almost no references to signs of addiction, there is no indication that staff were instructed to assess or document signs of addiction. And because the opioids were administered in a hospital, there was no risk of patients taking more or higher doses than were prescribed.

84. As a result of Manufacturing Defendants' efforts promoting the Porter-Jick Letter, it became a mainstay of the scientific literature. Google Scholar indicates that it has been cited in the literature over 1,000 times. In 1996, the American Pain Society and the American Academy

of Pain Management, Front Groups operating on behalf of the Manufacturing Defendants, issued a "landmark consensus," citing the Porter-Jick letter for the proposition that there is little risk of addiction or overdose in pain patients, and claiming less than one percent of opioid users become addicted. One Purdue-sponsored study, published in the journal *Pain* in 2003 and widely referenced since then (with nearly 600 citations on Google Scholar), claims that the risk of addiction to opioids is low absent a history of substance abuse, citing the Porter-Jick Letter.[25] It appears as a reference in two CME programs in 2012 sponsored by Purdue and Endo.[26]

85. Dr. Jick later complained that drug companies "pushing out new pain drugs" had misused the letter by citing it to conclude that opioids were not addictive, even though "that's not in any shape or form what we suggested in our letter."[27] A 2017 study published in the *New England Journal of Medicine* concluded the following about the Porter-Jick Letter:

> [W]e found that [the Porter-Jick letter] 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.[28]

3. Manufacturing Defendants Spread False and Misleading Statements Through "Unbranded" Marketing and Seemingly Independent Third Parties

a. Branded Marketing Regulations

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[25] C. Peter N. Watson et al., *Controlled-release oxycodone relieves neuropathic pain: a randomized controlled trial in painful diabetic neuropathy*, 105 Pain 71 (2003).

[26] AAPM, "Safe Opioid Prescribing Course," sponsored by Endo and Purdue; "Chronic Pain Management and Opioid Use," October 11, 2012, sponsored by Purdue. Each CME was available for online credit.

[27] National Public Radio, *Doctor Who Wrote 1980 Letter on Painkillers Regrets That It Fed The Opioid Crisis*, June 16, 2017, *available at* http://www.npr.org/sections/healthshots/2017/06/16/533060031/.

[28] Pamela T.M. Leung et al., *A 1980 Letter on the Risk of Opioid Addiction*, New England Journal of Medicine, *available at*: http://www.nejm.org/doi/full/10.1056/NEJMc1700150#t=article.

86. Generally speaking, drug companies' "branded marketing" is subject to rules and regulations requiring it to be truthful. "Branded marketing" is marketing that identifies and promotes a specific drug, and such marketing must (a) be consistent with its label and supported by substantial scientific evidence; (b) not include false or misleading statements or material omissions; and (c) fairly balance the drug's benefits and risks.[29] The Federal Food, Drug, and Cosmetic Act ("FDCA") prohibits the sale in interstate commerce of drugs that are "misbranded." A drug is "misbranded" if it lacks "adequate directions for use" or if the label is false or misleading "in any particular."[30] Labeling is misleading if it is not based on substantial evidence, if it materially misrepresents the benefits of the drug, or if it omits material information about or minimizes the frequency or severity of a product's risks.

b. Unbranded Marketing

87. To avoid regulatory scrutiny, Manufacturing Defendants also marketed opioids through unbranded advertising—in other words, advertising that promotes opioid use *generally* but does not name a specific prescription drug. By avoiding the naming of specific opioids, Manufacturing Defendants were able to promote deceptive marketing messages in their unbranded advertising to an even greater degree than in their branded materials reviewed by the FDA.

88. Similarly, on information and belief, Endo distributed a pamphlet with the Endo logo titled *Living with Someone with Chronic Pain*, which stated that "Most health care providers who treat people with pain agree that most people do not develop an addiction problem."

[29] 21 U.S.C. § 352(a); 21 C.F.R. §§ 1.21(a), 202.1(e)(3), 202.1(e)(6).

[30] 21 U.S.C. §§ 352.

89. In addition, Janssen runs a website, *Prescriberesponsibly.com* that falsely claims that concerns about opioid addiction are "overestimated." The website states that it is "published by Janssen Pharmaceuticals" and that Janssen "is solely responsible for its content."

90. Purdue also ran unbranded marketing campaigns under the banners *Partners Against Pain* and *In the Face of Pain*. These "educational" materials discussed pain and opioids generally—not particular Purdue products—in order to disseminate misleading messages about the risks and benefits of chronic opioid therapy.

91. Before shutting it down in 2016, Purdue maintained a website for *Partners Against Pain* at www.partnersagainstpain.com. In a 2010 press release, Purdue described the website as a site that would "help facilitate communication between patients, caregivers and healthcare professionals so that, together, they may successfully manage pain."

92. Through at least 2013, the *Partners Against Pain* website relied on and directed users to a 2001 guideline issued by two Front Groups, the American Pain Society and American Academy of Pain Medicine, which endorsed the concept of pseudoaddiction and claimed that patients who engage in drug-seeking behaviors may not be addicted but simply have undertreated pain. The guideline promoted on the *Partners Against Pain* website falsely claimed that "[p]seudoaddiction can be distinguished from true addiction in that the behaviors resolve when pain is effectively treated." And through at least 2010, the *Partners Against Pain* website itself listed "pseudoaddiction" as a "key term[] in pain management" and misleadingly stated that "it can be distinguished from true addiction in that the behaviors resolve when the pain is effectively treated."

93. Purdue, through *Partners Against Pain*, also created a "Pain Management Kit" that advocated the pseudoaddiction concept, referring prescribers to the 2001 American Pain

Society and American Academy of Pain Medicine guideline. The kit also introduced another resource—a set of drug abuse screening tools—by stating that "behaviors that are suggestive of drug abuse exist on a continuum, and pain-relief seeking behavior can be mistaken for drug-seeking behavior."

94. Purdue maintained a separate website, *In the Face of Pain* (www.inthefaceofpain.com), that downplayed the risks of chronic opioid therapy. Like *Partners Against Pain*, *In the Face of Pain* was another example of "unbranded" marketing that did not refer to Purdue products in particular. According to a settlement agreement between Purdue and the New York Attorney General, the website "create[d] the impression that it [was] neutral and unbiased."[31]

95. *In the Face of Pain* asserted that policies limiting access to opioids are "at odds with best medical practices" and encouraged patients to be "persistent" in finding doctors who would treat their pain. As of 2015, while a document linked to *In the Face of Pain* briefly mentioned opioid abuse, the site itself does not. At the same time, the website contained testimonials from several physician "advocates" speaking positively about opioids but failing to disclose that, from 2008 to 2013, Purdue paid 11 of the advocates a total of $231,000.

c. Key Opinion Leaders

96. Another way in which the Manufacturing Defendants promoted misleading messages about the risks and benefits of opioids for chronic pain was through doctors known as Key Opinion Leaders ("KOLs"). Manufacturing Defendants supported the KOLs by providing them with money, prestige, research funding, and avenues to publish. In return, KOLs delivered scripted talks, drafted misleading studies, presented deceptive continuing medical education

[31] In the Matter of Purdue Pharma, No. 15-1 S1, Assurance of Discontinuance, signed Aug. 19, 2015.

programs, and served on the boards and committees of groups that delivered messages and developed guidelines supporting chronic opioid therapy.

97. Manufacturing Defendants cited and promoted favorable studies or articles by these KOLs. By contrast, they did not support, acknowledge, or disseminate publications of doctors critical or skeptical of the use of chronic opioid therapy.

98. Upon information and belief, Manufacturing Defendants selected KOLs solely because they favored the aggressive treatment of chronic pain with opioids. Manufacturing Defendants' support helped these doctors become prominent members of the industry. In return, the KOLs wrote, consulted on, lent their names to books and articles, and gave speeches and CMEs supportive of chronic opioid therapy.

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

100. Dr. Portenoy was instrumental in promoting the regular use of opioids to treat chronic pain. He served on the American Pain Society ("APS") / American Academy of Pain Medicine ("AAPM") Guidelines Committees, which endorsed the use of opioids to treat chronic pain, first in 1997 and again in 2009. He was also a member of the American Pain Foundation, an advocacy organization almost entirely funded by Manufacturing Defendants.

101. Dr. Portenoy also made frequent media appearances promoting opioids and spreading misrepresentations. He appeared on Good Morning America in 2010 to discuss the use of opioids long-term to treat chronic pain. On this widely-watched program, broadcast in

Baltimore and across the country, Dr. Portenoy claimed: "Addiction, when treating pain, is distinctly uncommon. If a person does not have a history, a personal history, of substance abuse, and does not have a history in the family of substance abuse, and does not have a very major psychiatric disorder, most doctors can feel very assured that that person is not going to become addicted."[32]

102. Dr. Portenoy has acknowledged that he "gave innumerable lectures in the late 1980s and '90s about addiction that weren't true." Among the untrue assertions that he and other KOLs made in the 1990s was that "[l]ess than 1% of opioid users became addicted, the drugs were easy to discontinue and overdoses were extremely rare in pain patients." According to Dr. Portenoy, because the primary goal was to "destigmatize" opioids, he and other doctors promoting them overstated their benefits and glossed over their risks. Dr. Portenoy also conceded that "[d]ata about the effectiveness of opioids does not exist." Portenoy candidly stated: "Did I teach about pain management, specifically about opioid therapy, in a way that reflects misinformation? Well, . . . I guess I did."[33]

103. Another example of a KOL is Dr. Lynn Webster. Dr. Webster was the co-founder and Chief Medical Director of Lifetree Clinical Research, a pain clinic in Salt Lake City, Utah. Dr. Webster was also the President in 2013 and current board member of AAPM, a front group that supports chronic opioid therapy. Dr. Webster authored numerous CMEs sponsored by Cephalon, Endo, and Purdue, and received significant funding from Defendants.

104. Dr. Webster created and promoted the Opioids Risk Tool, a five question, one-minute screening tool relying on patient self-reports that purportedly allows doctors to manage

[32] Good Morning America television broadcast, ABC News, Aug. 30, 2010.

[33] Thomas Catan & Evan Perez, *A Pain-Drug Champion Has Second Thoughts*, Wall Street Journal, Dec. 15, 2012.

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 opioid-industry-supported guidelines. Versions of Dr. Webster's Opioid Risk Tool have appeared on, appear on, or have been 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 as a way to prevent "overuse of prescriptions" and "overdose deaths." This webinar was available to and was intended to reach prescribers in Baltimore.

105. Dr. Webster also was a leading proponent of the concept of "pseudoaddiction," the notion that drug-seeking behaviors associated with substance use disorders should be seen not as warnings, but as indications of undertreated pain. In Dr. Webster's description, the only way to differentiate the two was to increase a patient's dose of opioids. As he and his co-author wrote in a book entitled *Avoiding Opioid Abuse While Managing Pain* (2007), when faced with signs of aberrant behavior, increasing the dose "in most cases . . . should be the clinician's first response." Endo distributed this book to doctors. Years later, Dr. Webster reversed himself, as described below in Section IV.C.3, acknowledging that "[pseudoaddiction] obviously became too much of an excuse to give patients more medication."[34]

d. Front Groups

106. The Manufacturing Defendants also entered into arrangements with seemingly unbiased and independent patient and professional organizations to promote the long-term use of

[34] John Fauber & Ellen Gabler, *Networking Fuels Painkiller Boom*, Milwaukee Wisc. J. Sentinel, Feb. 19, 2012.

opioids for the treatment of chronic pain. Under the direction and control of the Manufacturing Defendants, these "Front Groups" generated treatment guidelines, unbranded marketing materials, and programs that misleadingly favored chronic opioid therapy.

107. These Front Groups depended on Manufacturing Defendants for funding. Manufacturing Defendants exercised control over programs and materials created by these groups by collaborating on, editing, and approving their content, and by funding their dissemination. Upon information and belief, Purdue maintained a consulting agreement with the front group American Pain Foundation that gave it direct, contractual control over its work. Manufacturing Defendants utilized many Front Groups, including instances in which several Manufacturing Defendants worked with the same Front Groups. Several of the most prominent are described below.

(1) American Pain Foundation

108. The most prominent of Manufacturing Defendants' Front Groups was the American Pain Foundation ("APF"). Headquartered in Baltimore, APF received more than $10 million in funding from opioid manufacturers from 2007 until it shut down in 2012. Endo alone provided more than half of APF's funding.

109. APF, at the behest of the Manufacturing Defendants, produced guides for patients, reporters, and policymakers that touted the benefits of opioids for chronic pain and trivialized their risks, particularly the risk of addiction. Although APF held itself out as an independent patient advocacy organization, in practice, it operated in close collaboration with the Manufacturing Defendants, who exercised control over its publications.

110. The U.S. Senate Finance Committee began looking into APF in May 2012 to determine the links, financial and otherwise, between the organization and the manufacturers of opioid painkillers. The investigation caused considerable damage to APF's credibility as an

objective and neutral third party and Manufacturing Defendants stopped funding it. Within days of being targeted by Senate investigation, APF's board voted to dissolve the organization "due to irreparable economic circumstances." APF "cease[d] to exist, effective immediately."[35]

111. In 2001, APF published a guide titled *Treatment Options: A Guide for People Living with Pain.* The guide, which was produced with grants from Cephalon and Purdue, misrepresented the risks and benefits associated with chronic opioid therapy. Published in Baltimore, the guide is still available online and was intended to reach Baltimore prescribers and pharmacists.[36]

112. Specifically, *Treatment Options* deceptively asserts that the long-term use of opioids to treat chronic pain could help patients function in their daily lives by stating that, when used properly, opioids "give [pain patients] a quality of life [they] deserve." Yet there is no available data to support that statement; in fact, available data demonstrates that patients taking prescription opioids on a long-term basis to treat chronic pain are less likely to participate in life activities like work.

113. *Treatment Options* also claims that addiction is rare and that addiction is evident from patients' conduct in self-escalating their doses, seeking opioids from multiple doctors, or stealing drugs. *Treatment Options* further minimizes the risk of addiction by claiming that it can be avoided through the use of screening tools, like "opioid agreements," which can "ensure [that patients] take the opioid as prescribed." Nowhere does *Treatment Options* explain to patients and prescribers that neither "opioid agreements" nor any other screening tools have been proven to

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[35]Charles Ornstein & Tracy Weber, *American Pain Foundation Shuts Down as Senators Launch Investigation of Prescription Narcotics*, ProPublica, May 8, 2012, *available at* https://www.propublica.org/article/senate-panel-investigates-drug-company-ties-to-pain-groups.

[36] *Treatment Options: A Guide for People Living with Pain*, American Pain Foundation, *available at* https://assets.documentcloud.org/documents/277605/apf-treatmentoptions.pdf.

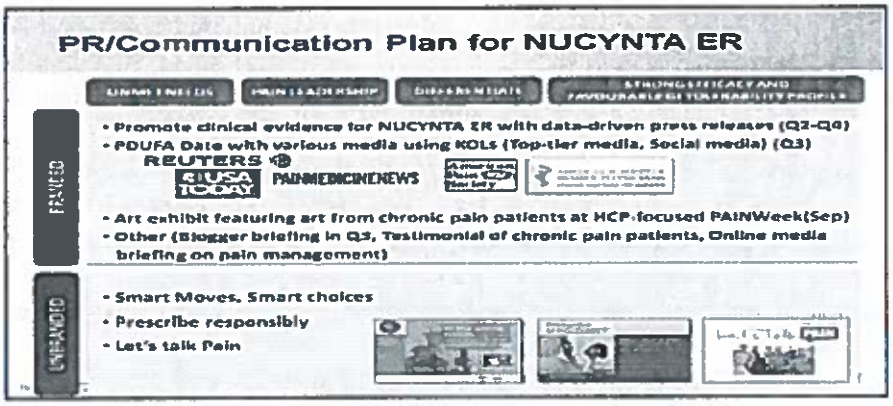
decrease the risks of addiction or make addiction easier to identify or manage, and the publication's assurances to the contrary are false and deceptive.

114. *Treatment Options* also promotes the use of opioids to treat chronic pain by painting a misleading picture of the risks of alternative treatments, most particularly NSAIDs. *Treatment Options* notes that NSAIDs can be dangerous at high doses, and attributes 10,000 to 20,000 deaths a year annually to NSAID overdose. According to *Treatment Options*, NSAIDs are different from opioids because opioids have "no ceiling dose," which is beneficial since some patients "need" larger doses of painkillers than they are currently prescribed. These claims misleadingly suggest that opioids are safe even at high doses and omit important information regarding the risks of high-dose opioids.

115. In 2009, APF published and distributed a book titled *Exit Wounds: A Survival Guide to Pain Management for Returning Veterans & Their Families*. *Exit Wounds* was written as a personal narrative of a veteran recovering from war injuries, and it described opioids as the "gold standard of pain medications" and minimized the risk of addiction. It claimed that physical dependence is often mistaken for addiction and that "[l]ong experience with opioids shows that people who are not predisposed to addiction are very unlikely to become addicted to opioid pain medications." Published in Baltimore, the book was sponsored by Purdue and distributed with grants from Janssen and Endo. *Exit Wounds* was distributed to veterans throughout the country, including, on information and belief, to veterans in Baltimore.

116. In 2009, APF also launched a website titled *Let's Talk Pain*. Janssen sponsored *Let's Talk Pain* in 2009, acting in conjunction with other Front Groups financed by Janssen.

117. Janssen exercised substantial control over the content of *Let's Talk Pain*. Indeed, Janssen's internal communications revealed that it viewed *Let's Talk Pain* as an integral part of its launch of the drug Nucynta ER:



118. On information and belief, a 2009 Janssen memo conceded, "[t]he *Let's Talk Pain Coalition* is sponsored by PriCara, a Division of Ortho-McNeil-Janssen Pharmaceuticals, Inc." and "[t]he Coalition and Pricara **maintain editorial control of all *Let's Talk Pain* materials and publications**" (emphasis added).

119. *Let's Talk Pain* contained numerous misrepresentations regarding long-term opioid therapy, including that opioids improve quality of life for patients suffering from moderate to severe chronic pain. As one example, the website hosted a "talk show," the very first episode of which contained the following exchange in a segment regarding the "safe use of opioids":

> **Teresa Shaffer (Patient advocate):** As a person who has been living with pain for over 20 years, opioids are a big part of my pain treatment. And I have been hearing such negative things about opioids and the risk factors of opioids. Could you talk with me a little bit about that?
>
> **Al Anderson, MD (Pain management physician):** The general belief system in the public is that the opioids are a bad thing to be giving a patient. Unfortunately, it's also prevalent in the medical profession, so patients have difficulty finding a doctor when they are suffering from ***pain for a long period of time,*** especially moderate to severe pain. And ***that's the patients that we really need to use the opioid methods of treatment,***

> because they are the ones who need to have some help with their function and they're the ones that need to have their pain controlled enough ***so that they can increase their quality of life.***

This video is still available on YouTube today and is accessible to patients and prescribers in and around Baltimore.[37]

120. The *Let's Talk Pain* website also promoted the misleading concept of pseudoaddiction. The website claimed that "pseudoaddiction" refers to patient behaviors including an "increased focus on obtaining medications" and "illicit drug use or deception," and that "[p]seudoaddiction is different from true addiction because such behaviors can be resolved with effective pain management." The concept of pseudoaddiction has never been empirically validated.

121. APF also ran an initiative called the National Initiative on Pain Control ("NIPC"), which developed and ran a website titled *painknowledge.com*. On information and belief, APF made a grant request to Endo to create an online "tool-kit" for NIPC and to promote *painknowledge.com*.

122. *Painknowledge.com* misrepresented that opioid therapy for chronic pain would lead to improvements in patients' ability to function. Specifically, the website instructed patients and prescribers that, with opioids, a patient's "level of function should improve" and that patients "may find [they] are now able to participate in activities of daily living, such as work and hobbies, that [they] were not able to enjoy when [their] pain was worse."

123. *Painknowledge.com* also deceptively minimized the risk of addiction by claiming that "[p]eople who take opioids as prescribed usually do not become addicted."

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[37] Episode 1: Safe Use of Opioids, *available at* https://www.youtube.com/watch?v=zeAlVAMRgsk (last accessed January 10, 2018).

124. Endo was the sole funder of painknowledge.com and continued to provide that funding despite being aware of the website's misleading contents.

125. Purdue also sponsored and was involved with APF in the creation and dissemination of *A Policymaker's Guide to Understanding Pain & Its Management*. It was originally published in Baltimore in 2011 and is available online today.[38] The *Policymaker's Guide* misrepresented that there were studies showing that the use of opioids for long-term treatment of chronic pain could improve patients' ability to function. Specifically, it claimed that that "multiple clinical studies" demonstrated that "opioids . . . are effective in improving [d]aily function, [p]sychological health [and] [o]verall health-related quality of life for people with chronic pain" and implied that these studies established that the use of opioids long-term led to functional improvement. The study cited in support of this claim specifically noted that there were no studies demonstrating the safety of opioids long-term and noted that "[f]or functional outcomes, the other [studied] analgesics were significantly more effective than were opioids."[39]

126. The *Policymaker's Guide* also misrepresented the risk of addiction. It claimed that pain generally had been "undertreated" due to "[m]isconceptions about opioid addiction" and that "less than 1% of children treated with opioids become addicted."

127. On information and belief, Purdue exercised editorial input over the contents of *A Policymaker's Guide*.

(2) The American Academy of Pain Medicine

128. A second Front Group through which Manufacturing Defendants disseminated misleading information about chronic opioid therapy is the American Academy of Pain Medicine

[38] *A Policymaker's Guide to Understanding Pain & Its Management*, American Pain Foundation, *available at* http://s3.documentcloud.org/documents/277603/apf-policymakers-guide.pdf (last accessed January 28, 2018).

[39] Furlan et al., *supra*.

("AAPM"). The AAPM, with the assistance, prompting, involvement, and funding of Manufacturing Defendants, issued treatment guidelines and sponsored and hosted medical education programs essential to Manufacturing Defendants' deceptive marketing of chronic opioids therapy. AAPM is funded by Manufacturer Defendants. It receives fifteen percent of its funding from pharmaceutical companies, and its state advocacy project is one hundred percent funded by "drugmakers and their allies."[40]

129. In 2009, Janssen sponsored a patient education guide issued by AAPM titled *Finding Relief: Pain Management for Older Adults*. Upon information and belief, Janssen's personnel reviewed, approved, and distributed the guide. The guide misleadingly features a man playing golf on the cover and lists examples of expected functional improvement from opioids, like sleeping through the night, returning to work, recreation, sex, walking, and climbing stairs. The guide states as a "fact" that "opioids may make it *easier* for people to live normally."

130. *Finding Relief* also describes a "myth" that opioids are addictive, and asserts as fact that "[m]any studies show that opioids are rarely addictive when used properly for the management of chronic pain." The guide further describes 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.

[40] Liz Essley Whyte et al., *Politics of pain: Drugmakers fought state opioid limits amid crisis*, The Center for Public Integrity, December 15, 2016, *available at* https://www.publicintegrity.org/2016/09/18/20200/politics-pain-drugmakers-fought-state-opioid-limits-amid-crisis.

131. As described below in Section IV.B.3.e, AAPM, in connection with the American Pain Society, developed guidelines that endorsed opioids to treat chronic pain and misleadingly claimed that the risk that patients would become addicted to opioids was low.

e. Treatment Guidelines

(1) Guidelines Issued by Groups Funded by Manufacturing Defendants

(a) Federation of State Medical Boards

132. The Federation of State Medical Boards ("FSMB") is an association of the various state medical boards in the United States. The state boards that comprise the FSMB membership, including Maryland's, have the power to license doctors, investigate complaints, and discipline physicians.

133. Manufacturer Defendants financed the FSMB's opioid- and pain-specific programs. From 1997 through 2012, FSMB received the following payments from Manufacturing Defendants:

Defendant	Fiscal Year	Amount
Purdue	2001	$38,324.56
	2002	$10,000
	2003	$85,180.50
	2004	$87,895.00
	2005	$244,000.00
	2006	$207,000.00
	2007	$50,000.00
	2008	$100,000.00
	Total Purdue Payments	**$822,400.06**
Endo	2007	$40,000.00
	2008	$100,000.00
	2009	$100,000.00
	2011	$125,000.00
	2012	$46,620.00
	Total Endo Payments	**$180,000.00**
Cephalon	2007	$30,000.00
	2008	$100,000.00
	2011	$50,000.00

	Total Cephalon Payments	**$180,000.00**

134. In 1998, the FSMB developed its *Model Guidelines for the Use of Controlled Substances for the Treatment of Pain* ("FSMB Guidelines"), which the FSMB acknowledged was produced "in collaboration with" pharmaceutical groups and Front Groups such as the American Pain Society and the American Academy of Pain Medicine.[41] The FSMB Guidelines describe opioids as "essential" for the treatment of chronic pain, do not mention the risk of overdose, and state that physicians' "inadequate understanding of addiction" may result in "inadequate pain control." The FSMB Guidelines were distributed widely to physicians and other health care providers. A 2004 iteration of the FSMB Guidelines repeated the same claims. These guidelines were posted online and available to and intended to reach prescribers in Maryland.

135. In 2007, the FSMB translated its guidelines into a book titled *Responsible Opioid Prescribing: A Physician's Guide*, written by Scott Fishman. *Responsible Opioid Prescribing* was distributed in each of the fifty states, including in Maryland. In total, more than 163,000 copies of the book were distributed nationwide through state medical boards and nonprofit organizations. In 2008 alone, FSMB generated approximately $36,000 in revenue from sales of *Responsible Opioid Prescribing* in Maryland. Through at least 2015, FSMB's website stated that the book was "widely used" as the "leading continuing medical education (CME) activity for prescribers of opioid medications."

136. Endo and Purdue made grants to the FSMB of $40,000 and $50,000, respectively, to fund the production of *Responsible Opioid Prescribing*. Other sponsors of the book included

[41] *Position of the Federation of State Medical Boards In Support of Adoption of Pain Management Guidelines*, (1998), Federation of State Medical Boards, *available at* https://www.fsmb.org/Media/Default/PDF/FSMB/Advocacy/1998_grpol_Pain_Management_Guidelines.pdf.

Cephalon, and Front Groups such as the American Academy of Pain Medicine, the American Pain Foundation, and the National Pain Foundation.

137. *Responsible Opioid Prescribing* contains many of the Manufacturer Defendants' misrepresentations described in this Complaint. The 2007 version taught that relief of pain improved patients' function, and described functional improvement as the goal of a "long-term therapeutic treatment course." It advised that opioids could be used safely even with high-risk patients, stating that while "[i]t may be tempting to assume that patients with chronic pain and a history of recreational drug use who are not adherent to a treatment regimen are abusing medications, . . . other causes of non-adherence should be considered before a judgment is made." It taught that behaviors such as "requesting drugs by name," "demanding or manipulative behavior," seeing more than one doctor to obtain opioids, and hoarding, were all signs of pseudoaddiction, rather than addiction. The book was updated in 2012, but the 2012 edition still taught that psuedoaddiction is real and that opioid addiction risk can be managed through risk screening.

(b) American Pain Society / American Academy of Pain Medicine

138. Purdue, Janssen, and Endo funded the American Pain Society ("APS") and the American Academy of Pain Medicine ("AAPM"). AAPM received $1.3 million from the pharmaceutical industry in 2011 and APS received $1.6 million from opioid companies in 2010 and 2011.

139. AAPM maintains a "Corporate Relations Council" which it describes as offering "many opportunities to interact with over 2,000 dedicated pain physicians." Participation in the Council costs $25,000 per year, and entitles 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. Manufacturing Defendants Endo, Purdue, Cephalon

and Actavis were members of the council and presented deceptive programs to doctors who attended this annual event.

140. In 1996, APS and APM issued a "consensus statement" co-authored by Dr. Portenoy, which stated that there was little risk of addiction or overdose among pain patients. The chairman of the committee that issued the statement, Dr. David Haddox, was a paid speaker for Purdue and was subsequently hired by Purdue. The statement was published on AAPM's website and remained on the website through at least 2008.

141. AAPM's presidents have included top industry-supported KOLs Perry Fine, Russell Portenoy, and Lynn Webster. Scott Fishman, a past president of AAPM, stated that he would place the organization "at the forefront" of teaching that "the risks of addiction are . . . small and can be managed."[42]

142. AAPM and APS also issued a 2001 set of recommendations, titled "Definitions Related to the Use of Opioids for the Treatment of Pain," that advanced the unsubstantiated concept of "pseudoaddiction." The term, coined by KOL Dr. David Haddox in a 1989 journal article, reflects the idea that signs of addiction may actually be the manifestation of undertreated pain and will resolve once the pain is effectively treated—*i.e.*, with more frequent or higher doses of opioids.[43] The 2001 AAPM/APS recommendations claimed that "clock-watch[ing]," "drug seeking," and "[e]ven such behaviors as illicit drug use and deception can occur in the patient's efforts to obtain [pain] relief." The 2001 AAPM/APS recommendations are still available online.

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[42] Interview by Paula Moyer with Scott M. Fishman, M.D., Professor of Anesthesiology and PainMedicine, Chief of the Division of Pain Medicine, Univ. of Cal., Davis (2005).

[43] David E. Weismann & J. David Haddox, *Opioid Pseudoaddiction—an Iatrogenic Syndrome*, 36 Pain 363-366 (1989).

143. The 2016 CDC Guideline rejects the concept of pseudoaddiction, explaining 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" to decide whether to "minimize risks of long-term opioid use by discontinuing opioids" because the patient is "not receiving a clear benefit."[44]

144. In 2009, AAPM and APS issued their own guidelines (the "AAPM/APS Guidelines"). The AAPM/APS Guidelines promote opioids as "safe and effective" for treating chronic pain. The guidelines are deemed "strong recommendations" despite "low quality evidence," and conclude that the risk of addiction is manageable for patients regardless of past abuse histories.

145. Fourteen of the 21 panel members who drafted the AAPM/APS Guidelines, including KOLs Dr. Portenoy and Dr. Perry Fine of the University of Utah, received support from Janssen, Cephalon, Endo, and Purdue. One of the panel members, Joel Saper, resigned from the panel because of his concerns over Manufacturing Defendants' influence over the project.

146. The AAPM/APS Guidelines were reprinted in the journal *Pain*, have been cited over 1,700 times in academic literature, were disseminated in Maryland during the relevant time period, and remain available online.

147. The Manufacturing Defendants have widely referenced and promoted the AAPM/APS Guidelines without disclosing the acknowledged lack of evidence to support them.

148. Beginning in 1995, APS began a campaign to make pain the "fifth vital sign" that doctors should monitor, along with blood pressure, heartbeat, and breathing. Manufacturing Defendants provided substantial funding to APS both to promote pain awareness generally and,

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[44] Deborah Dowell et al., *CDC Guideline for Prescribing Opioids for Chronic Pain—United States, 2016*, Centers for Disease Control and Prevention, *available at* https://www.cdc.gov/mmwr/volumes/65/rr/rr6501e1.htm.

on information and belief, to support the group's "Pain as the 5th Vital Sign" campaign. The Veterans Health Administration adopted this concept in its facilities nationwide in 1999, and the campaign spread from there to the private sector.

(c) Joint Commission on Accreditation of Healthcare Organizations

149. Reinforcing the APS campaign was the work of the Joint Commission on Accreditation of Healthcare Organizations ("JCAHO"), the organization that accredits hospitals across the United States. In 2001, JCAHO introduced its own pain treatment standards. The JCAHO standards call for the assessment of pain in all patients and in each patient-physician interaction, and promoted the concept of pain as the "fifth vital sign."

150. Around the time the JCAHO issued its standards, it developed a 2001 monograph titled *Pain: Current Understanding of Assessment, Management, and Treatments*. JCAHO developed the monograph in collaboration with the National Pharmaceutical Council, Inc., whose members include Allergan, Janssen, Purdue, and Cephalon. The monograph misleadingly stated that "[s]ome clinicians have inaccurate and exaggerated concerns about addiction, tolerance and risk of death. This attitude prevails despite the fact there is no evidence that addiction is a significant issue when persons are given opioids for pain control." Similarly, it notes under "Common Misconceptions About Pain" "[t]he incorrect belief that . . . [u]se of opioids in patients with pain will cause them to become addicted."[45]

151. In 2003, Manufacturing Defendants developed another monograph promoting the use of opioids to treat chronic pain in connection with JCAHO. The monograph states that it was produced as a "collaborative project between NPC and JCAHO."

[45] *Pain: Current Understanding of Assessment, Management, and Treatments*, December 2001, *available at* http://www.npcnow.org/system/files/research/download/Pain-Current-Understanding-of-Assessment-Management-and-Treatments.pdf.

152. The 2003 monograph misleadingly states that "[c]linicians' misconceptions about pain treatments could include an exaggerated fear of addiction resulting from use of opioids; confusion about the differences between addiction, physical dependence, and tolerance; or unwarranted concerns about the potential for the side effect of respiratory depression." It also misleadingly states that "[m]any practices are faulty and outdated (*e.g.*, promoting the idea that there is a high risk of addiction when opioids are taken for pain relief)."

153. Purdue and other Manufacturing Defendants worked closely with JCAHO to promote the misleading JCAHO standards and monographs. According to a report by the United States General Accounting Office, during 2001 and 2002, Purdue funded a series of nine programs throughout the country to educate hospital physicians and staff on how to comply with JCAHO's pain standards for hospitals and to discuss postoperative pain treatment. Purdue was one of only two drug companies that provided funding for JCAHO's pain management educational programs. Under an agreement with JCAHO, Purdue was the only drug company allowed to distribute certain educational videos and a book about pain management; these materials were also available for purchase from JCAHO's website.

154. As a result of the Manufacturing Defendants' promotional efforts, the misleading JCAHO standards have been widely integrated into medical practice.

(2) Guidelines Issued by Groups Not Funded by Manufacturing Defendants

155. The Manufacturer Defendants' influence over treatment guidelines is demonstrated by the fact that guidelines whose authors did not accept drug company funding reached very different conclusions. The 2012 *Guidelines for Responsible Opioid Prescribing in Chronic Non-Cancer Pain*, issued by the American Society of Interventional Pain Physicians ("ASIPP"), warned that "[t]he recent revelation that the pharmaceutical industry was involved in

the development of opioid guidelines as well as the bias observed in the development of many of these guidelines illustrate that the model guidelines are not a model for curtailing controlled substance abuse and may, in fact, be facilitating it." ASIPP's Guidelines further advise that "therapeutic opioid use, specifically in high doses over long periods of time in chronic non-cancer pain starting with acute pain, not only lacks scientific evidence, but is in fact associated with serious health risks including multiple fatalities, and is based on emotional and political propaganda under the guise of improving the treatment of chronic pain." ASIPP recommends long-acting opioids in high doses only "in specific circumstances with severe intractable pain" and only when coupled with "continuous adherence monitoring, in well-selected populations, in conjunction with or after failure of other modalities of treatments with improvement in physical and functional status and minimal adverse effects."[46]

156. Similarly, the 2011 *Guidelines for the Chronic Use of Opioids*, issued by the American College of Occupational and Environmental Medicine, recommend against the "routine use of opioids in the management of patients with chronic pain," finding "at least moderate evidence that harms and costs exceed benefits based on limited evidence," while conceding there may be patients for whom opioid therapy is appropriate.[47]

157. The Clinical Guidelines on Management of Opioid Therapy for Chronic Pain, issued by the U.S. Department of Veterans Affairs ("VA") and Department of Defense ("DOD") in 2010, notes that their review "revealed the lack of solid evidence based research on the

[46] Laxmaiah Manchikanti, et al., *American Society of Interventional Pain Physicians (ASIPP) Guidelines for Responsible Opioid Prescribing in Chronic Non-Cancer Pain: Part 1, Evidence Assessment*, 15 Pain Physician (Special Issue) S1-S66; *Part 2 – Guidance*, 15 Pain Physician (Special Issue) S67-S116 (2012), *available at* https://www.asipp.org/Guidelines.htm.

[47] *American College of Occupational and Environmental Medicine's Guidelines for the Chronic Use of Opioids* (2011), *available at* https://www.nhms.org/sites/default/files/Pdfs/ACOEM%202011-Chronic%20Pain%20Opioid%20.pdf.

efficacy of long-term opioid therapy," and that "critical research gaps on the use of opioids for chronic noncancer pain include: lack of effectiveness studies on long term benefits and harms of opioids (including drug abuse, addiction, and diversion)," and the 'lack of evidence on the utility of informed consent and opioid management plans," and "treatment of patients with chronic noncancer pain at higher risk for drug abuse or misuse."[48] More recently, in 2017, the VA and DOD noted the "lack of high-quality evidence that [long-term opioid therapy] improves pain, function, and/or quality of life," and that "non-opioid treatments are preferred for chronic pain," and that there is a "heightened risk for developing [opioid use disorder] in patients who receive [opioid therapy] beyond 90 days."[49]

f. Continuing Medical Education

158. CMEs are ongoing professional education programs provided to doctors. Doctors are required to attend a certain number and, often, type of CME program each year as a condition of their licensure. Requirements vary by state. These programs are delivered in person, often in connection with professional organizations' conferences, and 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.

159. In all, Defendants sponsored CMEs promoting chronic opioid therapy and supporting and disseminating the deceptive and biased messages described in this Complaint. The CMEs, while often generally titled to relate to the treatment of chronic pain, focus on

[48] Management of Opioid Therapy for Chronic Pain Working Group, *VA/DoD Clinical Practice Guideline for Management of Opioid Therapy for Chronic Pain*, May 2010, *available at* https://www.va.gov/painmanagement/docs/cpg_opioidtherapy_summary.pdf.

[49] *VA/DoD Clinical Practice Guideline for Opioid Therapy for Chronic Pain – Clinician Summary*, February 2017, *available at* https://www.healthquality.va.gov/guidelines/Pain/cot/VADoDOTCPGProviderSummary022817.pdf.

opioids to the exclusion of alternative treatments, inflate the benefits of opioids, and omit the risks and adverse effects of opioids for the treatment of chronic pain. On information and belief, Manufacturing Defendants were aware of and exercised control over the content of these CMEs and intended for the CMEs to reach and influence Maryland prescribers.

160. The American Medical Association ("AMA") has recognized 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 urges that "[w]hen possible, CME[s] should be provided without such support or the participation of individuals who have financial interests in the educational subject matter."[50]

161. The Manufacturing Defendants knowingly sponsored and exercised control over deceptive and misleading CMEs as follows:

a. Cephalon sponsored a CME titled *Optimizing Opioid Treatment for Breakthrough Pain*, which was available online beginning September 28, 2007 and was intended to reach Maryland prescribers. The CME misleadingly taught that Cephalon's Actiq and Fentora improved patients' quality of life and allowed for more activities when taken in conjunction with long-acting opioids. It also misleadingly minimized the risks associated with increased opioid doses by explaining that NSAIDs were less effective than opioids for the treatment of breakthrough pain because of their dose limitations, without disclosing the heightened risk of adverse events on high-dose opioids. KOL Dr. Lynn Webster is listed as the author of this CME. This CME remains available online today and was intended to reach Maryland prescribers.

b. Cephalon similarly used an educational grant to sponsor the CME *Breakthrough Pain: Improving Recognition and Management*, which was offered online beginning March 31, 2008 and was intended to reach Maryland prescribers. The purportedly educational document deceptively omitted Actiq's and Fentora's tolerance limitations, cited examples of patients who experienced pain from accidents, not from cancer, and, like Cephalon's *Optimizing Opioid Treatment CME*, taught that Actiq and

[50] Code of Medical Ethics Opinion 9.2.7, *Financial Relationships with Industry in Continuing Medical Education*, *available at* https://www.ama-assn.org/delivering-care/financial-relationships-industry-continuing-medical-education.

Fentora were the only products on the market that would take effect before the breakthrough pain episode subsided. This CME was available online and was intended to reach Maryland prescribers.

c. Purdue sponsored a 2011 CME webinar taught by KOL Dr. Lynn Webster titled *Managing Patient's Opioid Use: Balancing the Need and Risk.*[51] This CME deceptively instructed prescribers that screening tools and urine tests prevented "overuse of prescriptions" and "overdose deaths." This CME remains available online today and was intended to reach Maryland prescribers.

d. With the financial backing of Purdue, the American Medical Association issued a CME titled *Overview of Management Options* in 2003, 2007, 2010, and 2013. The CME was edited by KOL Dr. Russell Portenoy, among others, and misleadingly taught that other drugs, but not opioids, are unsafe at high doses. This CME remains available online today and was intended to reach Maryland prescribers.

e. Janssen, Purdue, Cephalon, and Endo sponsored a 2009 CME titled *Pharmacological Management of Persistent Pain in Older Persons* in connection with the American Geriatric Society. This CME falsely claimed that the risks of addiction "are exceedingly low in order patients with no current or past history of substance abuse." The study supporting this assertion does not analyze addiction rates by age, and addiction remains a significant risk for elderly patients.

f. Endo sponsored a National Initiative on Pain Control (NIPC) CME program in 2009 titled *Chronic Opioid Therapy: Understanding Risk While Maximizing Analgesia*, which promoted pseudoaddiction by teaching that a patient's aberrant behavior was the result of untreated pain. NIPC is an initiative of APF, and Endo and other pharmaceutical companies funded APF. In 2010 alone, Endo supplied over 50% of APF's income. On information and belief, Endo substantially controlled NIPC by funding NIPC projects; developing, specifying, and reviewing content; and distributing NIPC materials.

g. Endo sponsored a series of eNewsletter CMEs, which were edited by KOL Perry Fine and listed industry-backed KOLs like Dr. Lynn Webster as authors. These CMEs, which were distributed by NIPC, included such titles as *Persistent Pain in the Older Patient* and *Persistent Pain in the Older Adult*. They misleadingly taught that chronic opioid therapy has been "shown to reduce pain and improve depressive symptoms and

[51] *Available at* http://www.emergingsolutionsinpain.com/ce-education/opioid-management?option=com_continued&view=frontmatter&Itemid=303&course=209 (last accessed January 28, 2018).

cognitive functioning" and that opioids used by elderly patients present "possibly less potential for abuse than in younger patients." These statements lack evidentiary support and deceptively minimize the risk of addiction for elderly patients. They also misleadingly taught that withdrawal symptoms can be avoided entirely by tapering the dose by 10-20% per day for ten days.

h. Endo and Purdue sponsored a 2012 CME program titled *Chronic Pain Management and Opioid Use: Easing Fears, Managing Risks, and Improving Outcomes*. This presentation misleadingly recommended that use of screening tools, more frequent refills, and switching opioids could treat a high-risk patient showing signs of potentially addictive behavior.

C. Manufacturing Defendants' Scheme Misrepresented the Risks and Benefits of Opioids

162. Manufacturing Defendants' marketing of opioids for long-term use to treat chronic pain, both directly and with and through third parties, included information that was false, misleading, contrary to credible scientific evidence and their own labels, and lacked balance and substantiation. Their marketing materials omitted material information about the risks of opioids, and overstated their benefits. Moreover, Manufacturing Defendants inaccurately suggested that chronic opioid therapy was supported by evidence, and failed to disclose the lack of evidence in support of treating chronic pain with opioids.

163. As described in greater detail below, there are three primary categories of misleading and unfounded representations. Manufacturing Defendants and the third parties with which they worked:

- Misrepresented the risks of long-term opioid use;
- Overstated the benefits of long-term use of opioids to treat chronic pain; and
- Masked the signs of addiction by calling them "pseudoaddiction."

164. In addition to these misstatements, Purdue purveyed a fourth deception, namely, that OxyContin provides a full 12 hours of pain relief.

1. Manufacturing Defendants Misrepresented the Risks of Long-Term Opioid Use

165. The concealment and misrepresentation of the risks of long-term opioid use was central to Manufacturing Defendants' scheme. Manufacturing Defendants concealed and misrepresented the risks of long-term opioid use in the following ways: (a) omitting altogether, trivializing, and mischaracterizing the risks of addiction; (b) misrepresenting that addiction risk can be avoided or managed; and (c) failing to disclose increased risks of higher dosing.

166. To reach chronic pain patients, Manufacturing Defendants, and the Front Groups and KOLs that they directed, assisted, and collaborated with, had to overcome doctors' legitimate fears that opioids would cause patients to become addicted. The risk of addiction is an extremely weighty risk—condemning patients to, among other things, dependence, compulsive use, haziness, a lifetime of battling relapse, and a dramatically heightened risk of serious injury or death. Identifying benefits of opioid use to treat common chronic pain conditions weighty enough to justify that risk would have, and previously had, posed a nearly insurmountable challenge had it not been for the Manufacturing Defendants' campaign to convince doctors otherwise.

167. Acting directly or with and through third parties, each of the Defendants claimed that the potential for addiction from its drugs was relatively small or non-existent even though there was no scientific evidence to support those claims, and the available research contradicted them. A recent study-of-studies found that while the prevalence of "problematic use" of opioids ranged from <1% to 81%, rates of misuse were between 21% and 29%, and rates of addiction averaged between 8% and 12%.[52] Other studies have concluded that between 30 and 40 percent

[52] Kevin Vowels et al., *Rates of opioid misuse, abuse, and addiction in chronic pain: a systematic review and data synthesis*, 156 PAIN 569-76 (April 2015).

of individuals who use prescription opioids on a long-term basis will develop an opioid use disorder.[53]

168. Moreover, Manufacturing Defendants and their third-party allies have come to admit that some patients could become addicted, but that doctors can avoid or manage that risk by using screening tools or questionnaires. These tools, they say, identify those with higher addiction risks (stemming from personal or family histories of substance abuse, mental illness, or abuse) so that doctors can more closely monitor patients at greater risk of addiction.

169. There are three fundamental flaws in these assurances that doctors can identify and manage the risk of addiction. First, there is no reliable scientific evidence that screening works to accurately predict risk or reduce rates of addiction. Second, there is no reliable scientific evidence that high-risk or addicted patients can take opioids long-term without triggering addiction, even with enhanced monitoring and precautions. Third, there is no reliable scientific evidence that patients without any such "red flags" are free from the risks of becoming addicted.

170. Manufacturing Defendants and their third-party allies further claimed that patients and prescribers could increase doses of opioids indefinitely without added risk, even when pain was not decreasing or when doses had reached levels that were exceptionally high, suggesting that patients would eventually reach a stable, effective dose. Each of Manufacturing Defendants' claims also omitted warnings of increased adverse effects that occur at higher doses, and misleadingly suggested that there was no greater risk to higher dose opioid therapy.

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[53] Boscarino et al., *Risk factors for drug dependence among out-patients on opioid therapy in a large US health-care system*, *supra*; Boscarino et al., *Prevalence of prescription opioid-use disorder among chronic pain patients: comparison of the DSM-5 vs. DSM-4 diagnostic criteria*, *supra*.

171. These claims are false. Patients receiving high doses of opioids as part of long-term opioid therapy are three to nine times more likely to suffer overdose from opioid-related causes than those on low doses. As compared to available alternative pain remedies, scholars have suggested that tolerance to the respiratory depressive effects of opioids develops at a slower rate than tolerance to analgesic effects. Accordingly, the practice of continuously escalating doses to match pain tolerance can, in fact, lead to overdose even where opioids are taken as recommended. The FDA has itself acknowledged that available data suggest a relationship between increased doses and the risk of adverse effects. Moreover, it is harder for patients to terminate use of higher-dose opioids without severe effects of withdrawal, which contributes to a cycle of continued use, even when the drugs provide no pain relief and are causing harm—in other words, to a cycle of addiction.

172. Examples of the Manufacturing Defendants' misrepresentations regarding the risks of long-term opioid use are below:

a. On information and belief, in 2010 the FDA mandated Actavis to acknowledge to the doctors to whom it marketed its drugs that "[b]etween June 2009 and February 2010, Actavis sales representatives omitted and minimized serious risks associated with [Kadian]," including the risk of "[m]isuse, [a]buse, and [d]iversion of [o]pioids," and specifically, the risk that "[o]piod[s] have the potential for being abused and are sought by drug abusers and people with addiction disorders and are subject to criminal diversion."

b. On information and belief, Actavis trained its sales representatives to say that "there is no evidence that simply taking opioids for a period of time will cause substance abuse or addiction," and "that most substance-abusing patients in pain management practices had an abuse problem before entering the practice." On information and belief, Actavis also trained its sales representatives to "set dose levels on [the] basis of patient need, not on [a] predetermined maximal dose."

c. Cephalon and Purdue 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. It also taught patients that "opioid agreements" between doctors and patients can "ensure that you take the opioid as prescribed," and claimed that certain patients "need" a larger dose of their opioid, regardless of the dose currently prescribed.

d. Endo's advertisements for the 2012 reformulation of Opana ER claimed it was designed to be crush resistant, in a way that conveyed that it was less likely to be abused. This claim was false; the FDA warned in a May 10, 2013 letter that there was no evidence Endo's design "would provide a reduction in oral, intranasal or intravenous abuse" and Endo's "postmarketing data submitted are insufficient to support any conclusion about the overall or route-specific rates of abuse." Further, Endo instructed its sales representatives to repeat this claim about "design," with the intention of conveying Opana ER was less subject to abuse.

e. Endo sponsored a website, *painknowledge.com*, through APF and NIPC, which claimed in 2009 that: "[p]eople who take opioids as prescribed usually do not become addicted." It further claimed that opioids may be increased until "you are on the right dose of medication for your pain."

f. Endo sponsored CMEs published by APF's NIPC, of which Endo was the sole funder, titled *Persistent Pain in the Older Adult* and *Persistent Pain in the Older Patient*. These CMEs claimed that opioids used by elderly patients present "possibly less potential for abuse than in younger patients," which lacks evidentiary support and deceptively minimizes the risk of addiction for elderly patients.

g. Endo distributed an education pamphlet with the Endo logo titled *Living with Someone with Chronic Pain*, which inaccurately minimized the risk of addiction: "Most health care providers who treat people with pain agree that most people do not develop an addiction problem."

h. Janssen, Purdue, Cephalon, and Endo sponsored a 2009 CME titled *Pharmacological Management of Persistent Pain in Older Persons* in connection with the American Geriatric Society. This CME falsely claimed that the risks of addiction "are exceedingly low in order patients with no current or past history of substance abuse."

i. Purdue sponsored and Endo and Janssen provided grants to distribute APF's *Exit Wounds* (2009) to veterans, which taught that "[l]ong experience with opioids shows that people who are not predisposed to addiction are very unlikely to become addicted to opioid pain medications."

j. Janssen sponsored a patient education guide titled *Finding Relief: Pain Management for Older Adults* (2009), which its personnel reviewed and

approved and which its sales force distributed. This guide described a "myth" that opioids are addictive, and asserts as fact that "[m]any studies show that opioids are rarely addictive when used properly for the management of chronic pain." It also listed dose limitations as "disadvantages" of other pain medicines but omitted any discussion of risks of increased doses from opioids. The publication also falsely claimed that it is a "myth" that "opioid doses have to be bigger over time."

k. Janssen runs a website, *Prescriberesponsibly.com* that falsely claims that concerns about opioid addiction are "overestimated."

l. Purdue sponsored APF's *A Policymaker's Guide to Understanding Pain & Its Management*, which inaccurately claimed that less than 1% of children prescribed opioids will become addicted. This publication also asserted that pain is undertreated due to "misconceptions about opioid addiction," and that dose escalations are "sometimes necessary."

m. Purdue sponsored a 2012 CME program titled *Chronic Pain Management and Opioid Use: Easing Fears, Managing Risks, and Improving Outcomes*. This presentation recommended that use of screening tools, more frequent refills, and switching opioids could treat a high-risk patient showing signs of potentially addictive behavior.

n. Cephalon sponsored a CME written by KOL Dr. Lynn Webster, *Optimizing Opioid Treatment for Breakthrough Pain*, which taught that non-opioid analgesics and combination opioids that include aspirin and acetaminophen are less effective to treat breakthrough pain because of dose limitations.

o. Purdue sponsored a CME issued by the American Medical Association in 2003, 2007, 2010, and 2013. The CME, Overview of Management Options, was edited by KOL Dr. Russell Portenoy, among others, and taught that other drugs, but not opioids, are unsafe at high doses.

p. Janssen sponsored a patient education guide titled *Finding Relief: Pain Management for Older Adults* (2009), which its personnel reviewed and approved and its sales force distributed. This guide features a man playing golf on the cover and lists examples of expected functional improvement from opioids, like sleeping through the night, returning to work, recreation, sex, walking, and climbing stairs. The guide states as a "fact" that "opioids may make it easier for people to live normally."

2. Manufacturing Defendants Overstated the Benefits of Chronic Opioid Therapy

173. Each of the following materials was created with the expectation that, by instructing patients and prescribers that opioids would improve patients' function and quality of life, patients would demand opioids and doctors would prescribe them. These claims also encouraged doctors to continue opioid therapy in the belief that failure to improve pain, function, or quality of life could be overcome by increasing doses or prescribing supplemental short-acting opioids to take on an as-needed basis for breakthrough pain.

174. However, not only is there no evidence of improvement in long-term functioning, a 2006 study-of-studies found that "[f]or functional outcomes . . . other analgesics were significantly more effective than were opioids."[54] Studies of the use of opioids to treat chronic conditions for which they are commonly prescribed, such as low back pain, corroborate this conclusion and have failed to demonstrate an improvement in patients' function.

175. Yet each of the following statements by Manufacturing Defendants misleadingly suggests that the long-term use of opioids improve patients' function and quality of life, and that scientific evidence supports this claim:

a. On information and belief, Actavis trained its sales representatives to instruct prescribers that "most chronic benign pain patients do have markedly improved ability to function when maintained on chronic opioid therapy."

b. Actavis distributed a product advertisement that claimed that use of Kadian to treat chronic pain would allow patients to return to work, relieve "stress on your body and your mental health," and cause patients to enjoy their lives." The FDA warned Actavis such claims were misleading, writing: "We are not aware of substantial evidence or substantial clinical experience demonstrating that the magnitude of the effect of the drug has in alleviating pain, taken together with any drug-related side effects patients may experience . . . results in any overall positive impact on a patient's work, physical and mental functioning, daily activities, or enjoyment of life."

[54] Furlan et al., *supra*.

c. Cephalon and Purdue sponsored and Endo and Purdue distributed the FSMB's *Responsible Opioid Prescribing* (2007), which taught that relief of pain itself improved patients' function. *Responsible Opioid Prescribing* explicitly describes functional improvement as the goal of a "long-term therapeutic treatment course."

d. Cephalon sponsored the American Pain Foundation's *Treatment Options: A Guide for People Living with Pain* (2007), which taught patients that opioids when used properly "give [pain patients] a quality of life we deserve."

e. Cephalon sponsored a CME written by key opinion leader Dr. Lynn Webster, titled *Optimizing Opioid Treatment for Breakthrough Pain*, which taught that Cephalon's Actiq and Fentora improve patients' quality of life and allow for more activities when taken in conjunction with long-acting opioids.

f. Endo sponsored a website, *painknowledge.com*, through APF and NIPC, which 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."

g. A CME sponsored by Endo, titled *Persistent Pain in the Older Patient*, taught that chronic opioid therapy has been "shown to reduce pain and improve depressive symptoms and cognitive functioning."

h. Endo distributed handouts to prescribers that claimed that use of Opana ER to treat chronic pain would allow patients to perform work as a chef. This flyer also emphasized Opana ER's indication without including equally prominent disclosure of the "moderate to severe pain" qualification.

i. Purdue sponsored and Endo and Janssen provided grants to distribute APF's *Exit Wounds* to veterans, which taught that opioid medications "increase your level of functioning."

j. Janssen sponsored, developed, and approved content of a website, *Let's Talk Pain*, which featured an interview claiming that opioids "increase" patients' "quality of life."

k. Purdue sponsored APF's *A Policymaker's Guide to Understanding Pain & Its Management*, which inaccurately 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."

l. Purdue sponsored APF's *Treatment Options: A Guide for People Living with Pain* (2007), which counseled patients that opioids, when used properly, "give [pain patients] a quality of life we deserve."

3. Manufacturing Defendants Created Confusion by Promoting the Misleading Term 'Pseudoaddiction'

176. The concept of pseudoaddiction was coined by Dr. David Haddox, who went to work for Purdue, and popularized by Dr. Russell Portenoy, who consulted for Cephalon, Endo, Janssen, and Purdue. Much of the same language appears in Manufacturing Defendants' treatment of this issue, highlighting the contrast between "undertreated pain" and "true addiction," as if patients could not experience both simultaneously. As KOL Dr. Lynn Webster stated: "[Pseudoaddiction] obviously became too much of an excuse to give patients more medication. . . . It led us down a path that caused harm. It is already something we are debunking as a concept."[55]

177. Each of the Manufacturing Defendants' publications and statements below falsely states or suggests that the concept of "pseudoaddiction" is substantiated by scientific evidence and accurately describes the condition of patients who only need, and should be treated with, more opioids:

a. On information and belief, Actavis trained its sales representatives to direct doctors to be on the lookout for signs of "pseudoaddiction," which were defined as "[b]ehaviors (that mimic addictive behaviors) exhibited by patients with inadequately treated pain."

b. Cephalon and Purdue sponsored and paid to distribute FSMB's *Responsible Opioid Prescribing* (2007), which taught that behaviors such as "requesting drugs by name," "demanding or manipulative behavior," seeing more than one doctor to obtain opioids, and hoarding are all signs of pseudoaddiction. Endo also purchased copies of this book to distribute nationwide.

[55] John Fauber & Ellen Gabler, *Networking Fuels Painkiller Boom*, Milwaukee Wisc. J. Sentinel, Feb. 19, 2012.

c. Janssen's website, *Let's Talk Pain*, stated that "pseudoaddiction . . . refers to patient behaviors that may occur when pain is under-treated" and "[p]seudoaddiction is different from true addiction because such behaviors can be resolved with effective pain management."

d. Purdue's website, *Partners Against Pain*, relied on and directed users to the 2001 guideline issued by the AAPM and APS, which endorsed the concept of pseudoaddiction and claimed that patients who engage in drug-seeking behaviors may not be addicted by simply have undertreated pain. The guideline promoted on the *Partners Against Pain* website falsely claimed that "[p]seudoaddiction can be distinguished from true addiction in that the behaviors resolve when pain is effectively treated." And through at least 2010, the website itself listed "pseudoaddiction" as a "key term[] in pain management" and misleadingly stated that "it can be distinguished from true addiction in that the behaviors resolve when the pain is effectively treated."

e. Purdue sponsored APF's *A Policymaker's Guide to Understanding Pain & Its Management*, which states: "Pseudo-addiction describes patient behaviors that may occur when pain is undertreated. . . . Pseudo-addiction can be distinguished from true addiction in that this behavior ceases when pain is effectively treated."

4. Purdue Misleadingly Promoted OxyContin as Providing 12 Hours of Pain Relief

178. In addition to making the deceptive statements above, Purdue also dangerously misled doctors and patients about OxyContin's duration and onset of action.

179. 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, upon information and belief, adapted from Purdue's own sales materials:[56]

[56] Jim Edwards, *How Purdue Used Misleading Charts to Hide OxyContin's Addictive Power*, CBS News, Sept. 28, 2011, *available at* https://www.cbsnews.com/news/how-purdue-used-misleading-charts-to-hide-oxycontins-addictive-power/.

OxyContin PI Figure, Linear y-axis

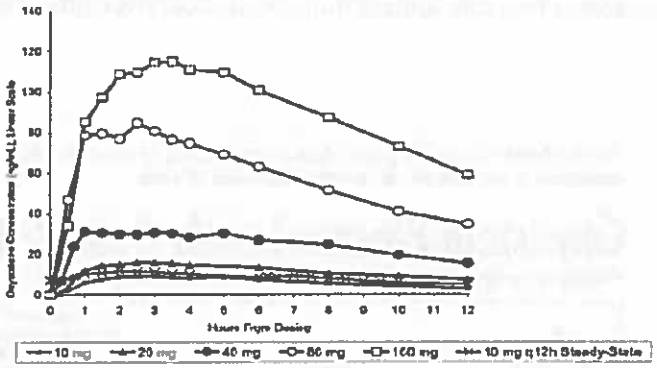
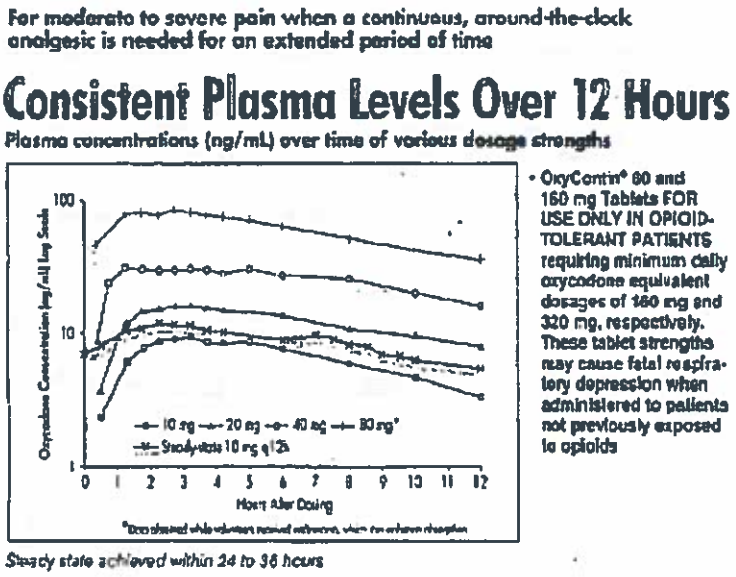


Figure 1

180. 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—OxyContin is roughly twice as powerful as morphine—triggers a powerful psychological response. OxyContin thus behaves more like an immediate release opioid, which Purdue itself once claimed was more addictive 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 not lasting for a full 12 hours and precipitating 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.) The combination of fast onset and end-of-dose failure makes OxyContin particularly addictive, even compared with other opioids.

181. Purdue nevertheless has falsely promoted OxyContin as effective for a full 12 hours. Its advertising in 2000 included claims that OxyContin provides "Consistent Plasma Levels Over 12 Hours." That claim was accompanied by a chart depicting plasma levels on a logarithmic scale, in other words, depicting 10 mg on the y axis so that it appeared to be half of

100 mg. 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 over time than it actually is:



More recently, other Purdue advertisements have emphasized "Q12h" (meaning twice-daily) dosing. It also instructed its sales representatives to focus on 12-hour dosing.

182. The information that OxyContin did not provide pain relief for a full 12 hours was known to Purdue and Purdue's competitors, but was not disclosed to general practitioners. Purdue's knowledge of some pain specialists' tendency to prescribe OxyContin three or four times per day was set out internal documents. Indeed "[e]ven before OxyContin went on the market, clinical trials showed many patients weren't getting 12 hours of relief."[57]

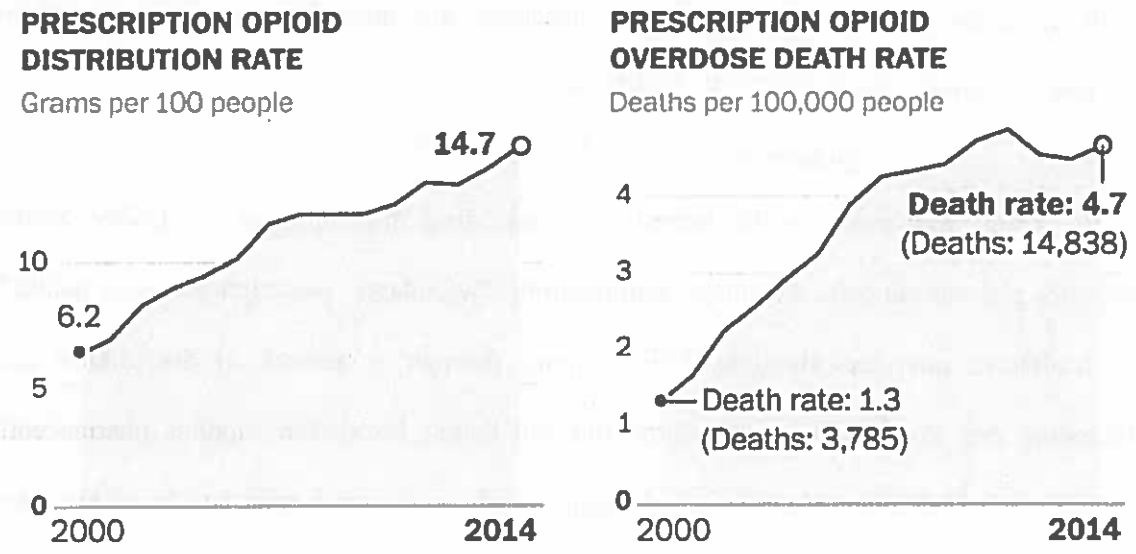
D. The Wholesaler and Manufacturer Defendants Failed to Track and Report Suspicious Sales as Required by Maryland and Federal Law

183. Drug manufacturers sell and deliver their drugs through wholesale distributors, who buy drugs in bulk from manufacturers and deliver orders of those drugs to pharmacies,

[57] Ryan, et al. Part One, *supra*.

hospitals, long-term care facilities, and other healthcare providers throughout the country. Wholesaler Defendants AmerisourceBergen, Cardinal Health, and McKesson Corporation account for approximately 85 to 90% of all revenues from drug distribution in the United States.

184. Unsurprisingly, as the sales and distribution of prescription opioids has increased, so too has the prescription opioid overdose death rate:



185. Because Wholesaler Defendants control the distribution of massive quantities of potentially dangerous and addictive controlled substances, each is required under the CSA to "design and operate a system to [identify] suspicious orders of controlled substances" and to report any such suspicious orders to "the Field Division Office of the [DEA] in his area." 21 C.F.R. § 1301.74(b). Suspicious orders include "orders of unusual size, orders deviating substantially from a normal pattern, and orders of unusual frequency." The CSA authorizes the

imposition of a fine of up to $10,000 per violation of the suspicious order reporting requirement. The provision requiring monitoring and reporting of suspicious orders in the CSA has been incorporated by regulation into Maryland Law. *See* Code of Maryland Regulations ("COMAR") 10.19.03.03 (requiring manufacturers, distributors, and dispensers of "controlled dangerous substances" including Manufacturing Defendants' prescription opioids to register with the Maryland Department of Health); 10.19.03.12 (requiring all such registrants to "guard against theft and unlawful diversion of controlled substances" and importing the security requirements set forth in, among others, 21 C.F.R. § 1301.74).

1. McKesson

186. McKesson is the largest wholesale drug distributor in the United States. It supplies pharmaceuticals, including Manufacturing Defendants' prescription opioid painkillers, to healthcare providers throughout the country through a network of distribution centers including one in Maryland. On information and belief, McKesson supplies pharmaceuticals including the Defendant Manufacturers' opioids to pharmacies and other healthcare providers in and around Baltimore.

187. In 2008, McKesson agreed to pay fines totaling over $13 million to settle charges that it violated the CSA by failing to report suspicious orders of opioids, including by failing to report sales of hydrocodone made to "internet pharmacies" and orders that were unusually large. As part of that settlement agreement, McKesson developed a Controlled Substance Monitoring Program ("CSMP"), but failed to fully implement and adhere to that compliance program. McKesson continued to fail to detect and report suspicious orders of controlled substances, including massive amounts of oxycodone and hydrocodone. Between June 2008 and May 2013, McKesson reported just sixteen orders as suspicious—all connected to a single customer.

188. In 2017 McKesson agreed to pay $150 million to settle the charges that it had again violated the CSA by failing to detect and report suspicious orders of controlled substances. McKesson also agreed to suspend entirely its distribution of controlled substances from distribution centers in four states. McKesson also acknowledged that "at various times [between January 2009 and January 2017] did not identify or report to DEA certain orders placed by certain pharmacies, which should have been detected by McKesson as suspicious, in a manner fully consistent with the requirements of" the 2008 settlement.[58]

189. McKesson is also currently under investigation by a multi-state coalition of attorneys general, including Maryland Attorney General Brian Frosh.

190. As a result of McKesson's failure to detect and report suspicious orders, dangerous quantities of prescription opioids including oxycodone and hydrocodone have flooded communities throughout the country, including Baltimore. On information and belief, prescription opioids distributed by McKesson through a distribution center in Maryland made their way into Baltimore and contributed to the opioid epidemic in the City.

2. Cardinal Health

191. Cardinal Health sells healthcare services and products, including as a wholesale distributor of prescription opioids made by the Manufacturing Defendants. Its pharmaceutical division had $109.1 billion in revenues in 2016. Cardinal Health supplies healthcare providers with pharmaceuticals through distribution centers, including one near Baltimore. On information and belief, Cardinal Health supplies pharmaceuticals including the Defendant Manufacturers' opioids to pharmacies and other healthcare providers in and around Baltimore.

[58] Department of Justice, *Administrative Memorandum of Agreement*, *available at* https://www.justice.gov/opa/press-release/file/928476/download.

192. In December 2016 Cardinal Health agreed to pay $44 million to settle charges that it violated the CSA by failing to report suspicious orders of controlled substances, including oxycodone, to pharmacies located in Maryland, Florida, and New York. Cardinal Health acknowledged that from January 2009 to May 2012, it failed to report suspicious orders to the DEA, and failed to maintain effective controls against diversion of controlled substances. In particular, Cardinal Health admitted the following:

> "Failure . . . to timely identify suspicious orders of controlled substances and inform the DEA of those orders, as required by 21 C.F.R. § 1301.74(b)";
>
> "Failure . . . to maintain effective controls against diversion of particular controlled substances into other than legitimate . . . 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
>
> "Failure . . . to execute, fill, cancel, correct, file with the DEA, and otherwise handle DEA "Form 222" order forms . . . for Schedule II controlled substances, as required by 21 U.S.C. § 828 and 21 C.F.R. Part 1305."

The press release announcing the Cardinal Health settlement specified that the allegations related to distribution of oxycodone.

193. Cardinal Health is also currently under investigation by a multi-state coalition of attorneys general, including Maryland Attorney General Brian Frosh.

194. As a result of Cardinal Health's failure to detect and report suspicious orders, dangerous quantities of prescription opioids including oxycodone and hydrocodone have flooded communities throughout the country, including Baltimore. On information and belief, prescription opioids distributed by McKesson through a distribution center in Maryland made their way into Baltimore and contributed to the opioid epidemic in the City.

3. AmerisourceBergen

195. AmerisourceBergen is a wholesale distributor of pharmaceuticals and handles approximately one fifth of the total distribution of pharmaceuticals supplied in the United States. It supplies pharmaceuticals, including Manufacturing Defendants' prescription opioid painkillers, to healthcare providers throughout the country through a network of distribution centers including one near Baltimore. On information and belief, AmerisourceBergen supplies pharmaceuticals including the Defendant Manufacturers' opioids to pharmacies and other healthcare providers in and around Baltimore.

196. The State of West Virginia sued AmerisourceBergen and Cardinal Health in 2012 alleging, among other claims, violation of the CSA, the state's consumer protection laws, and creation of a public nuisance. Unsealed records from that case revealed that, between 2007 and 2012, the Wholesaler Defendants supplied 423 million prescription opioid pain pills to the state. In other words, in six years the Wholesaler Defendants supplied enough prescription opioids to provide every single resident of the state with 232 pills. AmerisourceBergen alone supplied over 50 million doses of oxycodone and over 80 million doses of hydrocodone in the form of 38.4 million oxycodone pills and 80.3 million hydrocodone pills to the state in that time period. In 2016, AmerisourceBergen paid $16 million to the State of West Virginia to settle the lawsuit.

197. AmerisourceBergen is also currently under investigation by a multi-state coalition of attorneys general, including Maryland Attorney General Brian Frosh.

4. The Manufacturing Defendants

198. Each of the Manufacturing Defendants also constitutes a "registrant" as defined under the Controlled Substances Act and is therefore also required to design and implement a system to detect and report suspicious orders of controlled substances. *See* 21 C.F.R. §§ 1300.02(b), 1301.74(b); 21 U.S.C. § 823; COMAR §§ 10.19.03.03, 10.19.03.12 (same under Maryland law).

199. Each of the Manufacturing Defendants has failed to detect and report suspicious orders of controlled substances as required by the CSA. For example, according to a 2016 investigation by the *Los Angeles Times*, Purdue failed to report suspicious distributions to a given pharmacy even where a Purdue employee had personally witnessed the diversion of its drugs at that pharmacy and where its drugs were being diverted and sold on the streets.[59] Despite knowing of illicit prescribing from a particular "pill mill," Purdue did not report those suspicions until years after law enforcement shut down the clinic—after the clinic had prescribed more than 1.1 million OxyContin pills. In August 2017, two physicians operating pill mills in and around were indicted for charges relating to the prescription of unnecessary opioids to patients, including the prescription of 283,666 doses of oxycodone by a single physician to Medicaid beneficiaries in just over four years. Other prescribers in the City of Baltimore and/or prescribing opioids to City residents have also been charged with offenses relating to the overprescription of opioid painkillers. The Manufacturing Defendants' failure to timely report these and other suspicious sales violated the CSA and Maryland law.

E. Rosen-Hoffberg Operated as a "Pill Mill" To Serve the Addicts that Manufacturing Defendants' Marketing Scheme Engendered

200. Defendant Rosen-Hoffberg is a pain clinic with locations in Towson and Owings Mills, Maryland. In reality, Rosen- Hoffberg operates as a "pill mill." A pill mill is a physician's office, clinic, or health care facility that prescribes controlled dangerous substances without a legitimate medical purpose.

201. Rosen-Hoffberg operates under the direction of Dr. Norman B. Rosen and Dr. Howard J. Hoffberg. Dr. Rosen is listed as Rosen-Hoffberg's founder and medical director, and Dr. Hoffberg is listed as the associate medical director. Doctors Rosen and Hoffberg are licensed

[59] Harriet Ryan et al., *More than 1 million OxyContin pills ended up in the hands of criminals and addicts. What the drugmaker knew*, L.A. Times, July 10, 2016, *available at* http://www.latimes.com/projects/la-me-oxycontin-part2/.

Maryland physicians. Both Doctors Rosen and Hoffberg reportedly possess specialty board certifications in pain medicine.

202. Rosen-Hoffberg's website, www.whyhurt.biz, describes itself as a "unique private practice dedicated to serving patients with acute or chronic pain, or who have any physical and/or stress-related disability from any cause." It further describes its goal as "maximiz[ing] the quality of life of people who have acute and/or chronic pain or disability from any congenital or acquired disease or other condition involving the nerves, muscles, joints, or soft tissues." It describe its areas of specialty as including "Acute/Chronic Pain (from any cause)," neck and low back pain, headaches, orthopedic rehabilitation, "Sports and Work Related Injuries," fibromyalgia and myofascial pain syndrome, arthritis, pelvic pain, geriatrics, neuromuscular rehabilitation, carpal tunnel syndrome and other nerve entrapment syndromes, and stress management and wellness.

203. Echoing the Manufacturing Defendants' deceptive campaign to rebrand pain as the "fifth vital sign," Rosen-Hoffberg's website describes pain as "one of the most important 'vital signs' (along with pulse, blood pressure, weight, breathing rate and height)."

204. The website notes that "we are willing to prescribe opioids," though it advises patients that "the use of opioids is more effective when used as part of a multi-disciplinary approach, which we provide."

205. ProPublica has compiled a database of prescriptions issued in 2015 to patients participating in Medicare's prescription drug benefit program, known as Medicare Part D. Medicare Part D serves more than 42 million people and pays for more than one in four

prescriptions written in the United States. ProPublica's database, titled "Prescriber Checkup," show red flags hanging all over Rosen-Hoffberg.[60]

206. Prescriber Checkup shows that, in 2015, Dr. Hoffberg issued 7,046 Part D prescriptions, more than all but fifteen prescribers in the same specialty working in Maryland that year. Moreover, it showed that Dr. Hoffberg prescribed opioids to *92% of his patients.* While startling on its own terms, prescribers within the same specialty prescribed opioids to only 14% of their patients, a rate that Dr. Hoffberg exceeded by approximately 657%. The data also show that Dr. Hoffberg filled an average of 20 prescriptions per patient, as compared to an average in Maryland of 8 prescriptions per patient within the same specialty.

207. With respect to Dr. Rosen, Prescriber Checkup showed that he filled 1,041 Part D prescriptions in 2015, and that he prescribed opioids to 88% of his patients.

208. Moreover, Dr. Rosen has been the subject of multiple public disciplinary actions before the Maryland State Board of Physicians related to his excessive opioid prescribing for patients with chronic pain and for his failure to monitor patients for addiction and diversion.

209. On June 30, 2017, the Maryland State Board of Physicians (the "Board") issued a public reprimand to Dr. Rosen for "violat[ing] the prevailing standards of quality care from 2005-2007 by prescribing excessive amounts of opioids and failing to monitor [a] patient's risks for addiction and diversion."[61] Specifically, the Board found that: Dr. Rosen relied "almost exclusively on opioids to manage the patient's pain in 2006 and 2007"; that, in 2007, Dr. Rosen increased the patient's dosage of opioids to 40 pills per day, totaling over 1,200 tablets in one four-week period, levels which were "very, very high and outside the standard of care"; that "Dr. Rosen's regimen of short-acting opioid pills was ineffective"; that "Dr. Rosen . . . and other

[60] ProPublica, *Prescriber Checkup*, updated Aug. 2017, *available at* https://projects.propublica.org/checkup/.

[61] *In the Matter of Norman B. Rosen, M.D.*, No. 2008-0018, June 30, 2017.

practitioners recognized the patient's risk factors for potential addiction" but "continued to prescribe high levels and volumes of this short-acting opioid for a patient with unremarkable pathology based on the patient's requests"; that Dr. Rosen "never screened the patient to verify that he was taking all the oxycodone prescribed"; that "a patient taking 40 pills a day raises a concern that some of it could go elsewhere"; and that "Dr. Rosen ignored the inherent risks to the patient and society in this case, and deviated from the standard of care."[62]

210. On November 13, 2017, a disciplinary panel of the Board brought further public charges against Dr. Rosen related to his opioid prescribing practices. In the course of its investigation of Dr. Rosen, the board obtained ten patient records from Dr. Rosen and referred them to a peer review entity. The peer reviewers found that Dr. Rosen "consistently prescribed excessively high dosages of highly addictive short-acting opioids and long-acting opioids over prolonged periods of time in the absence of clinical evidence to support the dosages prescribed"; that Dr. Rosen "maintained patients on excessively high levels of opioids for months and even years despite lack of improvement of functionality or pain control"; that Dr. Rosen "failed to adequately monitor patients for the potential risk of diversion or addiction"; that Dr. Rosen "failed to significantly modify his treatment plan when patients demonstrated aberrant behavior" that "would raise concern for diversion"; that Dr. Rosen "failed to taper or wean patients from excessive dosages of opioids in spite of the lack of functional improvement or pain control over extended periods of time"; and that Dr. Rosen "continued to maintain or escalate opioid doses in spite of patient behavior indicating opioid use disorder."[63]

211. The Centers for Medicare and Medicaid Services ("CMS") maintains a database showing payments made by drug and medical device companies to physicians and teaching

[62] *Id.*

[63] *In the Matter of Norman B. Rosen, M.D.*, No. 2016-0856B, November 13, 2017.

hospitals. This data highlights the troubling connections between the Manufacturing Defendants and Rosen-Hoffberg.

212. For every year that they are available, the CMS data show that Dr. Hoffberg received payments from pharmaceutical companies well above the national mean. In 2013, Dr. Hoffberg received payments of $36,147.38, as compared to the national mean of $1,583.31. In 2014, Dr. Hoffberg received payments of $63,988.69, as compared to the national mean of $3,379.13. In 2015, Dr. Hoffberg received payments of $60,569.87, as compared to the national mean of $3,269. And in 2016, Dr. Hoffberg received payments of $18,041.61, as compared to the national mean of $3,273.71.

213. Not only do the CMS data show the extent of payments from the pharmaceutical companies to Dr. Hoffberg, they show Dr. Hoffberg's connections to the Manufacturing Defendants specifically. In 2015, for example, Dr. Hoffberg received $17,810.44 from Purdue and $14,487.28 from Cephalon. Similarly, in 2014, Dr. Hoffberg received $14,597.64 from Cephalon and $8,356.50 from Purdue.

214. Dr. Hoffberg repeated and promulgated the misleading messages developed by the Manufacturing Defendants described above regarding the use of opioids to treat chronic pain in Baltimore.

215. On October 14, 2017, Dr. Hoffberg repeated and promulgated the Manufacturing Defendants' misleading messages at a CME presentation at St. Agnes Hospital in Baltimore.[64] The presentation, titled *Updates in Opioid Management for Chronic Pain*, promotes the use of opioids for the treatment of chronic pain as "effective," "time honored" and "medically

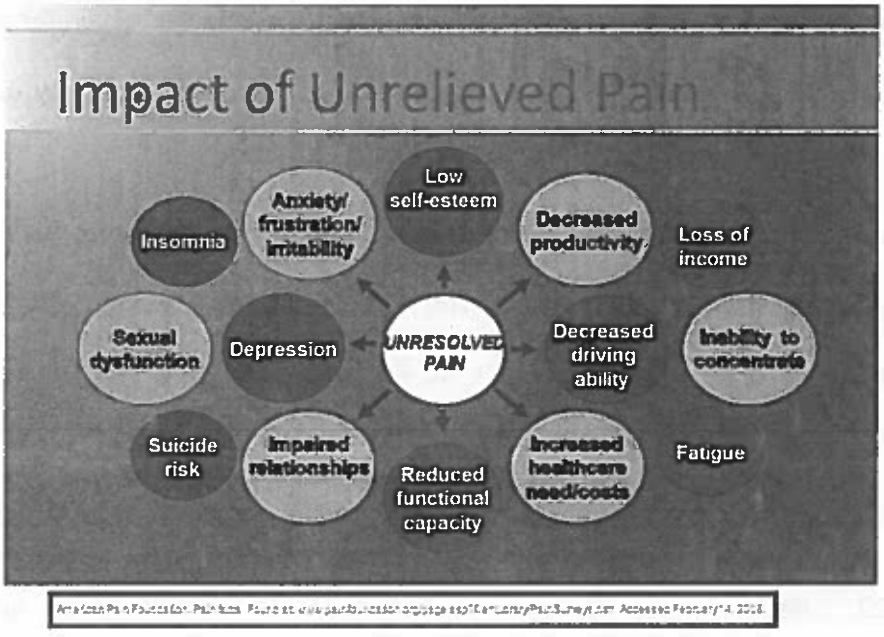
[64] As of January 23, 2018, the entire presentation was available to watch online at: https://www.tsncommunications.com/pain-management-and-beyond/.

necessary." In the presentation, Dr. Hoffman taught that "pain is still considered the fifth vital sign." He also repeated and promoted the misleading concept of pseudoaddiction, as follows:

> The patients who are the more problematic patients, when they do have pain, what do you do for them? Inadequate pain management can be mistaken for addiction and they have aberrant behavior and clock-watching and dose escalation and really what they are is they're called pseudoaddiction, which means that once you give them a better dosing of their pain medicine then they will end up to be compliant patients that will be appreciative and thankful for the care that you provide.[65]

216. In the Baltimore CME presentation, Dr. Hoffberg promoted the use of "opioid agreements" and the Opioids Risk Tool developed by KOL Dr. Lynn Webster, despite the fact that neither "opioid agreements" nor any other screening tools have been scientifically validated to decrease the risks of addiction or make addiction easier to identify or manage.

217. In the Baltimore CME presentation, Dr. Hoffberg even displayed the following slide regarding the "impact of unrelieved pain," which indicates at the bottom of the slide that it was created by the now-defunct Baltimore-based Front Group, American Pain Foundation:



[65] *Id.*

218. The City of Baltimore has paid, through its employee health plan, for numerous opioid prescriptions issued by Rosen-Hoffberg for long-term treatment of chronic pain.

219. In 2015, for example, the City's health plan paid for 16 opioid prescriptions written by Dr. Hoffberg for 7 City employees, 5 of whom filled multiple prescriptions. These prescriptions were written for Oxycontin, Nucynta ER, Butrans, and Hysingla ER, and each was for a supply of 15 days or longer. Those data points do not cover any additional prescriptions written by Dr. Hoffberg for generic opioids, nor do they cover any prescriptions written for individuals covered under the City's workers compensation plans.

220. In 2014, the City's health plan paid for 33 opioid prescriptions written by Dr. Hoffberg for 8 City employees, 5 of whom filled multiple prescriptions. These prescriptions were written for Oxycontin, Nucynta ER, Opana ER, and Butrans, and each was for a supply of 15 days or longer. One of Dr. Hoffberg's patients for whose prescriptions the City paid filled 20 prescriptions of Nucynta ER that year alone, for a total of 367 days-worth of supply, or 760 tablets. Again, such data does not cover any additional prescriptions written for generic opioids, which generally make up a vast majority of the total prescriptions covered by the City's health and workers compensation plans.

221. The establishment of Rosen-Hoffberg as a pill mill that supplied individuals with massive quantities of prescription opioids with few questions asked encouraged the development of opioid use disorders, ensured a source for drugs for individuals with those disorders, and exacerbated the opioid crisis in Baltimore.

F. The Manufacturing and Wholesaler Defendants Knew or Should Have Known Rosen-Hoffberg Was Operating a Pill Mill and Turned a Blind Eye

222. Pharmaceutical companies, including the Manufacturing and Wholesaler Defendants, maintain highly sophisticated and granular prescribing databases. They know where

their drugs are being prescribed, in what quantities, and by whom. They also know who is not prescribing their drugs or prescribing drugs manufactured by competitors.

223. Manufacturing Defendants thus knew precisely how many of their opioids, and their competitors' opioids, Rosen-Hoffberg was prescribing. They knew that Rosen-Hoffberg was endangering patients.

224. In order to calibrate how to influence prescribers and monitor the effectiveness of their marketing efforts, Defendants purchase, manipulate, and analyze data available from QuintilesIMS (now known as "IQVIA"), whose clients include "[n]early all of the top 100 global pharmaceutical and biotechnology companies."[66] In its most recent Annual Report, QuintilesIMS stated that it is "a leading global information provider for the healthcare industry" and maintains "one of the largest and most comprehensive collections of healthcare information in the world, which includes more than 530 million comprehensive, longitudinal, anonymous patient records spanning sales, prescription and promotional data, medical claims, electronic medical records and social media."[67] Its dataset contains over 10 petabytes of unique data, and includes "over 85% of the world's prescriptions by sales value."[68] QuintilesIMS data is expensive, proprietary and in the sole possession of Defendants. According to QuintilesIMS, "[t]he breadth of the intelligent, actionable information [it] provide[s] is not comprehensively available from any other source . . . and would be difficult and costly for another party to replicate."[69]

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[66] Form 10-K, Quintiles IMS Holdings Inc., filed February 16, 2017, at 12.

[67] *Id.*

[68] Form S-1, IMS Health Holdings, Inc., filed Jan. 2, 2014, at 1.

[69] Form 10-K, Quintiles IMS Holdings Inc., filed February 16, 2017, at 5.

225. Although the prescribing data from QuintilesIMS or data separately maintained by Manufacturing and Wholesaler Defendants is not freely available to the public, what public data exist provide a window into what Manufacturing and Wholesaler Defendants should have surmised about Rosen-Hoffberg's operations. As described above, ProPublica's "Prescriber Checkup" show Dr. Hoffberg and Dr. Rosen as outlier prescribers of opioids. Moreover, several of the Manufacturing Defendants made substantial payments directly to Dr. Hoffberg. And Dr. Rosen's disciplinary history before the Maryland State Board of Physicians related to his overprescribing of opioids is a matter of public record.

G. Defendants' Conduct Has Directly Caused Harm to the City of Baltimore and Created a Public Nuisance

226. Through their direct promotional efforts and with the help of the third parties they helped and controlled, Manufacturing Defendants accomplished precisely what they set out to do: fundamentally alter the perception among the medical community and the public of the appropriateness and necessity of treating chronic pain with long-term use of opioid painkillers. As a direct result, prescribers in Baltimore began prescribing opioids for long-term use to treat chronic pain—most of whom would never have considered doing so prior to the Manufacturing Defendants' promotional campaign.

227. In the absence of the Manufacturing Defendants' deceptive marketing, prescribers throughout the country would have gone on, in most cases, prescribing opioid painkillers only when medically necessary or reasonably required to treat chronic pain. As outlined below, the impact of the Manufacturing Defendants' deceptive marketing on prescribers' and patients' use of prescription opioids is evidenced by: (1) the massive increase in opioid prescribing nationally, which occurred side by side with the Manufacturing Defendants' marketing; (2) the City's own increased spending on opioid prescriptions, including through the City's employee and retiree

health insurance and workers' compensation programs; and (3) the consequences of massive overprescription of opioids—including abuse and addiction, overdose, and death—that have been imposed on Baltimore and its residents.

1. Increase in Opioid Prescribing Nationally

228. As described further above, the Manufacturing Defendants' campaign was massively successful in shifting prevailing medical views regarding long-term opioid use to treat chronic pain. Between 2000 and 2012, the total number of opioid prescriptions filled soared from 174 million to over 255 million nationwide. A study of nearly 8 million doctor visits revealed that between 2000 and 2010, the rate of prescribing opioids for pain increased by 73% at the same time as the number of office visits in which patients complained of pain remained constant and the rate of prescribing non-opioid painkillers fell.[70]

229. Those changes occurred at precisely the same time as Manufacturing Defendants were spending millions to market their drugs as safe and effective for long-term use to treat chronic pain. In particular, between 2000 and 2015, and on information and belief:

- Actavis spent up to $5 million quarterly;
- Cephalon's quarterly spending climbed steadily from under $1 million in 2000 to peak at more than $27 million in a single year (2007);
- Endo's quarterly spending climbed from between $2 and $4 million per quarter to a high of over $10 million per quarter in 2007 ($38 million total for the year) following the roll-out of Opana ER;
- Janssen's quarterly spending increased dramatically from less than $5 million per quarter to a high of over $35 million quarterly in 2011, coinciding with the launch of Nucynta ER (for a total spent in 2011 of $142 million);

[70] Matthew Daubresse et al., *Ambulatory Diagnosis and Treatment of Nonmalignant Pain in the United States, 2000-2010*, 51(10) Medical Care 870-78 (October 2013).

- Purdue's quarterly spending began high—over $15 million—and then decreased notably as Purdue came under investigation by the Department of Justice before rebounding for totals of over $100 per year from 2011 onward.

2. Baltimore's Increased Spending on Opioid Prescriptions

230. At the same time—commensurate with the Manufacturing Defendants' comprehensive (and expensive) promotion of prescription opioids for long-term use to treat chronic pain and the resulting uptick in prescription rates—the costs to the City of Baltimore tied directly to prescription opioids has also increased. For example, based on a preliminary review of currently available data, the amount paid by the City for opioids prescribed to City employees went from approximately $300,000 in 2006 to over $1.4 million in 2010 alone.—and those numbers fail to account for the full volume of generic prescription opioids doled out in the same time periods.

231. Most directly, the City has paid millions for prescription opioids prescribed to patients covered by the City's health insurance and workers compensation plans. The City provides comprehensive health care benefits to its employees and retirees, including prescription drug coverage. These benefits are provided under various health plans that the City self-insures. Employees and retirees covered under these plans pay a portion of the cost of prescription drugs that they receive, and the City itself funds the remainder. The City's workers' compensation program pays directly for all costs associated with opioids, including treatment related to any adverse outcomes from chronic opioid therapy, such as addiction treatment.

232. Doctors who treat City employees and retirees and their dependents are bound to the terms of the provider agreements entitling them to participate in the City-funded health plans. These agreement allow prescribers to charge only for treatments that are medically necessary; in other words, treatments prescribed in accordance with generally accepted standards of medical practice and which are clinically appropriate and considered effective for the patient's illness,

injury, or disease. In turn, the City is obligated to pay for all medically necessary treatment of covered employees.

233. In the course of prescribing opioids on a long-term basis to treat chronic pain, prescribers certify that the treatment is medically necessary and that the drugs being prescribed are being dispensed for an FDA-approved purpose and in return, the health plans authorize payment from City funds.

234. As described throughout the Complaint, most use of opioids on a long-term basis to treat chronic pain is not medically necessary as defined by the City's health benefits plans. Long-term safety and efficacy of such use is not supported by reliable scientific evidence and is often not the medically appropriate treatment for chronic pain in light of the relevant risks and benefits. Yet Manufacturing Defendants undertook a systematic campaign to convince prescribers to use opioids as the first-line treatment for chronic pain. In so doing, the Manufacturing Defendants caused prescribers and pharmacies to submit claims to the City's health plans that were false by:

- (1) causing prescribers to write prescriptions for long-term use of opioids to treat chronic pain supported by Manufacturing Defendants' misleading, false, and incomplete representations regarding the relative risks, benefits, superiority, and appropriateness of those opioids;
- (2) causing prescribers to therefore certify that such prescriptions were "medically necessary" when, in fact, they were not supported by substantial scientific evidence showing either that the risks associated with the drugs were outweighed by their benefits or that the drugs were safe and effective for long-term use to treat chronic pain; and
- (3) causing prescribers to write opioid prescriptions when long-term use of those drugs render patients physically dependent on continued use at higher doses.

235. To the extent that prescription of opioids for long-term use to treat chronic pain could have been considered "medically necessary" because such treatment was consistent with

then-accepted professional and community standards, any such medical consensus existed precisely because such standards of practice were formed to conform to the false and misrepresentative view of pain treatment that was created by the Manufacturing Defendants' deceptive marketing. That marketing co-opted every input upon which prescribers rely—from academic publications, to licensing board guidelines, to educational seminars, to patient expectations.

236. For the majority of patients who experience moderate chronic pain, long-term opioid use should never have been prescribed because that course of therapy was not necessary or medically appropriate. But for the Manufacturing Defendants' marketing campaign and the resulting shift in prevailing attitudes towards long-term opioid use, such prescriptions would not have been eligible for reimbursement, and the City would not have knowingly paid for claims for drugs that were not eligible for coverage.

237. The fact that the City would pay for those ineligible prescriptions was the foreseeable and intended consequence of Manufacturing Defendants' deceptive marketing scheme. Manufacturing Defendants set out to alter the medical consensus regarding long-term opioid therapy precisely so that prescribers would prescribe and so that payors such as the City would pay for long-term prescriptions of opioids precisely so that the Manufacturing Defendants would continue to profit off of the sales of such drugs.

a. Examples of Opioid-Related Claims Paid by Baltimore's Health Plans and Workers' Compensation Program

238. Healthcare expenses for individuals with opioid use disorders cost employers approximately twice as much on average as expenses for non-abusers. Based on a preliminary review, between 2005 and 2016, the City of Baltimore paid more than $8 million to cover the costs of opioids prescribed to City employees and retirees, not including costs paid for workers

compensation.[71] In 2016, for example, the City paid $980,245 for over 18,000 opioid prescriptions, nearly all of which were prescriptions lasting more than two weeks and the substantial majority of which were for a thirty-day supply of opioids. Those figures are conservative, as they do not cover the costs paid by the City for opioids prescribed to retirees on Medicare—who are also covered by self-insured, City-funded plans—or for opioids prescribed to those on workers compensation, the costs of which are paid entirely by the City. Costs to the City include coverage of the Manufacturing Defendants' branded drugs—including OxyContin, Kadian, Duragesic, Actiq, Opana, Opana ER, Nuycanta, Fentora, and more—as well as generics including oxycodone, hydrocodone, morphine, and fentanyl. Although the vast majority of opioids prescribed are generics, branded opioids account for the majority of the costs to the City.

239. Even more significantly, as of 2016, nearly all—98%—of long-acting opioid prescriptions written were for non-cancer, non-end-of-life care patients. The average number of days of opioids provided to City employees and non-Medicare retirees in a single year was a staggering *225 days*—meaning that almost all prescription opioids funded by the City of Baltimore are used as part of a long-term course of opioid treatment. The City therefore estimates that a substantial percentage of these tens of thousands of claims were false claims because they were for opioids prescribed for a period longer than twelve weeks and were prescribed to treat non-cancer/palliative care patients.

240. City employees and retirees who have used long-term opioids to treat chronic pain have also required additional services and supplies necessitated by the adverse effects of opioids—including additional office visits, toxicology screens, hospitalization for overdoses and infections, rehabilitation and substance abuse-related therapy, and other treatments. These additional services and supplies caused the City to incur additional and consequential costs. For

[71] That estimate does not include the total cost to the City of all generic opioid prescriptions.

example, the City has paid several millions more to cover the costs of antidotes and addiction treatment required for individuals covered under its health plans. Moreover, as described above, research suggests that long-term opioid use to treat chronic pain is associated with slower returns to work. The City has therefore paid additional sums under its workers' compensation plan attributable in whole or in part to opioid-related disability.

3. Baltimore's Increased Costs Related to Opioid Abuse, Addiction, and Death

241. As described above, the sharp increase in sales of prescription opioids has resulted in a dramatic rise in substance use disorders, overdose, and death. In 2014 alone, almost two million Americans abused or were dependent on prescription opioids, resulting in approximately 19,000 deaths involving prescription opioids. By the following year, the number of deaths had increased to 22,000. Those statistics do not account for the corresponding steep rise in heroin overdose deaths, which increased 20.6% between 2014 and 2015 and are increasingly common in Baltimore. The effects of the epidemic are even more wide-reaching than those statistics convey.

a. Public Health Services

242. The epidemic of opioid use disorders is overwhelming the healthcare system: more than 1,000 individuals are treated in emergency rooms throughout the country every day for misusing prescription opioids. Maryland has the highest rate of opioid-related inpatient hospital stays of any state in the country, and the second-highest rate of opioid-related emergency department visits.

243. The City of Baltimore maintains a $12.2 million public health budget, a significant portion of which is devoted to treating opioid abuse. For example, the City spends approximately $1.6 million annually on treating substance use disorders; has trained nearly

30,000 people how to administer the opioid overdose antidote naloxone; and has distributed at least 12,904 naloxone kits. The City is also coordinating an Overdose Education and Naloxone Training in its Drug Treatment Court Program. Moreover, the City, in conjunction with the State and other partners, is developing a Stabilization Center where individuals with substance use disorders can receive treatment on demand. That Center will provide 24/7 urgent care for individuals with substance use disorders, including intensive inpatient and low-intensity outpatient settings. The Center will also connect individuals with substance use disorders to case management and other necessary services such as housing and job training. The City is also expanding and promoting medication-assisted treatment of individuals with opioid use disorders, which combines behavioral therapy with FDA-approved medications. The City remains on the cutting edge of innovation for incorporating medication-assisted treatment, including providing medications in structured clinical settings and expanding access to buprenorphine by offering services in recovery centers, emergency shelters, and mental health facilities. The City is building a "hub-and-spokes" treatment network to increase the number of prescribers throughout the City that prescribe buprenorphine, enabling the City to reach more people with much-needed treatment.

b. Paramedic Services

244. The Baltimore City Fire Department responds to thousands of 911 calls annually, a large and growing number of which arise from opioid use. For example, between 2008 and 2009, Emergency Medical Services providers administered naloxone—which is only effective to reverse the effects of an opioid overdose—a total of 1,297 times, an average of 100 times per month. That number underestimates the total number of opioid-related medical emergencies, since many opioid-related injuries and overdoses are not life threatening. Each and every Fire Department medical response call imposes additional costs on the City.

c. Policing Services

245. Like the Fire Department, Baltimore City Police Department ("BPD") officers are equipped with naloxone and being trained how to administer it. Recognizing the need to enlist police officers in the effort to save lives, at least 416 BPD officers have been trained on the administration of naloxone, resulting in administration of the drug by officers on at least 72 occasions. Moreover, to address crimes associated with opioid abuse, the BPD has partnered with the Mayor's Office and others to establish a Law Enforcement Assisted Diversion pilot program, through which officers may redirect individuals engaged in low-level drug or prostitution activity into community-based services instead of jail and prosecution. The BPD also invests a significant proportion of its total resources in combatting gangs and gang violence associated with the heroin trade—the market for which has been expanded significantly as the availability and cost of prescription opioids make heroin a more attractive option for those with opioid use disorders.

d. Criminal Justice Costs

246. More than 75,000 individuals are arrested each year in Baltimore, the majority of which are for drug offenses. Eight of every ten individuals in Baltimore jails and prisons use illegal substances and four out of ten have a diagnosed mental illness including substance use disorders. The City has expended significant resources establishing Drug Treatment Courts and Mental Health Treatment Courts to divert individuals from the criminal justice system and provide effective treatment to individuals with opioid use disorders.

e. Combating Homelessness

247. Opioid use disorders frequently lead to homelessness or keep those who are homeless from successfully finding and maintaining housing. Thus, as the opioid epidemic in Baltimore has grown more severe, City agencies have been required to devote increasing

resources toward combating homelessness and its effects. The City spends nearly $11 million on homeless services, including on providing temporary and permanent housing, health care, and outreach and counseling services for homeless individuals.

V. CAUSES OF ACTION

COUNT ONE: PUBLIC NUISANCE (AGAINST ALL DEFENDANTS)

248. Baltimore realleges and incorporates by reference each of the allegations contained in the preceding paragraphs of this Complaint as though fully set forth herein.

249. Defendants, individually and in concert with each other, have contributed to, and/or assisted in creating and maintaining a condition that is a significant interference with the public health, the public safety, the public peace, the public comfort, and the public convenience.

250. The public nuisance created by Defendants' actions is substantial and unreasonable—it has caused and continues to cause significant harm to the community and the harm inflicted outweighs any offsetting benefit.

251. This injury to the public includes, but is not limited to (a) widespread dissemination of false and misleading information regarding the risks and benefits of opioids to treat chronic pain; (b) distortion of the medical standard of care for treating chronic pain, resulting in pervasive overprescribing of opioids and the failure to provide more appropriate pain treatment; (c) high rates of opioid abuse, injury, overdose, and death, and their impact on Baltimore families and communities; (d) increased health care costs for individuals, families, employers, and the City; (e) lost employee productivity resulting from the cumulative effects of long-term opioid use, addiction, and death; (f) the creation and maintenance of a secondary, criminal market for opioids; and (g) greater demand for emergency services and law enforcement paid for by the City at the ultimate cost of taxpayers.

252. Defendants knew or should have known that their promotion of opioid use would create a public nuisance.

253. Defendants' actions were, at the least, a substantial factor in opioids becoming widely available and widely used. Absent Defendants' actions, opioid use would not have become so widespread, and the enormous public health hazard of opioid overuse, abuse, and addiction that now exists would have been averted.

254. The health and safety of Baltimoreans, including those who use, have used, or will use opioids, as well as those affected by users of opioids, is a matter of great public interest and of legitimate concern to Baltimore and the entire state.

255. Defendants' conduct has injuriously affected, and continues to affect, Baltimore property, patrons, employees, and a considerable number of people within Baltimore, and across the state.

256. Defendants' conduct also constitutes a nuisance *per se* because it independently violates other applicable statutes. As set forth below, the Manufacturing Defendants have violated the Maryland Consumer Protection Act and the Maryland False Claims Statute.

257. Baltimore seeks an order that provides for abatement of the public nuisance Defendants have created, enjoins Defendants from creating future common-law nuisances, and awards Baltimore damages in an amount to be determined at trial. Baltimore pursues these remedies in its sovereign capacity for the benefit of the general public.

COUNT TWO: NEGLIGENCE (AGAINST ALL DEFENDANTS)

258. Baltimore realleges and incorporates by reference each of the allegations contained in the preceding paragraphs of this Complaint as though fully set forth herein.

259. Each of the Manufacturing Defendants owed Baltimore a duty to promote and market opioids truthfully and to disclose the true risk of addiction associated with the risk of

opioids. Each of the Manufacturing Defendants breached those duties by, among other things, circulating false and misleading information concerning the risks and benefits of opioids and downplaying or omitting the risks of addiction arising from their use.

260. Each of the Manufacturing Defendants and Wholesaler Defendants also owed the duty to report suspicious sales; the duty not to fill suspicious orders; the duty to abide by any government agreements entered into regarding the same; and the duty to comply with the federal CSA, 21 C.F.R. § 1301.74(b), and parallel state regulations, COMAR 10.19.03.12. Each of the Manufacturing Defendants and Wholesaler Defendants breached these duties by failing to design and operate a system that would disclose the existence of suspicious orders of controlled substances or by failing to report such suspicious orders to the appropriate regulators.

261. Each of the Pill Mill Defendants owed a duty to prescribe only those medications which were medically necessary and appropriate; to minimize the risks of diversion; and to comply with the standard of care expected of medical professionals. They breached those duties by writing prescriptions which were not medically necessary and which prescriptions deviated from that standard of care.

262. The City of Baltimore suffered both injuries and pecuniary losses proximately caused by the Defendants' breaches. Among other things, Baltimore has experienced an unprecedented opioid addiction and overdose epidemic costing millions in health insurance, treatment services, emergency visits, treatment for related illnesses and accidents, payments for fraudulent prescriptions, and lost productivity to Baltimore's workforce.

COUNT THREE: MARYLAND CONSUMER PROTECTION ACT (AGAINST MANUFACTURING DEFENDANTS)

263. Baltimore realleges and incorporates by reference each of the allegations contained in the preceding paragraphs of this Complaint as though fully set forth herein.

264. Maryland's Consumer Protection Act ("CPA") makes it unlawful for any business to engage in "any unfair or deceptive trade practice," including making any "[f]alse, falsely disparaging, or misleading oral or written statement, visual description, or other representation of any kind which has the capacity, tendency, or effect of deceiving or misleading consumers." Md. Comm. L. § 13-301(1). It also prohibits fraud-based deception, including "[d]eception, fraud, false pretense, false premise, misrepresentation, or knowing concealment, suppression, or omission of any material fact with the intent that a consumer rely on the same in connection with" the sale of any consumer goods or services. *Id.* § 13-301(9).

265. The CPA authorizes a private right of action for "any person . . . to recover for injury or loss sustained [] as a result of" an unfair or deceptive trade practice. Md. Comm. L. § 13-408(a). "Person" is in turn defined to include a "corporation . . . or any other legal or commercial entity." Md. Comm. L. § 13-101(h).

266. The Manufacturing Defendants are "persons" as defined in the CSA and are required to comply with the provisions of the CSA in their marketing, promotion, sale, and distribution of prescription drugs.

267. At all times relevant to this Complaint, Manufacturing Defendants violated the CSA by engaging in the deceptive marketing and promotion of their products both by (1) making false and misleading statements which had the capacity, tendency, or effect of misleading consumers and by (2) making false representations and misleading omissions of material fact with the intent that consumers would rely on those representations. In particular, Manufacturing Defendants engaged in deceptive marketing and promotion of their products by:

(1) making and disseminating false or misleading statements and other representations about the use of opioids to treat chronic pain which had the capacity, tendency, or effect of misleading customers;

(2) causing false or misleading statements about opioids to be made or disseminated;

(3) making statements to promote the use of opioids to treat chronic pain that omitted or concealed material facts; and

(4) failing to correct prior misrepresentations and omissions about the risks and benefits of opioids.

268. The Manufacturing Defendants' statements regarding the use of opioids on a long-term basis to treat chronic pain were not and are not supported by, or were contrary to, substantial scientific evidence, as confirmed by recent pronouncements by the CDC and FDA based on such evidence. Moreover, false and misleading material omissions by Manufacturing Defendants rendered even seemingly truthful statements about opioids false and misleading because they were materially incomplete. At the time Manufacturing Defendants disseminated their false and misleading statements or caused such statements to be made or disseminated, they knowingly failed to include material facts regarding the risks and benefits of long-term use of opioids to treat chronic pain, and intended that recipients of their marketing messages would rely upon such omissions.

269. At all times relevant to this Complaint, Manufacturing Defendants violated Md. Comm. L. § 13-303 by making misrepresentations including but not limited to the following:

(1) Claiming or implying that opioids would improve patients' function and quality of life;

(2) Mischaracterizing the risk of opioid use disorders and abuse, including by stating or implying that "steady state" and abuse-deterrent properties meant that drugs were less likely to be addictive or abused, and that specific opioid drugs were less addictive or less likely to be abused than other opioids;

(3) Claiming or implying that addiction can be avoided or successfully managed through the use of screening and other tools;

(4) Promoting the misleading concept of pseudoaddiction and emphasizing the prevalence of dependence, thus obscuring the relationship between dependence and addiction and concealing the true risk of addiction;

(5) Claiming or implying that increasing the dose of opioids poses no significant additional risk to patients;

(6) Misleadingly depicting the safety profile of opioids by minimizing their risks and adverse effects while emphasizing the risks of competing products, including NSAIDs and acetaminophen; and

(7) As to Purdue, mischaracterizing OxyContin's onset of action and duration of efficacy to imply that the drug provides a full 12 hours of pain relief, when Purdue was aware that it does not.

270. By reason of the Manufacturing Defendants' foregoing deception, misrepresentations, and omissions of material fact, Manufacturing Defendants obtained income, profits, and other benefits it would not otherwise have obtained.

271. By reason of that same conduct, the City of Baltimore incurred harm and was damaged in ways it would not otherwise have been, as described above in Part IV.G.

COUNT FOUR: MARYLAND FALSE CLAIMS STATUTE (AGAINST MANUFACTURING DEFENDANTS)

272. Baltimore realleges and incorporates by reference each of the allegations contained in the preceding paragraphs of this Complaint as though fully set forth herein.

273. A person is liable under Maryland's prohibition on submission of false claims, Md. Gen. L. § 8-102(b), when that person:

(1) knowingly present[s] or cause[s] to be presented a false or fraudulent claim for payment or approval; [or]

(2) knowingly make[s], use[s], or cause[s] to be made or used a false record or statement material to a false or fraudulent claim.

274. A "claim" is in turn defined as:

a request or demand, under a contract or otherwise, for money or other property, whether or not the governmental entity has title to the money or property, that is:

(i) presented to an officer, employee, or agent of a governmental entity; or

(ii) made to a contractor, a grantee, or another recipient, if the money or other property is to be spent or used on a governmental entity's behalf or to advance an interest of a governmental entity, and the governmental entity:

1. provides or has provided any portion of the money or other property requested or demanded; or

2. will reimburse the contractor, grantee, or other recipient for any portion of the money or other property that is requested or demanded.

Md. Gen. L. § 8-101(b)(1). "Governmental entity" includes "a municipal corporation." Md. Gen. L. § 8-101(e)(3). Moreover, "knowing" or "knowingly" explicitly does not require "proof of specific intent to defraud" but rather means that a person either "has actual knowledge that the information is false"; "acts in deliberate ignorance of the truth or falsity of the information"; or "acts in reckless disregard of the truth or falsity of the information." *Id.* § 8-101(f)(1).

275. The Manufacturing Defendants' practices, as described in the Complaint, violated Md. Gen. L. § 8-102(b). The Manufacturing Defendants, through their deceptive marketing of opioids for long-term use to treat chronic pain, presented or caused to be presented false or fraudulent claims and knowingly used or caused to be used false statements to get false or fraudulent claims paid or approved by the City.

276. The Manufacturing Defendants knew, deliberately ignored, or recklessly disregarded, at the time of making or disseminating these statements, or causing such statements to be made and disseminated, that such statements were untrue, false, misleading, or unsupported by substantial and reliable scientific evidence, and were made for the purpose of inducing the City, through its employees and contractors, to pay for opioids for long-term treatment of chronic pain. Manufacturing Defendants also knew or should have known that their marketing and promotional efforts had the effect of creating untrue, false, and misleading impressions regarding

the risks, benefits, superiority, and appropriateness of using opioids on a long-term basis to treat chronic pain.

277. Manufacturing Defendants' scheme caused prescribers to write prescriptions for opioids to treat chronic pain on a long-term basis that were presented to the City's employee health and workers' compensation plans for payment. Prescribers and other health care providers, and/or other agents of the health plans and workers' compensation program, expressly or impliedly certified to the City that the opioids prescribed were medically necessary and reasonably required to treat chronic pain because those persons were influenced by the false and misleading statements disseminated by Manufacturing Defendants through the deceptive marking campaign described above in Parts IV.B-C. To the extent such prescribing patterns were considered customary or consistent with then-generally accepted medical standards, those standards were influence, dictated, and ultimately corrupted by the Manufacturing Defendants' deceptive marketing.

278. Manufacturing Defendants knew or should have known that, as a natural and foreseeable consequence of their actions, governments such as the City of Baltimore would necessarily end up paying for long-term prescriptions of opioids to treat chronic pain—prescriptions that were written and dispensed as a result of the Manufacturing Defendants' misrepresentations. Those misrepresentations—which were made and caused to be made by the Manufacturing Defendants—were material to the City's decision to pay the costs of long-term opioid therapy to treat chronic pain because they falsely assured that such treatment was medically necessary.

279. The City has as a result paid millions of dollars for opioid prescriptions that were represented to it as being medically necessary. These prescriptions would not have been written

or covered or reimbursed but for Manufacturing Defendants' deceptive, fraudulent, and unlawful marketing practices.

280. The City has paid and will continue to pay consequential health care costs necessitated by the Manufacturing Defendants' deceptive, fraudulent, and unlawful marketing practices, in the form of drugs for persons who are physically dependent upon and addicted to opioids and in the form of treatment costs for those dealing with opioid use disorders, overdose, and other adverse effects.

VI. PRAYER FOR RELIEF

WHEREFORE, Plaintiff respectfully requests the Court enter judgment against Defendants:

(a) awarding judgment in its favor and against Defendants on each cause of action asserted in the Complaint;

(b) assessing treble damages for payments made by or on behalf of the City of Baltimore for opioid prescriptions covered by the City's Employee and Retiree Health Benefits and Workers' Compensation programs;

(c) assessing the maximum statutory civil penalties for each violation of Maryland's false claims statute;

(d) assessing the maximum statutory civil penalties for each violation of the Maryland Consumer Protection Act;

(e) permanently enjoining Manufacturing Defendants from making further false or misleading statements or otherwise engaging in deceptive practices as described in the Complaint;

(f) requiring the Defendants to abate the public nuisance their conduct has created;

(g) permanently enjoining the Manufacturing and Wholesaler Defendants from failing to report suspicious orders of opioids as required by the Controlled Substances Act and under Maryland law;

(h) ordering defendants to pay costs, losses, and damages for the injuries sustained by the City of Baltimore, acting on its own behalf and on behalf of its inhabitants, as a proximate result of the Defendants' unlawful conduct as described in the Complaint, including restitution, civil penalties, disgorgement of unjust enrichment, punitive damages, and attorneys' fees and costs; and

(i) awarding other such relief as the Court deems proper.

Respectfully Submitted,

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