IN THE CIRCUIT COURT OF COOK COUNTY, ILLINOIS
COUNTY DEPARTMENT – CHANCERY DIVISION

THE PEOPLE OF THE STATE OF ILLINOIS Plaintiff, v. PURDUE PHARMA L.P. and PURDUE PHARMA INC., Defendants.	)	No. 2019CH04406

COMPLAINT FOR INJUNCTIVE AND OTHER RELIEF

Now comes the Plaintiff, THE PEOPLE OF THE STATE OF ILLINOIS, by KWAME RAOUL, THE ATTORNEY GENERAL OF THE STATE OF ILLINOIS, and brings this action against PURDUE PHARMA L.P. and PURDUE PHARMA INC., for violations of the Illinois Consumer Fraud and Deceptive Business Practices Act ("Consumer Fraud Act"), 815 ILCS 505/1 *et. seq.*, and to abate and remedy the statewide public nuisance created by Defendants, and states as follows:

SUMMARY OF THE CASE

Purdue has engaged in an unlawful scheme to push more and more of its opioids into Illinois for its own profit. Between 2008 and 2017, while lives were being lost, families ruined, and communities damaged, Purdue sent its employees into Illinois to market its drugs hundreds of thousands of times, downplaying the terrible risks of its opioid products and telling doctors and their patients that such risks could be controlled. Purdue more than tripled prescriptions of its opioids in Illinois, all while knowing its drugs were dangerous, and were being misused, abused, and diverted. Purdue persisted in marketing directly to doctors who had addicted patients and

whose patients were likely diverting its drugs for unlawful use. Purdue persisted in using terms like "pseudo addiction," persisted in targeting seniors, and persisted in pushing continuing use of its drugs at higher and higher doses. Purdue's unlawful conduct has inflicted massive harm on our State and its residents. It must be stopped.

PUBLIC INTEREST

1. The Illinois Attorney General believes this action to be in the public interest of the citizens of the State of Illinois and brings this lawsuit pursuant to the Illinois Consumer Fraud and Deceptive Business Practices Act, 815 ILCS 505/7(a) and his common law authority to represent the People of the State of Illinois.

JURISDICTION AND VENUE

2. This action is brought for and on behalf of THE PEOPLE OF THE STATE OF ILLINOIS, by KWAME RAOUL, THE ATTORNEY GENERAL OF THE STATE OF ILLINOIS, pursuant to the provisions of the Consumer Fraud Act and his common law authority as THE ATTORNEY GENERAL OF THE STATE OF ILLINOIS to represent THE PEOPLE OF THE STATE OF ILLINOIS.

3. Venue for this action properly lies in Cook County, Illinois, pursuant to section 2-101 of the Illinois Code of Civil Procedure, 735 ILCS 5/2-101, in that some of the activities complained of herein out of which this action arose occurred in Cook County.

PARTIES

4. Plaintiff, THE PEOPLE OF THE STATE OF ILLINOIS, by KWAME RAOUL, THE ATTORNEY GENERAL OF THE STATE OF ILLINOIS, is charged with enforcement of the Consumer Fraud Act. The Attorney General is also authorized to bring this action pursuant to his

common law authority to represent the People of the State of Illinois and *parens patriae* authority to bring an action to abate a public nuisance and vindicate the rights of the public.

5. Defendant PURDUE PHARMA L.P. is a limited partnership organized under the laws of Delaware with its principal place of business in Stamford, Connecticut.

6. Defendant PURDUE PHARMA INC. is a New York corporation with its principal place of business in Stamford, Connecticut.

7. Purdue Pharma L.P. is in the business of manufacturing, marketing, promoting, and selling Purdue's drugs, including by employing sales representatives and paying doctors to promote Purdue's branded opioid products.

8. Purdue Pharma Inc. is in the business of manufacturing, marketing, promoting, and selling Purdue's drugs, directly or as the general partner of Purdue Pharma L.P.

9. Purdue Pharma Inc. and Purdue Pharma L.P. acted together to carry out all of the misconduct alleged in this Complaint.

10. Purdue Pharma Inc. controls Purdue Pharma L.P. as its general partner and is liable for the misconduct of the partnership. Purdue Pharma Inc. is also the general partner of Purdue Holding L.P., which holds the sole limited partnership interest in Purdue Pharma L.P.

11. Purdue Pharma Inc. and Purdue Pharma L.P. have shared the same physical offices, the same CEO, and many of the same officers.

12. For purposes of this Complaint, any references to the acts and practices of Defendants PURDUE PHARMA L.P. and PURDUE PHARMA INC. (collectively "Defendants" or "Purdue") shall mean that such acts and practices are by and through the acts of Defendants' members, owners, directors, employees, salespersons, representatives, and/or other agents.

13. In May 2007, Purdue Pharma L.P. and Purdue Pharma Inc. entered into a Consent Judgment with the State of Illinois based principally on Purdue's direct promotion of OxyContin up to May 8, 2007, the effective date of the Consent Judgment. In this Complaint, the State does not seek relief against Purdue pursuant to the Illinois Consumer Fraud Act based on conduct by Purdue on or before May 8, 2007 relating to Purdue's promotional and marketing practices regarding OxyContin. References in the Complaint to conduct that occurred before this date are mentioned to establish Purdue's knowledge, a pattern of behavior, or other facts that are relevant to conduct occurring after May 8, 2007.

TRADE AND COMMERCE

14. Subsection 1(f) of the Consumer Fraud Act (815 ILCS 505/1(f)), defines "trade" and "commerce" as follows:

> The terms 'trade' and 'commerce' mean the advertising, offering for sale, sale, or distribution of any services and any property, tangible or intangible, real, personal, or mixed, and any other article, commodity, or thing of value wherever situated, and shall include any trade or commerce directly or indirectly affecting the people of this State.

15. At all times relevant hereto, Purdue engaged in trade or commerce in the State of Illinois by marketing, selling, and promoting opioid drugs in Illinois.

16. Purdue markets and sells opioid products under several brands. The descriptions and indications as listed in each drug's label are as follows:

a. OxyContin (oxycodone hydrochloride extended release), which is an opioid agonist tablet 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."[1] Prior to April 2014, OxyContin was indicated for the "management of moderate to severe pain

[1] Highlights of Prescribing Information: OXYCONTIN, https://www.accessdata.fda.gov/drugsatfda_docs/label/2016/022272s034lbl.pdf (Last accessed March 22, 2019).

when a continuous, around-the-clock opioid analgesic is needed for an extended period of time."[2]

b. MS Contin (morphine sulfate extended release), which is an opioid agonist tablet 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."[3] Prior to April 2014, MS Contin was 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."[4]

c. Dilaudid (hydromorphone hydrochloride), which is an opioid agonist indicated for "the management of pain severe enough to require an opioid analgesic and for which alternative treatments are inadequate."[5] Prior to 2016, Dilaudid injection was indicated for the "management of pain where an opioid analgesic is appropriate."[6]

d. Dilaudid-HP (hydromorphone hydrochloride), which is an opioid agonist indicated for the "use in opioid-tolerant patients who require higher doses of opioids for the management of pain severe enough to require an opioid analgesic and for which alternate treatments are inadequate."[7] Prior to 2016, Dilaudid-HP injection was indicated for "the management of moderate-to-severe pain in opioid-tolerant patients who require higher doses of opioids."[8] Dilaudid-HP has also previously been indicated "for the relief of moderate-to-severe pain in opioid-tolerant patients who require larger than usual doses of opioids to provide adequate pain relief."[9]

e. Butrans (buprenorphine), which is an opioid partial agonist transdermal patch and indicated for the "management of pain severe enough to require daily, around-the-clock, long-term opioid treatment and for which

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[2] Highlights of Prescribing Information: OXYCONTIN, https://www.accessdata.fda.gov/drugsatfda_docs/label/2010/022272lbl.pdf (Last accessed March 22, 2019).
[3] Highlights of Prescribing Information: MS CONTIN, https://www.accessdata.fda.gov/drugsatfda_docs/label/2016/019516s049lbl.pdf (Last accessed March 22, 2019).
[4] MS Contin Label, https://www.accessdata.fda.gov/drugsatfda_docs/label/2010/019516s034lbl.pdf (Last accessed March 22, 2019).
[5] Highlights of Prescribing Information: DILAUDID, https://www.accessdata.fda.gov/drugsatfda_docs/label/2017/019034s029lbl.pdf (Last accessed March 22, 2019).
[6] Highlights of Prescribing Information: DILAUDID, https://www.accessdata.fda.gov/drugsatfda_docs/label/2011/019034s021lbl.pdf (Last accessed March 22, 2019).
[7] Highlights of Prescribing Information: DILAUDID HP, https://www.accessdata.fda.gov/drugsatfda_docs/label/2017/019034s029lbl.pdf (Last accessed March 22, 2019).
[8] Highlights of Prescribing Information: DILAUDID HP, https://www.accessdata.fda.gov/drugsatfda_docs/label/2011/019034s021lbl.pdf (Last accessed March 22, 2019).
[9] Dilaudid-HP Label: https://www.accessdata.fda.gov/drugsatfda_docs/label/2009/019034s018lbl.pdf (Last accessed March 22, 2019).

alternative treatment options are inadequate."[10] Prior to April 2014, Butrans was indicated for "the management of moderate to severe chronic pain in patients requiring a continuous, around-the-clock opioid analgesic for an extended period of time."[11]

f. Hysingla ER (hydrocodone bitartrate), which is an opioid agonist tablet 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."[12]

g. Targiniq ER (oxycodone hydrochloride and naloxone hydrochloride), which is a combination product of oxycodone, an opioid agonist, and naloxone, an opioid antagonist 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."[13]

BACKGROUND

The Massive Opioid Public Health Epidemic

17. Opioids are killing people in Illinois and across the United States. Drug overdose is now the leading cause of death for adults under fifty-five.[14] Recent increases in overdose deaths have been so steep that they have contributed to a reduced life expectancy in the United States, something Americans have not seen since World War II.[15]

[10] Highlights of Prescribing Information: BUTRANS, https://www.accessdata.fda.gov/drugsatfda_docs/label/2016/021306s024lbl.pdf (Last accessed March 22, 2019).
[11] Highlights of Prescribing Information: BUTRANS, https://www.accessdata.fda.gov/drugsatfda_docs/label/2010/021306s000lbl.pdf (Last accessed March 22, 2019).
[12] Highlights of Prescribing Information: HYSINGLA, https://www.accessdata.fda.gov/drugsatfda_docs/label/2018/206627s007s008lbl.pdf (Last accessed March 22, 2019).
[13] Highlights of Prescribing Information: Targiniq ER, https://www.accessdata.fda.gov/drugsatfda_docs/label/2018/205777s010s011lbl.pdf (Last accessed March 22, 2019).
[14] https://www.nytimes.com/interactive/2018/11/29/upshot/fentanyl-drug-overdose-deaths.html (Last accessed March 19, 2019).
[15] *Id.*

18. Opioids cause about two thirds of all fatal drug overdoses in this country.[16] From 1999 through 2017, nearly 400,000 Americans died of an opioid overdose, approximately 130 lives lost each day.[17]

19. The opioid crisis is also accelerating. As described below, doctors have prescribed opioids for decades, and the risks related to their use are not new. However, while approximately 8,048 people died of an opioid-related overdose in 1999, 47,600 died of an opioid-related overdose in 2017.[18] For the first time in history, Americans are now more likely to die from an opioid overdose than a car crash.[19]

20. The devastating public health consequences of the opioid epidemic extend beyond overdose deaths to addiction, withdrawal, and related concerns. A baby is born in this country suffering from neonatal opioid withdrawal syndrome about every fifteen minutes.[20] In 2014 alone, approximately 32,000 babies were born suffering from this withdrawal syndrome, a more than five-fold increase since 2004.[21] In 2016, the number of new foster care cases involving parents who are using drugs hit the highest point in more than three decades.[22]

21. The opioid crisis did not start by chance or by accident. From 1991 to 2011, the total number of opioid prescriptions dispensed by U.S. pharmacies nearly tripled.[23] Opioid-related

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[16] https://www.cdc.gov/mmwr/volumes/67/wr/mm675152e1.htm?s_cid=mm675152e1_w (Last accessed March 19, 2019).
[17] https://www.cdc.gov/drugoverdose/epidemic/index.html (Last accessed March 12, 2019).
[18] https://www.drugabuse.gov/related-topics/trends-statistics/overdose-death-rates (Last accessed March 20, 2019).
[19] https://www.npr.org/2019/01/14/684695273/report-americans-are-now-more-likely-to-die-of-an-opioid-overdose-than-on-the-ro (Last accessed March 19, 2019).
[20] https://www.drugabuse.gov/related-topics/trends-statistics/infographics/dramatic-increases-in-maternal-opioid-use-neonatal-abstinence-syndrome (Last accessed March 20, 2019).
[21] *Id.*
[22] "Opioid crisis straining foster systems as kids pried from homes," Dec. 12, 2017, available at: https://www.nbcnews.com/storyline/americas-heroin-epidemic/opioid-crisis-strains-foster-system-kids-pried-homes-n828831 (Last accessed March 26, 2019).
[23] https://www.drugabuse.gov/publications/research-reports/relationship-between-prescription-drug-abuse-heroin-use/increased-drug-availability-associated-increased-use-overdose (Last accessed March 20, 2019).

deaths increased almost the same amount over the same period.[24] Reported overdose deaths involving prescription opioids also increased almost five times in less than two decades, going from 3,442 in 1999 to 17,029 in 2017.[25] By 2015, almost half of all opioid deaths in the United States involved prescription opioids.[26]

22. The crisis now goes beyond drug dealers and problematic prescribers and into Americans' homes. One report indicates that nearly seventy percent of people who misused prescription drugs obtained them from family and friends, including stealing someone else's medication from a home medicine cabinet.[27]

23. The simple act of filling an opioid prescription is itself a significant risk factor for overdose,[28] and opioids can also be deadly even when taken as prescribed.[29] In other words, the opioid epidemic is not a crisis of abuse; it is a crisis of overuse.

24. Prescription opioids have also fueled the illicit market for heroin, which can be cheaper and easier to obtain. A great number of people who inject heroin – in some studies, more than 80 percent – report abusing prescription opioids first, a pattern that is especially high for young people.[30]

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[24] *Id.*
[25] https://www.drugabuse.gov/related-topics/trends-statistics/overdose-death-rates (Last accessed March 20, 2019).
[26] Rose A. Rudd *et al.*, *Increases in Drug and Opioid-Involved Overdose Deaths – United States, 2010-2015,* 65 Morbidity and Mortality Weekly Report 1145 (2016).
[27] https://www.nm.org/about-us/northwestern-medicine-newsroom/press-releases/2018/northwestern-medicine-lurie-and-dea-national-prescription-drug-take-back-day (Last accessed March 21, 2019).
[28] Deborah Dowell, Tamara M. Haegerich & Roger Chou, *CDC Guideline for Prescribing Opioids for Chronic Pain – United States, 2016,* 65 Morbidity and Mortality Weekly Report 1, 22 - 24 (2016) (2016 CDC Guideline).
[29] Letter from Janet Woodcock, MD, Dir., Center for Drug Eval. and Research, to Andrew Kolodny, M.D. (Sept. 10, 2013), available at: https://www.supportprop.org/wp-content/uploads/2014/12/FDA_CDER_Response_to_Physicians_for_Responsible_Opioid_Prescribing_Partial_Petition_Approval_and_Denial.pdf (Last accessed March 29, 2019).
[30] https://www.drugabuse.gov/publications/research-reports/relationship-between-prescription-drug-heroin-abuse/prescription-opioid-use-risk-factor-heroin-use (Last accessed March 26, 2019); Al-Tayyib, PhD, *et al.*, "Prescription opioids prior to injection drug use: comparisons and public health implications," Addict. Behav. 2017 Feb.; 65: 224-28.

25. In addition to the vast human toll opioids have taken on individuals and their families and friends, the epidemic has had drastic consequences for the country's economy. By one estimate, the total costs associated with opioid overdoses, death, and use disorders in this country, including a tremendous loss of productivity in the workforce, exceeded $1 trillion from 2001 to 2017.[31] Hospital costs for the treatment of babies with opioid withdrawal syndrome spiked from approximately $90 million in 2004 to over $560 million in 2014, with over eighty percent of those charges paid by state Medicaid programs.[32]

26. Nevertheless, huge quantities of opioids are still being manufactured and prescribed in this country each year. In 2016, for example, retail pharmacies dispensed 214,881,622 opioid prescriptions.[33] That is enough for about two out of every three Americans to get a bottle of pills.

27. Illinois and its citizens have suffered the effects of the opioid epidemic alongside the rest of the country, and the crisis here has unfortunately mirrored the national trends. Emergency room visits for opioid overdoses rose by 66% between just July 2016 and September 2017.[34] And opioids are now responsible for the vast share – almost eighty percent in 2017 – of all drug overdose deaths in Illinois.[35]

28. Nearly 18,000 people in Illinois died from an opioid overdose between 1999 and 2017.[36] In 2016, opioid-related overdoses claimed the lives of 1,946 Illinoisans. That is more than one

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[31] https://www.ama-assn.org/delivering-care/opioids/understanding-opioid-epidemic-s-economic-toll (Last accessed March 19, 2019).

[32] https://www.drugabuse.gov/related-topics/trends-statistics/infographics/dramatic-increases-in-maternal-opioid-use-neonatal-abstinence-syndrome (Last accessed March 20, 2019).

[33]https://www.cdc.gov/drugoverdose/maps/rxrate-maps.html (Last accessed March 29, 2019).

[34] "Illinois emergency rooms see 66 percent spike in opioid overdose visits: report," Chicago Tribune, March 6, 2018, available at: http://www.chicagotribune.com/business/ct-biz-opioid-overdoses-emergency-rooms-0307-story.html (Last accessed April 1, 2019).

[35] *Id.*

[36] Centers for Disease Control and Prevention, National Center for Health Statistics. Multiple Cause of Death 1999-2017 on CDC WONDER Online Database, released December, 2018. Data are from the Multiple Cause of Death

and a half times the number of homicides and nearly twice the number of fatal car accidents in the state that year.[37] In 2017, opioid overdoses killed 2,202 people in Illinois, a more than 100% increase compared to 2013.[38]

29. As in the rest of the country, the explosion of the opioid epidemic in Illinois was not random or accidental. The state has been flooded with dangerous drugs. [redacted]

30. The total number of opioid prescriptions filled in Illinois increased by 25%, or nearly 2 million prescriptions, from 2008 to 2014.[39] Although there was a modest decline in prescriptions in later years, the totals remained staggeringly high. In 2014, 2015, and 2016, prescribers wrote 62.3, 59.1, and 56.8 prescriptions per 100 persons, respectively.[40] Trends in the overall number of prescriptions written also only capture part of the crisis, as the number of overdose deaths specifically related to prescription opioid drugs more than doubled in Illinois between 2013 and 2016.[41]

Files, 1999-2017, as compiled from data provided by the 57 vital statistics jurisdictions through the Vital Statistics Cooperative Program, http://wonder.cdc.gov/mcd-icd10.html (Last accessed Mar 12, 2019).

[37] State of Illinois Comprehensive Opioid Data Report, Illinois Department of Public Health, December 4, 2017, p. 3 available at: http://www.dph.illinois.gov/sites/default/files/publications/publicationsdoil-opioid-data-report.pdf (Last accessed March 26, 2019).

[38] Illinois Department of Public Health, Drug Overdose Deaths by Sex, Age Group, Race/Ethnicity and County, Illinois Residents, 2013-2018, March 8, 2010, available at: http://www.dph.illinois.gov/sites/default/files/publications/Drug-Overdose-Deaths-Aug2018.pdf (Last accessed March 26, 2019).

[39] Reichert, Jessica; *et al.*, Opioid Prescribing in Illinois: Examining Prescription Drug Monitoring Program Data, May 23, 2018, at p. 3, available at: http://www.icjia.state.il.us/assets/articles/PMP_Article_050918.pdf (Last accessed March 27, 2019).

[40] Centers for Disease Control and Prevention Surveillance Report of Drug-Related Risks and Outcomes, United States 2017 at p. 41, available at: https://www.cdc.gov/drugoverdose/pdf/pubs/2017-cdc-drug-surveillance-report.pdf (Last accessed March 26, 2019).

[41] State of Illinois Comprehensive Opioid Data Report, *supra* note 37, at p. 10.

31. The epidemic has also significantly affected the Illinois economy. By one estimate, the rise in opioid dependency from 1999 to 2015 led to a reduction in the Illinois work force totaling over 84,000 prime-age workers and a loss of over one billion work hours. That translates into a $69.2 billion loss in economic output and a 60% reduction in GDP growth.[42]

32. Between 2011 and 2016, there was a 53% increase in the neonatal abstinence syndrome (NAS) rate in Illinois.[43] Along with the clear human tragedy, there are substantial economic costs associated with these births. Babies born with NAS may experience a variety of withdrawal symptoms, medical complications, and prolonged hospital stays. In 2015, the median length of an Illinois hospital stay after birth was 13 days longer for infants with NAS, and median hospital charges for infants with NAS were ten times higher.[44]

33. The State has spent and continues to spend substantial public resources on medical services, law enforcement, prosecution, corrections, worker's compensation, diversion programs, probation, treatment, and child welfare related to opioids. For example:

a. Between Q1 2014 and Q3 2016, statewide hospitalization rates for all opioid overdoses increased 42%, opioid analgesic overdoses increased 45%, and heroin overdoses increased 39%.[45] These numbers continue to rise at alarming rates, with the number of emergency department visits for suspected opioid overdoses increasing by 66% in Illinois between July 2016 and September 2017.[46]

b. Emergency medical service (EMS) providers are often the first responders on the scene of an opioid overdose. Under the Heroin Crisis Act, all EMS vehicles in Illinois must be equipped with naloxone, a drug that can quickly reverse an opioid overdose. 9,272 EMS naloxone administrations were reported to the Illinois Department of Public Health for 2015, a 32.6% increase over 2013. Further, in large part due to the presence of fentanyl and other synthetic opioids in substances being used, the number of EMS runs that required two administrations of

[42] https://www.americanactionforum.org/project/opioid-state-summary/illinois/ (Last accessed March 19, 2019)
[43] State of Illinois Comprehensive Opioid Data Report, *supra* note 37, at p. 20.
[44] *Id.*
[45] State of Illinois Comprehensive Opioid Data Report, *supra* note 37, at p. 12.
[46] Emergency Department Data Show Rapid Increases in Opioid Overdoses, CDC Press Release, Mar. 6, 2018, available at: https://www.cdc.gov/media/releases/2018/p0306-vs-opioids-overdoses.html (Last accessed March 26, 2019).

naloxone increased by over 50% from 2013-2015, and the number of runs requiring three administrations increased over 75%.[47]

c. 19,289, or nearly 30%, of publicly-funded drug treatment admissions in Illinois in 2015 were for persons who indicated opioids as their primary substance of abuse.[48]

d. In 2016, 2,241 Illinois prisoners indicated opioids as their primary substance of misuse. In 2017, nine Illinois drug and mental health courts reported one-third of their participants had an opioid use related diagnosis.[49]

34. As detailed below, Purdue understood the risks associated with opioids, but chose to market its products in ways that led to substantial increases in both the quantity and power of the drugs coming into Illinois. It is substantially responsible for this crisis.

The Severe Risks of Opioids Far Outweigh Their Benefits

35. Opioids are central nervous system depressant drugs that attach to receptors in the brain, spinal cord, gastrointestinal tract, and elsewhere in the body and modulate function. Opioids reduce the intensity of pain signals reaching the brain, but they can also have serious side effects, including respiratory depression and death.

36. Opioids are a class of narcotic drugs that include heroin, certain prescription pain relievers, and synthetically manufactured analogues such as fentanyl. There are several different opioid medications – morphine, hydrocodone, oxycodone, oxymorphone, hydromorphone, tapentadol, buprenorphine, and methadone being the most common.

37. Opioids come in two basic formulations: immediate-release and extended-release. Immediate-release opioids deliver the full dose quickly as the substance dissolves. Extended-release opioids are concentrated forms of immediate-release drugs, but contained in a time-

[47] State of Illinois, The Opioid Crisis in Illinois Data and the State's Response, at pp. 2-4, available at: http://www.dhs.state.il.us/OneNetLibrary/27896/documents/OpioidCrisisInIllinois_051617.pdf (Last accessed March 26, 2019).
[48] *Id.* at p. 6.
[49] Reichert, *supra* note 39, at p. 3.

release matrix that is supposed to release the drug over time. OxyContin, for example, is oxycodone in a time-release matrix that claims to deliver the drug over 12 hours.

38. The immediate-release opioid market is heavily generic. The extended-release market consists far more of branded products. Purdue's drugs compose a majority of the extended-release market.

39. By design and marketing, Purdue's drugs are intended for long-term use, and Purdue has chosen to market them heavily for long-term use for chronic pain.

Opioids are highly addictive

40. Opioids are extremely addictive and opioid use can result in tolerance, dependence, cravings, and withdrawal symptoms. Studies have found diagnosed addiction rates in primary care settings as high as 26%.[50] Among opioid users who received four prescriptions in a year, 41.3% meet diagnostic criteria for a lifetime opioid-use disorder.[51]

41. A 2017 CDC study determined that the probability of long-term opioid use escalates most sharply after five days, and surges again when one month of opioids are prescribed.[52] A patient initially prescribed one month of opioids has a 29.9% chance of still using opioids at one year.[53] In one study, almost 60% of patients who used opioids for 90 days were still using opioids five years later.[54]

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[50] Dowell, *supra* note 28, at 22-24.
[51] Joseph A. Boscarino, Stuart N. Hoffman & John J. Han, *Opioid-Use Disorder Among Patients on Long-Term Opioid Therapy: Impact of Final DSM-5 Diagnostic Criteria on Prevalence and Correlates,* 6 Substance Abuse and Rehabilitation 83 (2015); *see also* Joseph A. Boscarino *et al.*, *Prevalence of Prescription Opioid-Use Disorder Among Chronic Pain Patients: Comparison of the DSM-5 vs. DSM-4 Diagnostic Criteria,* 30 Journal of Addictive Diseases 185 (2011) (showing a 34.9% lifetime opioid use disorder).
[52] Anuj Shah, Corey J. Hayes & Bradley C. Martin, *Characteristics of Initial Prescription Episodes and Likelihood of Long-Term Opioid Use – United States, 2006-2015,* 66 Morbidity and Mortality Weekly Report 265-269 (2017).
[53] *Id.*
[54] Bradley C. Martin *et al.*, *Long-Term Chronic Opioid Therapy Discontinuation Rates from the TROUP Study,* 26 J. Gen. Internal. Med. 1450 (2011).

42. Patients whose initial prescription was for an extended-release opioid – such as Purdue's OxyContin – have the highest probabilities of continued use with a 27.3% likelihood of using opioids one year later, and a 20.5% likelihood of using opioids three years later.[55]

43. In 2013, the FDA observed that extended-release opioids, like those Purdue markets, present "disproportionate safety concerns" and that the data show that the risk of misuse and abuse is greater for extended-release opioids.[56]

44. The risks of addiction and negative side effects or complications increase when opioids are administered long-term.[57] In 2013, the FDA noted that the data show that risk of misuse and abuse is greatest for extended-release opioids and observed that these drugs are often used chronically.[58]

45. One study has shown that the duration of opioid therapy is a strong risk factor for opioid use disorder— a problematic pattern of opioid use leading to clinically significant impairment or distress.[59] In fact, a study published in 2015 found that 1 in 5 patients on long-term opioid treatment will develop opioid use disorder.[60]

46. Opioids are most dangerous when taken long-term and when taken in high doses.

47. Higher doses of opioids are dangerous in a number of ways. A CDC clinical evidence review found that higher opioid dosages were associated with increased risks of motor vehicle

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[55] Shah, *supra* note 52.
[56] Woodcock Letter (Sept. 10, 2013), *supra* note 29.
[57] *See e.g.* Wilson M. Compton & Nora D. Volkow, *Major Increases in Opioid Analgesic Abuse in the United States: Concerns and Strategies,* 81 Drug and Alcohol Dependence 103, 104 92006) (noting increased risk of addiction for long-term administration of opioids).
[58] Woodcock Letter (Sept. 10, 2013), *supra* note 29.
[59] Mark J. Edlund *et al.*, *The Role of Opioid Prescription in Incident Opioid Abuse and Dependence Among Individuals with Chronic Non-Cancer Pain,* 30 Clin. J. Pain 557-564 (2014).
[60] Louisa Degenhardt *et al.*, *Agreement between definitions of pharmaceutical opioid use disorders and dependence in people taking opioids for chronic non-cancer pain (POINT): a cohort study,* 2 the Lancet Psychiatry 314-322 (2015).

injury, opioid use disorder, and overdose, and that the increased risk rises in a dose-dependent manner.[61]

48. Another study found that higher daily doses and possible opioid misuse were also (a) strong predictors of continued use, and (b) associated with increased risk of overdoses, fractures, dependence, and death.[62]

49. Accordingly, in 2016 the CDC recommended that physicians carefully reassess increasing opioid doses beyond 50 morphine milligram equivalents (MMEs), and avoid exceeding 90 MMEs/day.[63] Roughly translated, a single 60 mg pill of oxycodone, the active ingredient in OxyContin, is 90 MME; a 40 mg pill is 60 MME; and a single 30 mg pill is 45 MME. Since patients are supposed to take 12-hour OxyContin twice a day, a prescription for 30 mg pills of OxyContin is already at the CDC's upper threshold.

50. For patients taking a daily dose of more than 120 MMEs over a period greater than 90 days, the chance of developing an opioid use disorder increases 122-fold.[64]

51. At high doses, patients are also at higher risk of poor functional status, increased pain sensitivity, and continuation of opioid treatment for a prolonged period.[65]

Opioids are deadly and dangerous

52. The last 20 years have also proven that opioids are deadly. As Dr. Thomas Frieden, the Director of the CDC from 2011 to 2017, explained, "We know of no other medication routinely used for a nonfatal condition that kills patients so frequently."[66]

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[61] Dowell, *supra* note 28, at 22-24.
[62] Edlund, *supra* note 59.
[63] Dowell, *supra* note 28, at 22-24.
[64] Edlund, *supra* note 59.
[65] Ballantyne JC. *Opioid analgesia: perspectives on right use and utility.* Pain physician 2007; 10:479-91.
[66] Thomas R. Frieden & Debra Houry, *Reducing the Risks of Relief – The CDC Opioid-Prescribing Guideline,* 374 New Eng. J. Med. 1501 (2016).

53. Overdose risk from opioids begins at very low doses, doubling when the daily dose is between 20 MMEs and 49 MMEs; by 100 MMEs, the risk of death increases 9-fold.[67]

54. In Illinois alone, nearly 18,000 people died from an overdose involving an opioid between 1999 and 2017.[68]

55. Overall, 1 in every 550 patients on opioid treatment dies of opioid-related causes a median of 2.6 years after their first opioid prescription. That number increases to 1 in 32 for patients receiving 200 MMEs/day.[69]

56. Aside from overdose, long-term opioid use is associated with a significant increase in mortality from other causes, such as cardiovascular events.[70]

57. Opioids are also associated with numerous other side effects including gastrointestinal problems, delayed recovery from injury, cognitive impacts, endocrine impacts, hyperalgesia (increased sensitivity to pain), increased risk of fractures, gastrointestinal bleeding, hospitalization among the elderly, tolerance (need for increasing dose to maintain effect), dependence (causing withdrawal if stopped), and addiction.[71]

58. Opioids carry special risks for certain vulnerable populations. Neonatal abstinence syndrome (NAS) was first described in the 1970s, identified among neonates whose mothers most commonly used heroin or were on methadone maintenance. NAS refers to the collection of signs and symptoms that occur when a newborn prenatally exposed to opiates experiences opioid

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[67] Dunn, *et al.*, *Overdose and Prescribed Opioids: Associations Among Chronic Non-Cancer Patients*, Ann Intern. Med 152(2): 85 – 92 (January 19, 2010).
[68] Centers for Disease Control and Prevention, National Center for Health Statistics. Multiple Cause of Death 1999-2017 on CDC WONDER Online Database, released December, 2018. Data are from the Multiple Cause of Death Files, 1999-2017, as compiled from data provided by the 57 vital statistics jurisdictions through the Vital Statistics Cooperative Program. Accessed at http://wonder.cdc.gov/mcd-icd10.html on Mar 12, 2019.
[69] Frieden, *supra* note 66.
[70] Wayne A. Ray *et al.*, *Prescription of Long-Acting Opioids and Mortality in Patients With Chronic Noncancer Pain,* 315 J. Am. Med. Ass'n 2415 (2016).
[71] Donald Teater, Nat'l Safety Council, *The Psychological and Physical Side Effects of Pain Medications* (2014), citing Leonard Paulozzi *et al.*, *CDC Grand Rounds Prescription Drug Overdoses – a U.S. Epidemic,* 61 Morbidity and Mortality Weekly Report 10 (2012).

withdrawal.[72] The syndrome is primarily characterized by irritability, tremors, feeding problems, vomiting, diarrhea, sweating, and, in some cases, seizures.

59. National surveillance studies have demonstrated that the incidence of NAS increased from 1.2 per 1,000 hospital births in 2009 to 5.8 per 1,000 births in 2012 – a 70% increase in only three years. Since 2000, there has been a five-fold increase in NAS.[73]

60. Since 2011, the rate of NAS in Illinois has similarly risen. In fact, from 2011 to 2016, there was a 53% statewide increase in the NAS rate in Illinois, according to hospital discharge data for all Illinois hospitals.[74] This problem has been particularly dire in Illinois' rural communities where the incidence of NAS rose by 212% between 2011 and 2015.[75]

61. Opioids also pose risks for children and adolescents. Most of the use in this population is off-label as opioids are not approved for children. Use of prescription opioid pain medication before high school graduation is associated with a 33% increase in the risk of later opioid misuse.[76] The misuse of opioids in adolescents strongly predicts the later onset of heroin use.[77] Nonetheless, the 2016 CDC guidelines found that there have been significant increases in opioid prescribing for children and adolescents, for conditions such as headaches and sports injuries.

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[72] Chasnoff, I, Gardner, S. (2015). Neonatal abstinence syndrome: a policy perspective – Journal of Perinatology (2015) 35: 539-541.

[73] Patrick SW, Schumacher RE, Benneyworth BD, Krans EE, McAllister JM, Davis MM. (2012). Neonatal abstinence syndrome and associated health care expenditures. Journal of the American Medical Association, 307(18): 1934-1940; Patrick SW, Davis MM, Lehman CU, Cooper WO. (2015). Increasing incidence and geographic distribution of neonatal abstinence syndrome: United States, 2009-2012. Journal of Perinatology, 35(8): 650-655.

[74] Illinois Department of Public Health, Neonatal Abstinence Syndrome Advisory Committee Annual Report to the General Assembly, 03/31/2018 at p. 7, available at: http://www.dph.illinois.gov/sites/default/files/publications/publicationsowhnas-annual-report.pdf at pg 7(Last accessed March 22, 2019).

[75] The State of Rural Health in Illinois: Great Challenges and a Path Forward at p. 3, available at: https://www.siumed.edu/sites/default/files/u9451/rhs_stateofillinois_final1115.pdf (Last accessed March 21, 2019).

[76] Dowell, *supra* note 28.

[77] *Id.*

62. Opioids also pose special risks for older patients as well. Older patients on opioids are particularly prone to breathing complications, confusion, drug interaction problems, and an increased risk for falls and fractures.[78]

63. In addition, researchers in a 2010 study of older adults, published in the *Archives of Internal Medicine*, found greater risk in "[a]ll-cause mortality after only 30 days for oxycodone and codeine users."[79]

The unproven and transient benefits associated with long-term opioid use do not outweigh the significant risks

64. Not only is it undisputed that opioids carry serious risks of addiction, adverse health outcomes, and death, but any corresponding benefits of opioid treatment, particularly for long-term, chronic pain, are unproven.

65. The CDC published a Guideline for Prescribing Opioids for Chronic Pain in 2016. This guideline, published after a "systematic review of the best available evidence" by an expert panel free of conflicts of interest,[80] determined that no study exists to show opioids are effective for outcomes related to pain, function, and quality of life.[81]

66. Indeed, as Dr. Frieden of the CDC and Dr. Debra Houry, the Director of the National Center for Injury Prevention and Control, explained in 2016: "the science of opioids for chronic pain is clear: for the vast majority of patients, the known, serious, and too-often-fatal risks far outweigh the unproven and transient benefits."[82]

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[78] Resources List Opioid Use in the Older Adult Population, Issue I Volume 1 at p. 1, available at: https://www.samhsa.gov/capt/sites/default/files/resources/resources-opiod-use-older-adult-pop.pdf (Last accessed March 26, 2019).
[79] Solomon, Daniel, *et al.*, The Comparative Safety of Opioids for Nonmalignant Pain in Older Adults. Archives of Internal Medicine, 2010, 170(22):1979-1986.
[80] Dowell, *supra* note 28, at 2.
[81] *Id.* at p. 9.
[82] Frieden, *supra* note 66.

67. Opioids, when used long-term, cause tolerance, meaning larger and larger doses are necessary to get the same effect.[83] Long-term use also causes dependence, meaning that attempts to stop using the drug cause withdrawal symptoms. In addition, long-term opioid use is associated with hyperalgesia, or heightened sensitivity to pain.[84]

68. While opioids may provide relief in the short term, they fail for their stated purpose of relieving pain and improving function when used long-term. In 2009, Dr. Andrea Rubinstein described a common experience for patients on long-term opioid treatment:

> 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.[85]

69. The 2016 CDC guideline notes that "patients who do not experience clinically meaningful pain relief early in treatment (i.e. within 1 month) are unlikely to experience pain relief with longer-term use."[86]

70. A 2006 Danish study found that "it is remarkable that opioid treatment of chronic non-cancer pain does not seem to fulfill any of the key outcome goals: pain relief, improved quality of life and improved functional capacity."[87]

71. Similarly, a 2008 study in the journal *Spine* found that long-term opioid users are more likely to be disabled and unable to work, as well as more likely to be addicted.[88]

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[83] Mitchell H. Katz, *Long-term Opioid Treatment of Nonmalignant Pain*, 170 Archives of Internal Med. 1422 (2010).
[84] Marion S. Greene & R. Andrew Chambers, *Pseudoaddiction: Fact or Fiction? An Investigation of the Medical Literature,* 2 Current Addiction Reports 310 (2015).
[85] A. Rubinstein, *Are we Making Pain Patients Worse?,* Sonoma Medicine, (Fall 2009).
[86] Dowell, *supra* note 28, at 13.
[87] Jorgen Erickson *et al.*, *Critical Issues on Opioids in Chronic Non-Cancer Pain: Ann Epidemiological Study,* 125 Pain 172, 176-77 (2006).
[88] Jeffrey Dersh *et al.*, *Prescription Opioid Dependence Is Associated With Poorer Outcomes in Disabling Spinal Disorders,* 33 Spine 2219 (2008).

72. A 2012 study in *The Journal of Pain*, which followed 69,000 women over three years, found that patients who received opioid treatment were less likely to have improvement in pain, and had worsened function.[89]

73. In 2012, a group of medical providers petitioned the FDA to impose limits on opioid use. The FDA considered the state of evidence and concluded that it was "not aware of adequate and well-controlled studies of opioid use longer than 12-weeks."[90] The FDA went on to note that more data was needed "on the point at which the risk of opioid use at escalating doses and longer durations of treatment may outweigh the benefits of opioid analgesic therapy."[91]

74. One recent study published by the *Journal of the American Medical Association* found that treatment with opioids was not superior to treatment with non-opioid medications for improving pain-related function over 12 months. The results of the study do not support the initiation of opioid therapy for moderate to severe chronic back pain or hip or knee osteoarthritis pain.[92]

75. Analyses of workers' compensation claims have found that workers who take opioids are almost four times more likely to reach costs over $100,000, owing to greater side effects and slower returns to work.[93] In addition, receiving an opioid for more than seven days increased patients' risk of being on work disability one year later, and an opioid prescription as the first treatment for a workplace injury doubled the average length of the claim.

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[89] Frieden, *supra* note 66, citing Jennifer Brennan Braden *et al.*, *Predictors of Change in Pain and Physical Functioning Among Post-Menopausal Women with Recurrent Pain Conditions in the Women's Health Initiative Observational Cohort,* 13 J. Pain 64 (2012).
[90] Woodcock Letter, (Sept 10, 2013), *supra* note 29.
[91] *Id.*
[92] Erin E. Krebs, MD, MPH, *et al.*, *Effect of Opioid vs Nonopioid Medications on Pain-Related Function in Patients With Chronic Back Pain or Hip or Knee Osteoarthritis Pain The SPACE Randomized Clinical Trial*, JAMA, 2018, 319(9):872-882
[93] Gary M. Franklin *et al.*, *Early Opioid Prescription and Subsequent Disability Among Workers With Back Injuries,* 33 Spine 199 (2008).

76. Despite the tremendous increase in opioid prescriptions from 1999 to 2015, the overall prevalence of patient-reported pain has remained consistent.[94] Thus, the massive expansion of prescribing opioids for pain has made little progress in reducing chronic pain.

Despite the scientific evidence, Purdue profited handsomely by pushing opioids for long-term use

77. Purdue's decision to promote expansive opioid use without good evidence of their benefits when used for chronic pain and in spite of the recognized risks created an opioid epidemic.

78. There are no reliable clinical studies supporting the use of opioids long-term, however, there exists a wealth of evidence establishing that opioids are both addictive and deadly.

79. Purdue, nevertheless, continued to market opioids as necessary to address long-term chronic pain.

80. Purdue's stated motive for promoting opioids was providing pain relief, but its underlying motive was profit. Purdue's aggressive marketing of opioids for the most dangerous kind of opioid use— long-term at high doses— has been exceedingly financially lucrative.

81. Purdue, which is a privately-owned family company, has generated an estimated $35 billion in sales since 1995, with annual revenues around $3 billion.[95] In 2012, the extended-release opioid market recorded $5.2 billion in sales. OxyContin alone generated $2.8 billion, or more than half of that amount. In 2014, the total opioid market reached $11 billion and some have projected that it will continue generating these levels of revenues.[96]

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[94] https://www.cdc.gov/drugoverdose/data/prescribing.html (Last accessed March 22, 2019).
[95] Alex Morrell, *The OxyContin Clan: The $14 Billion Newcomer to Forbes 2015 List of Richest U.S. Families,* Forbes, July 1, 2015, https://www.forbes.com/sites/alexmorrell/2015/07/01/the-oxycontin-clan-the-14-billion-newcomer-to-forbes-2015-list-of-richest-u-s-families/#7563a67875e0 (Last accessed March 22, 2019).
[96] GBI Research, *Despite Substance Abuse Concerns, the US Opioid Market Will Hit $17.7 Billion by 2021,* March 31, 2016, http://gbiresearch.com/media-center/press-releases/despite-substance-abuse-concerns-the-us-opioid-market-will-hit-177-billion-by-2021 (Last accessed March 22, 2019).

PURDUE'S UNFAIR AND DECEPTIVE ACTS AND PRACTICES

82. Purdue has engaged in numerous deceptive and unfair acts and practices designed to push opioids for long-term use at high doses, all to increase its sales of opioids. Purdue did this despite the lack of evidence that opioids improve patients' quality of life and function long-term and despite the well-documented risks of its drugs.

Purdue misled providers and patients about the risk of opioid addiction

83. Purdue misled health care providers and patients about the adverse effects of opioids, particularly the risk of addiction.

84. Purdue funded, influenced, and distributed third-party publications of doctor and patient "educational" materials, as well as created and disseminated unbranded materials, which misled their target audiences about the danger of prescription opioids. These publications downplayed the true risk of addiction and asserted that patients should be persistent in getting opioids for their pain, while doctors were following the appropriate approach, with manageable risk, by prescribing opioids long-term. For example:

In the Face of Pain

85. Purdue maintained the website, *In the Face of Pain*, from 2008 through 2015, which asserted that policies limiting access to opioids are "at odds with best medical practices" and encouraged patients to be "persistent" in finding doctors who will treat their pain.

86. While encouraging patients to be "persistent" in finding doctors who will treat their pain, Purdue failed to inform patients about the grave risk of addiction and other dangers associated with opioids.

87. The website contained testimonials from several dozen physician "advocates" speaking positively about opioids. Eleven of these advocates received a total of $231,000 in payments from Purdue from 2008 to 2013.[97] Purdue omitted this material fact from the site.[98]

88. Purdue deactivated *In the Face of Pain* in the face of an investigation, and later settlement, by the New York Attorney General.[99]

89. [redacted]

Treatment Options: A Guide for People Living with Pain

90. Purdue sponsored the American Pain Foundation'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.

91. The *Treatment Options* guide also stated "[d]espite the great benefits of opioids, they are often underused," and emphasized that "[r]estricting access to the most effective medications for treating pain is not the solution to drug abuse or addiction."

92. The brochure also explained that opioid "under-use has been responsible for much unnecessary suffering."

Exit Wounds

93. Purdue sponsored American Pain Foundation's *Exit Wounds* (2009), which, among other things, taught veterans 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."

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[97] Attorney General of the State of New York, *In the Matter of Purdue Pharma L.P.*, Assurance No.: 15-151 (August 19, 2015).
[98] *Id.*
[99] *Id.*

94. Although the term "very unlikely" is not defined, the overall presentation suggests that the rate is so low as to be immaterial.

A Policymaker's Guide to Understanding Pain & Its Management

95. Purdue sponsored American Pain Foundation's *A Policymaker's Guide to Understanding Pain & Its Management,* which inaccurately claimed that less than 1% of children prescribed opioids would become addicted.

96. The Guide also misleadingly concluded that "[u]nfortunately, too many Americans are not getting the pain care they need and deserve. Some common reasons for difficulty in obtaining adequate care include...misconceptions about opioid addiction."[100]

Providing Relief, Preventing Abuse

97. *Providing Relief, Preventing Abuse,* a pamphlet published by Purdue for prescribers and law enforcement, includes pictures of the signs of injecting or snorting opioids—skin popping, track marks, and perforated nasal septa—under the heading "Indications of Possible Drug Abuse." But since it is uncommon for opioid addicts to resort to these extremes – they more typically become dependent and addicted to swallowing pills – such statements have the effect of misleading prescribers about the true scope of addiction.

98. [redacted]

Resource Guide for People with Pain

99. Similarly, another Purdue publication, the *Resource Guide for People with Pain*, falsely assured patients and doctors that although many people "believe that opioid medications are addictive," that "the truth" is that if these medications are properly prescribed and taken as directed, they "give relief— not a 'high.'"

[100] This claim also appeared in a 2009 publication by American Pain Foundation, *A Reporter's Guide.*

100. Contrary to Purdue's representations, up to 26% of opioid users in primary care settings and as many as 30% or even 40% of long-term opioid users experience problems with addiction. Purdue's representations that the risk of addiction was either low or acceptable were misleading.

101. In fact, when it was commercially advantageous, Purdue argued that its own opioid product, OxyContin, was unsafe. Purdue discontinued the marketing of its original formulation of OxyContin upon introduction of a reformulation in 2010. This meant that other manufacturers could petition the FDA for permission to make generic OxyContin. The FDA's regulations required it to determine whether original OxyContin was voluntarily withdrawn from sale for "safety or effectiveness reasons" before approving a generic version.[101]

102. Purdue submitted a citizen petition to the FDA on July 13, 2012, arguing that if generic OxyContin were allowed, "abuse of extended release oxycodone could return to the levels experienced prior to the introduction of reformulated OxyContin." In short, Purdue argued that the very same product it had marketed, sold, and profited from for years had such a significant risk of abuse that it should be banned.

103. On April 18, 2013, the FDA, at Purdue's urging, found that Purdue had voluntarily withdrawn original OxyContin from sale for safety reasons "in light of the extensive and well-documented history of OxyContin abuse," thereby closing the door on generic manufacturers.[102]

104. By blocking generic versions of original OxyContin, Purdue continued to profit from its OxyContin brand of extended-release oxycodone. After years of deceptively promoting and profiting in the face of a growing abuse and addiction crisis, that very Purdue-fueled crisis served as the justification for further competitive advantage and associated profits.

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[101] 21 C.F.R. 314.161.

[102] Federal Register, Vol. 78, No. 75, Thursday, April 18, 2013, Notices, at 23274.

Purdue made deceptive claims about the extent to which addiction risk can be managed and addiction prevented

105. Purdue knew it probably could not persuade doctors to disregard the risk of opioid addiction entirely and, therefore, sought to reassure doctors that they could effectively manage risks and prevent addiction in their patients by using tools that Purdue and its third-party groups provided.

106. Purdue deceptively claimed that screening patients could effectively manage addiction risk.

107. Purdue sponsored American Pain Foundation's *Treatment Options: A Guide for People Living with Pain* (2007), which falsely reassured patients that "opioid agreements" between doctors and patients can "ensure that you take the opioid as prescribed."

108. [redacted]

109. Purdue sales representatives gave the *Partners Against Pain* "Pain Management Kit," which contained several "drug abuse screening tools," to prescribers, including prescribers in Illinois. These screening tools included the "Opioid Risk Tool" – a five question, one-minute screening tool that relies on patient self-reporting to identify whether there is a personal history of substance abuse, sexual abuse, or "psychological disease."

110. Purdue also promoted the Opioid Risk Tool in CME material, including a 2013 CME entitled *Is It Pain?*

111. Convincing prescribers that they could effectively manage risk and prevent addiction was essential to Purdue's marketing strategy of increasing the number of prescriptions of opioids and its own branded drugs.

112. This strategy was essential for Purdue to help prescribers feel comfortable prescribing these highly addictive products; however, Purdue did not know whether its recommended tools could in fact reduce the risk of opioid addiction.

113. A 2014 Evidence Report by the Agency for Healthcare Research and Quality "systematically review[ed] the current evidence on long-term opioid therapy for chronic pain" and identified "[n]o study" that had "evaluated the effectiveness of risk mitigation strategies, such as use of risk assessment instruments, opioid management plans, patient education, urine drug screening, prescription drug monitoring program data, monitoring instruments, more frequent monitoring intervals, pill counts, or abuse-deterrent formulations on outcomes related to overdose, addiction, abuse or misuse."[103]

114. Similarly, the evidence shows that methods for preventing abuse and addiction, such as patient contracts, more frequent refills, and urine drug screening, often do not work when prescribing opioids to high-risk patients.[104]

115. Indeed, the 2016 CDC Guideline notes that there are no studies assessing the effectiveness of risk mitigation strategies such as screening tools, patient agreements, urine drug testing or pill counts "for improving outcomes related to overdose, addiction, abuse, or misuse."[105]

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[103] *The Effectiveness and Risks of Long-term Opioid Treatment of Chronic Pain,* Agency for Healthcare Res. & Quality, Sept. 19, 2014.

[104] Michael Von Korff *et al.*, *Long-Term Opioid Therapy Reconsidered,* 155 Annals of Internal Med. 325 (2011); 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 S1 (2012).

[105] Dowell, *supra* note 28, at 11.

116. Furthermore, in practice, opioids are all too often prescribed by providers for patients at serious risk for addiction or who are already addicted to opioids – often at high doses.[106] Purdue continued marketing to providers even when it had evidence that such was the case.

Purdue deceptively claimed that abuse-deterrent formulations could lower opioid abuse and addiction risk

117. In 2010, Purdue introduced a reformulation of OxyContin and discontinued marketing its original formulation. The 2010 reformulation instituted what Purdue calls the "abuse-deterrent" formulation of OxyContin. Purdue later designed Hysingla ER to likewise have "abuse-deterrent" properties.

118. Because Purdue's extended-release opioids are essentially very large doses of opioids placed in a timed-release matrix designed to release the drug over time, if the time release formulation can be defeated, then the user can get the concentrated dose all at once. In addition, by dissolving the drug, the user can inject it directly into the bloodstream to receive a high. The abuse-deterrent formulations were designed to make opioid pills harder to crush, dissolve, or otherwise manipulate so as to defeat this problem.

119. Purdue acknowledges that abuse-deterrent formulations "are designed to provide patients with pain relief when taken as directed while also deterring abuse by snorting and injection." Purdue's website states that these formulations are "intended to help deter the abuse, misuse, and diversion of these prescription pain medications— while ensuring that patients in pain continue to have appropriate access to these important therapies."[107]

120. As Purdue was the first opioid manufacturer to create an FDA-approved abuse-deterrent formulation, it has featured prominently in Purdue's marketing of its drugs. [redacted]

[106] Karen H. Seal, *et al.*, *Association of Mental Health Disorders With Prescription Opioid and High-Risk Opioid Use in US Veterans of Iraq and Afghanistan,* 307 J. Am. Med. Ass'n 940 (2012).
[107] *Opioids with Abuse Deterrent Properties,* Purdue Pharma, https://www.purduepharma.com/healthcare-professionals/responsible-use-of-opioids/opioids-with-abuse-deterrent-properties/ (Last accessed March 22, 2019).

[redacted]

121. [redacted]

122. [redacted]

123. Indeed, Purdue sales representatives frequently emphasized the abuse-deterrent formulation when marketing OxyContin and Hysingla ER directly to Illinois prescribers. For instance:

a. [redacted]

b. [redacted]

c. [redacted]

d. [redacted]

e. [redacted]

124. Most prescription opioids that are abused, however, are swallowed whole, and oral ingestion is equally risky. In fact, studies suggest that only about 10% to 20% of all opioid users snort or inject pills; there is no evidence that orally-administered opioids are less addictive.[108] Indeed, in its medical review of Purdue's New Drug Application for the reformulated OxyContin, the FDA found that "the tamper resistant properties will have no effect on abuse by the oral route (the most common mode of abuse)" and that "[w]hile the reformulation is harder to crush or chew, possibly mitigating some accidental misuse, oxycodone HCl is still relatively easily extracted."[109]

125. Similarly, in its 2012 medical office review of Purdue's application to include abuse deterrence in its FDA label for OxyContin, the FDA noted that the vast majority of deaths were associated with oral consumption, and that only 2% of deaths linked to OxyContin were associated with recent injection and 0.2% with snorting the drug.[110]

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[108] Catherine S. Hwang *et al.*, *Primary Care Physicians' Knowledge and Attitudes Regarding Prescription Opioid Abuse and Diversion,* 32 Clinical J. Pain 279 (2016).
[109] New Drug Application 22-272, OxyContin, Division Director Summary Review for Regulatory Action, at 7 (Dec. 30, 2009).
[110] FDA_2013 summary review, Reference ID 325870, 4-5.

126. The CDC also observed that abuse-deterrent technologies do not prevent overdose through oral intake.[111]

127. Purdue's efforts to associate abuse-deterrent formulas with safety have paid off. In a 2016 survey, 46% of physicians surveyed erroneously believed that abuse-deterrent formulations were less addictive than non-abuse-deterrent formulations.[112]

128. The 2016 CDC guideline found no evidence or studies to support the notion that abuse-deterrent formulations have any effectiveness as a risk mitigation strategy for deterring or preventing abuse. In fact, the CDC noted one study that suggested that the abuse-deterrent formulation was associated with increased use of other opioids, including heroin.[113]

129. After being informed of a newspaper story critical of Purdue's marketing of its abuse-deterrent formulation in late 2016, [redacted]

130. In 2016, The Pharmaceutical Manufacturing Research Services, Inc. filed a citizen's petition with the FDA, asking the FDA to withdraw its approval of abuse-deterrent labeling on OxyContin. The petition asserted that it was "exceedingly easy" to extract the active ingredient from OxyContin via small volume extraction. In fact, it is easier to extract the active ingredient from OxyContin than it is to extract from Opana, Endo Pharmaceutical's extended-release drug;[114] the latter was so unsafe that the FDA requested it be removed from the market.[115]

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[111] Dowell, *supra* note 28, at 2.
[112] Hwang *et al.*, *supra* note 108.
[113] Dowell, *supra* note 28, at 2.
[114] February 19, 2016 Citizen Petition, Pharmaceutical Manufacturing Research Services, Inc.
[115] *FDA Requests Removal of Opana ER for Risks Related to Abuse,* FDA, June 8, 2017, https://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm562401.htm (Last accessed March 22, 2019).

131. Since the introduction of the reformulated OxyContin, there is little data to suggest that it has meaningfully reduced abuse.[116] And, in fact, as noted above, despite the introduction of abuse-deterrent formulas in 2010, opioid deaths have continued to accelerate.

Purdue deceptively used terms like dependence, tolerance and "pseudo addiction" to downplay the risk of addiction

132. Purdue also downplayed the problem of addiction by simply re-labeling it. According to Purdue, the signs of addiction are actually the product of untreated pain, which should be treated by prescribing even more opioids.

133. The term "pseudo addiction" was coined by Dr. J. David Haddox, who later became Purdue's vice president of health policy. "Pseudo addiction" was meant to differentiate between "undertreated pain" and "true addiction" – as if the two were mutually exclusive.

134. Purdue promoted the idea of "pseudo addiction" even though there was no competent scientific evidence supporting this concept. For example:

Responsible Opioid Prescribing

135. The 2007 Purdue-sponsored book *Responsible Opioid Prescribing* warns doctors to "[b]e aware of the distinction between *pseudo addiction* and addiction."[117] (Emphasis in original). It explains that "[p]atients who are receiving an inadequate dose of opioid medication often 'seek' more pain medications to obtain pain relief," and "[t]his is called pseudoaddiction because healthcare practitioners can mistake it for the drug-seeking behavior of addiction."[118] This confusion arises because the "same behavioral signs [of pseudo addiction] can [also] indicate addiction."[119]

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[116] *Id.*
[117] *Responsible Opioid Prescribing* (2007), at 62.
[118] *Id.*
[119] *Id.*

136. Prescribers were instructed to differentiate pseudo- from "true" addiction by "observ[ing] as closely as possible the functional consequences of opioid use. Whereas pseudoaddiction resolves when the patient receives adequate analgesia, addictive behavior does not."[120]

137. In short, to determine whether a patient is addicted to opioids, doctors are to give the patient more opioids and then see if he keeps engaging in "demanding or manipulative behavior" *after* his demands are met or the manipulation has achieved its desired result.[121]

138. Examples of behaviors listed in the Purdue-sponsored book as "LESS indicative of addiction" include "hoard[ing] medications," "tak[ing] someone else's pain medications" and "us[ing] more opioids than recommended."[122]

139. By comparison, the Purdue-sponsored book identifies addiction-indicating behaviors as being much more extreme, including "[stealing] money to obtain drugs," "[p]erform[ing] sex for drugs," and "[p]rostitut[ing] others for money to obtain drugs."

Clinical Issues in Opioid Prescribing

140. A 2008 Purdue pamphlet entitled *Clinical Issues in Opioid Prescribing* represented that conduct like "illicit drug use and deception" was not evidence of "true" addiction, but instead an indication of "pseudo addiction" caused by untreated pain. It explained: "Pseudo addiction is a term which has been used to describe patient behaviors that may occur when pain is untreated .... Even such behaviors as illicit drug use and deception can occur in the patient's efforts to obtain relief. Pseudo addiction can be distinguished from true addiction in that the behaviors resolve when the pain is effectively treated."

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[120] *Id.*
[121] *Id.*
[122] *Responsible Opioid Prescribing (2007), at 63.*

A Policymaker's Guide to Understanding Pain & Its Management

141. Purdue sponsored *A Policymaker's Guide to Understanding Pain & Its Management*, which deceptively promoted the concept of "pseudo addiction" by explaining that "[p]atients with unrelieved pain may become focused on obtaining medications and may otherwise seem inappropriately 'drug seeking,' which may be misidentified as addiction by the patient's physician."

Exit Wounds

142. Purdue sponsored *Exit Wounds*, which sought to reassure veterans about addiction concerns by explaining that although they may become physically dependent on opioids, they will not become addicted.

143. This book taught that "[t]his Physical dependence means that a person will develop symptoms and signs of withdrawal (e.g., sweating, rapid heart rate, nausea, diarrhea, goose bumps, or anxiety) if a drug medication is suddenly stopped or the dose is lowered too quickly. . . . Physical dependence is normal. This does not mean you are addicted."

144. It also stated that "[o]pioid medications can, however, be abused or used as recreational drugs, and some people who use drugs in this way *will* become addicted. Addiction is a disease state in which people can no longer control their use of a drug that is causing them harm." (Emphasis in original.)

Providing Relief, Preventing Abuse

145. Purdue directly disseminated materials about "pseudo addiction" to Illinois health care providers. Following the entry of a 2007 Consent Judgment, Purdue was obligated to provide information about abuse and diversion to prescribers. Purdue designed a brochure entitled *Providing Relief, Preventing Abuse.* Under the guise of education, Purdue sent annual "Dear

Healthcare Provider" letters to Illinois health care providers and enclosed two copies of *Providing Relief, Preventing Abuse*. Purdue represented that "[t]he brochure contains important information" about topics like "definitions related to the use of opioids for the treatment of pain," as well as [i]ndicators of possible abuse" and "[s]trategies for identifying opioid abusers." Various editions of *Providing Relief, Preventing Abuse* contained deceptive statements about "pseudo addiction."

146. The 2008 edition of *Providing Relief, Preventing Abuse* explained that the term "pseudo addiction" describes health care providers' misinterpretation of relief-seeking behaviors in a person whose pain is inadequately treated as drug-seeking behaviors common in the setting of abuse. According to Purdue's pamphlet, the lack of appropriate response to the behaviors can result in their escalation by the patient, in an attempt to get adequate analgesia.

147. The 2008 edition of *Providing Relief, Preventing Abuse* further explained that "[p]seudoaddiction can be distinguished from addiction in that the behaviors resolve when pain is effectively treated."

148. Additionally, a 2010 Purdue *Training Guide for Healthcare Providers* on OxyContin taught that "[b]ehaviors that suggest drug abuse exist on a continuum, and pain-relief seeking behavior can be mistaken for drug-seeking behavior."

149. By 2011, Purdue had revised the brochure, and the second edition of *Providing Relief, Preventing Abuse* explained that:

> [s]ome patients may exhibit behaviors aimed at obtaining pain medication because their pain treatment is inadequate. The term *pseudoaddiction* has emerged in the literature to describe the inaccurate interpretation of these behaviors in patients who have pain that has not been effectively treated. Pseudoaddiction behaviors can be distinguished from addiction by the fact that, when adequate analgesia is achieved, the patient who is seeking pain relief demonstrates improved function, uses the medications as prescribed, and does not use drugs in a manner that persistently causes sedation or euphoria.

150. By 2014, the term "pseudo addiction" no longer appeared in *Providing Relief, Preventing Abuse*, but the brochure included an "Other Considerations" section that taught "[s]ome patients may exhibit behaviors aimed at obtaining pain medication because their pain treatment is inadequate. Such behaviors may occur occasionally even with successful opioid therapy for pain; a pattern of persistent occurrences should prompt concern and further assessment."

151. Purdue's *Providing Relief, Preventing Abuse* was widely disseminated by Purdue in Illinois, [redacted] Purdue sales representatives also often referenced or provided the brochure during sales calls with Illinois prescribers.

152. Purdue also disseminated the Definitions Related to the Use of Opioids for the Treatment of Pain section of an American Pain Society consensus statement through the *Partners Against Pain* website. American Pain Society defined "pseudo addiction" in the same terms endorsed by Purdue:

> Physical dependence, tolerance, and addiction are discrete and different phenomena that are often confused.... Pseudo addiction is a term which has been used to describe patient behaviors that may occur when pain is undertreated. Patients with unrelieved pain may become focused on obtaining medications, may "clock watch," and may otherwise seem inappropriately "drug seeking." Even such behaviors as illicit drug use and deception can occur in the patient's efforts to obtain relief. Pseudo addiction can be distinguished from true addiction in that the behaviors resolve when pain is effectively treated. Physical dependence on and tolerance to prescribed drugs do not constitute sufficient evidence of psychoactive substance use disorder or addiction. They are normal responses that often occur with the persistent use of certain medications....A patient who is physically dependent on opioids may sometimes continue to use these despite resolution of pain only to avoid withdrawal. Such use does not necessarily reflect addiction.

153. Purdue also directly promoted the concept of "pseudo addiction" or the concept that signs of addiction are in fact just physical dependence, to Illinois prescribers during sales calls. For example:

a. [redacted]

b. [redacted]

c. [redacted]

d. [redacted]

e. [redacted]

154. Purdue Key Opinion Leader Dr. Lynn Webster acknowledged: "[Pseudo addiction] 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."[123]

155. The 2016 CDC Guideline confirms the invalidity of the concept of "pseudo addiction," explaining that "patients who do not experience clinically meaningful pain relief early in treatment (i.e. within 1 month) are unlikely to experience pain relief with longer-term use."[124] The CDC Guideline went on to advise that prescribers should "reassess[] pain and function within 1 month" to decide whether to "minimize the risks of long-term opioid use by discontinuing opioids." Thus, the CDC Guideline advises that physicians should consider *discontinuing* opioid use for those patients who are exhibiting behaviors that indicate ineffective pain relief, not *increase* their doses.

Purdue deceptively downplayed the symptoms of withdrawal and the ability to manage them

156. Purdue also downplayed the impact of addiction by representing that physical dependence on opioids is not the same as addiction and could be addressed by gradually tapering patients' dosages to avoid withdrawal. Purdue downplayed the difficult and painful effects that many patients experience when dosages are lowered or opioids are discontinued, and which decrease the likelihood that those patients will be able to stop using opioids.

157. For example, Purdue sponsored the American Pain Foundation's *A Policymaker's Guide to Understanding Pain & Its Management,* which taught that "[s]ymptoms of physical dependence can often be ameliorated by gradually decreasing the dose of medication during

[123] John Fauber & Ellen Gabler, *Networking Fuels Painkiller Boom,* Milwaukee Wisc. J. Sentinel, Feb. 19, 2012.
[124] Dowell, *supra* note 28, at 2.

discontinuation," but did not disclose the significant hardships that often accompany cessation of use, even gradual tapering off.

158. Similarly, a 2010 Purdue *Training Guide for Healthcare Providers* on OxyContin claimed that patients who were physically dependent on opioids, but who had not developed an "addiction disorder" "[c]an generally discontinue their medicine with mild to no withdrawal syndrome once their symptoms are gone by gradually tapering the dosage according to their doctor's orders."

159. In fact, it is very difficult to stop using opioids once they have been prescribed. It is not, as Purdue implied, a simple matter to taper the drug and stop using opioids.

Purdue misrepresented opioids' ability to improve function and quality of life

160. Purdue made deceptive and unsubstantiated claims regarding the improved quality of life and function resulting from opioids in general and its own drugs in particular.

161. Opioids may initially improve function by providing pain relief in the short term, but there is no evidence that opioids improve patients' function in the long-term.

162. Despite the lack of evidence of improved function long term, Purdue deceptively promoted opioids as improving function and quality of life without disclosing the lack of evidence for this claim. For example:

Responsible Opioid Prescribing

163. Purdue sponsored The Federation of State Medical Boards' *Responsible Opioid Prescribing* (2007), which taught that relief of pain itself improved patients' function: "While significant pain worsens function, relieving pain should reverse that effect and improve function."

164. In fact, on the first page, *Responsible Opioid Prescribing* represents that patients "rely on opioids for . . . improved function."[125]

165. Purdue provided $800,000 in grants to support various Federation initiatives related to opioids, including $100,000 to disseminate *Responsible Opioid Prescribing* and $50,000 to fund Dr. Scott Fishman's production of the book.

166. According to the Federation, 500 copies of the book were distributed to Illinois prescribers by 2012.[126]

Treatment Options: A Guide for People Living with Pain

167. Purdue 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."

168. The *Treatment Options* guide notes that non-steroidal anti-inflammatory drugs *(e.g.,* aspirin or ibuprofen) have greater risks with prolonged duration of use, but there was no similar warning for opioids.

A Policymaker's Guide to Understanding Pain & Its Management

169. Purdue sponsored the American Pain Foundation's *A Policymaker's Guide to Understanding Pain & Its Management* (2011), which inaccurately claimed that "[m]ultiple clinical studies have shown that long-acting opioids, in particular, are effective in improving" "[d]aily function," "[p]sychological health," and "health-related quality of life for people with chronic pain," with the implication that these studies presented claims of long-term improvement.

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[125] Scott M. Fishman, *Responsible Opioid Prescribing,* Federation of State Medical Boards, Waterford Life Sciences (2007).

[126] Letter from Humayun J. Chaudhry, DO, FACP, Federation of State Medical Boards, to Sen. Max Baucus and Charles Grassley, (June 8, 2012).

170. But in fact, the sole reference for these claims (i) noted the absence of long-term studies and (ii) actually stated that "[f]or functional outcomes, the other analgesics were significantly more effective than were opioids."[127]

Exit Wounds

171. Purdue sponsored *Exit Wounds*, which taught veterans that opioid medications "increase your level of functioning."

Managing Patient's Opioid Use: Balancing the Need and the Risk

172. Purdue sponsored a Continuing Medical Education (CME) presentation entitled *Managing Patient's Opioid Use: Balancing the Need and the Risk*, which made unsubstantiated and false claims about improved functionality.

173. [redacted]

174. [redacted] Upon information and belief, these deceptive statements about opioids' ability to improve function were included in the final presentation.

175. Purdue also published misleading studies to enhance the perception that opioids are effective long-term for chronic pain conditions. One study asserts that OxyContin is safe and effective for the chronic pain condition osteoarthritis. The study, sponsored by Purdue, involved

[127] Andrea D. Furlan *et al.*, *Opioids for Chronic Noncancer Pain: A Meta-analysis of Effectiveness and Side Effects*, 174 Canadian Med. Ass'n J. 1589 (2006).

(1) providing oxycodone for 30 days, and then (2) randomizing participants and providing a placebo, IR oxycodone with acetaminophen (like Percocet), or OxyContin. Only 107 of the 167 patients advanced to the second phase of the study, and most participants who withdrew left because of adverse events (nausea, vomiting, drowsiness, dizziness, or headache) caused by the opioid or because the opioid provided ineffective treatment. Despite relating to a chronic condition, opioids were provided only short-term.

176. Although the authors of the study even acknowledge that the "results.... should be confirmed in trials of longer duration to confirm the role of opioids in a chronic condition such as OA [osteoarthritis],"[128] the study concluded that "[t]his clinical experience shows that opioids were well tolerated with only rare incidence of addiction and that tolerance to the analgesic effects was not a clinically significant problem when managing patients with opioids long-term."[129] This statement is not supported by the data because (a) a substantial number of patients dropped out because of adverse effects, (b) there was no reported data regarding addiction, and (c) the study was not long-term.

177. Purdue sales representatives promoted these misleading studies and the concept that opioid use can improve quality of life and function directly to Illinois prescribers during sales calls. For example:

a. [redacted]

[128] Jacques R. Caldwell *et al.*, *Treatment of Osteoarthritis Pain with Controlled Release Oxycodone or Fixed Combination Oxycodone Plus Acetaminophen Added to Nonsteroidal Anti-inflammatory Drugs: A Double Blind, Randomized, Multicenter, Placebo Controlled Trial,* 26 J. Rheumatology 862 (1999).
[129] *Id.*

[redacted]

b. [redacted]

c. [redacted]

d. [redacted]

178. As noted above, the available evidence indicates opioids do not improve function or quality of life when taken long-term – indeed, they may harm patients' health.[130] [redacted] Purdue's claims to the contrary were misleading.

179. Purdue knew these unsubstantiated and false claims would influence health care providers. [redacted]

[130] *See, e.g.* Furlan *et al.*, *supra* note 127; *see also* Dersh *et al.*, *supra* note 88.

[redacted]

180. Purdue's claims that opioids improve function and quality of life long-term are deceptive. There is no evidence supporting these claims; in fact, the evidence shows the claims are untrue.

Purdue deceptively claimed OxyContin was effective for 12 hours

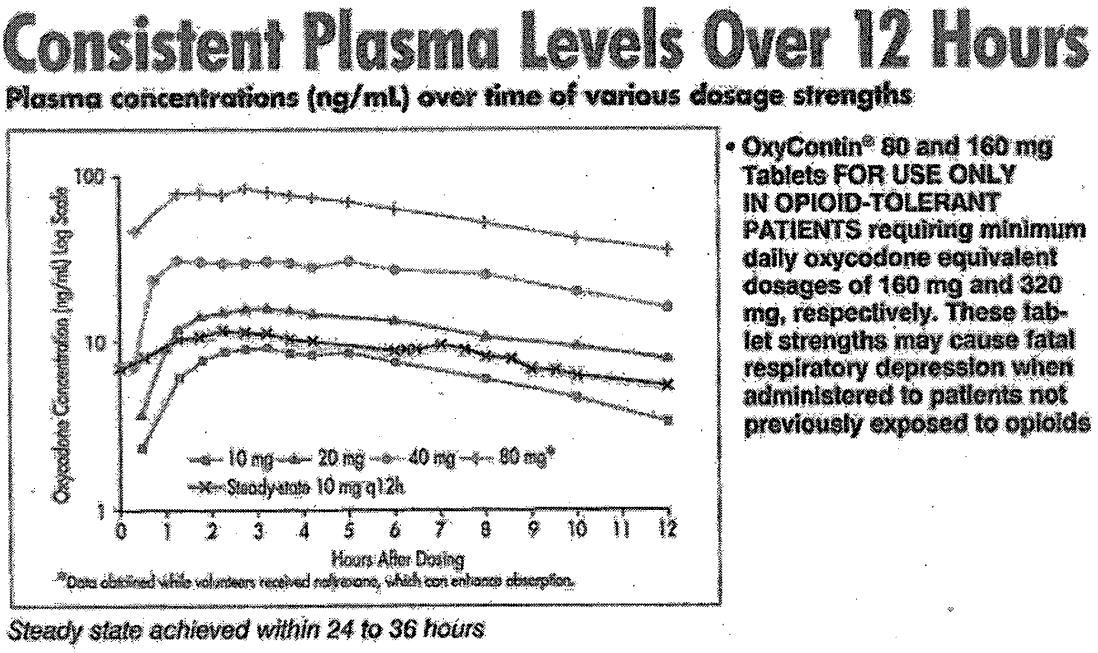
181. In addition to claiming improved function and quality of life from long-term opioid use, Purdue also deceptively promoted OxyContin as delivering a full 12 hours of "steady state" pain relief. This meant that OxyContin was purportedly less likely to result in crashes and cravings that lead to addiction and abuse. In reality, OxyContin does not last for 12 hours in many patients, a fact Purdue has known since the product's launch.

182. OxyContin has been FDA-approved for twice-daily "Q12" dosing frequency since its debut in 1996. Purdue chose to submit OxyContin for approval with 12-hour rather than 8-hour dosing, and then made the 12-hour claim central to its marketing campaign.

183. Under FDA guidelines for establishing dosing, Purdue merely had to show that OxyContin lasted for 12 hours for at least half of patients, and Purdue submitted a single study that cleared that bar. The OxyContin label indicates that "[t]here are no well-controlled clinical studies evaluating the safety and efficacy with dosing more frequently than every 12 hours," and Purdue has conducted no such studies.

184. Purdue promoted OxyContin as providing continuous, round-the-clock pain relief with the convenience of not having to wake up to take a third or fourth pill. The advertising claimed that OxyContin provides "Consistent Plasma Levels Over 12 Hours" and included a chart depicting plasma levels on a logarithmic scale. The chart deceptively concealed the steep decline

in OxyContin's effectiveness over 12 hours by manipulating the scale of the chart's Y-axis to make 10 mg appear to be half of 100 mg. This sleight of hand manipulated the curve and made the absorption rate appear more steady or consistent than it really was.



185. Purdue senior medical director, Dr. J. David Haddox, told a reporter in 2001 that "[a] lot of these people say, 'Well, I was taking the medicine like my doctor told me to,' and then they start taking them more and more and more....I don't see where that's my problem."[131]

186. The FDA found in 2008 that a "substantial number" of chronic pain patients taking OxyContin experience "end of dose failure" with little or no pain relief at the end of the dosing period.[132]

187. In a 2013 public hearing, Dr. David Egliman testified:

> Now, why did we get to a Q12 dose? It wasn't because of the data on efficacy of the drug. It was because Purdue Pharma needed something to distinguish its drug from other

[131] Quoted in Harriet Ryan *et al.*, *You Want a Description of Hell?" OxyContin's 12-hour Problem,* Los Angeles Times, May 5, 2016.
[132] 2008 FDA response to Citizen Petition by Connecticut Attorney General.

> short-acting narcotics, and this became the main marketing device to increase profits. On the other hand, the data showed something else. As you can see, at 10 milligrams, the OxyContin product release was effective for less than six hours in at least 25 percent of patients. And the 20 and 30 milligram dose were effective for less than 10 hours in at least 50 percent of patients. Other Purdue studies, all of them in fact, allowed rescue or short-acting oxy to cover patients who had pain breakthrough before 12 hours. However, this does not—and this information is omitted from the label.[133]

188. Nevertheless, Purdue still emphasized 12-hour dosing in detailing visits to Illinois prescribers, though that often did not match the physicians' anecdotal experience. Purdue was well aware of the common practice of prescribing OxyContin more frequently than 12 hours to address end-dose failure experienced by the patients, up to three or four doses per day. For instance:

a. [redacted]

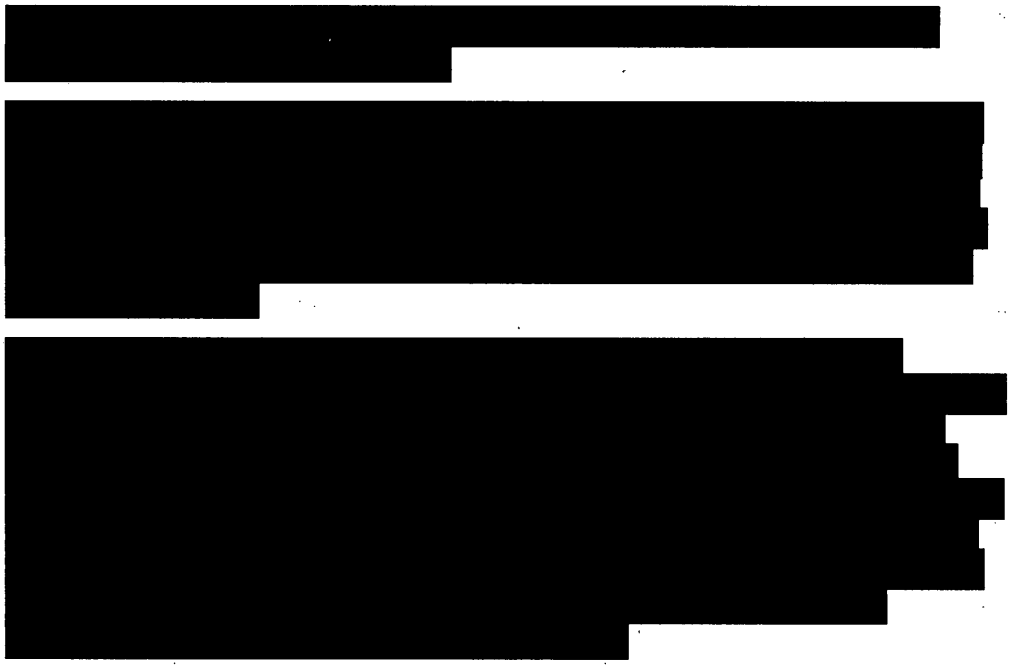
b. [redacted]

189. Purdue did promote a "solution": increase the *dosage* of the opioid, rather than the frequency, even though higher dosing carries higher risks of addiction and overdose.

190. Purdue's solution exposed patients to higher highs and lower lows, increasing their craving for their next pill. But sales representatives were trained to reassure prescribers that there is no ceiling on the amount of OxyContin a patient could be prescribed. And many prescribers followed the recommendation of the sales representatives to increase the dose rather than the frequency of OxyContin. For example:

a. [redacted]

[133] Testimony of David Egilman, *Impact of Approved Drug labeling on Chronic Opioid Therapy* at 90:22-91:11, FDA Center for Drug Evaluation and Research Public Hearing (Feb. 8, 2013).



191. These 12-hour pain relief misrepresentations are particularly dangerous because when patients are inadequately dosed, they begin to experience distressing psychological and physical withdrawal symptoms, followed by a euphoric rush with their next dose -- a cycle that fuels addiction. Many patients will exacerbate this cycle by taking their next dose ahead of schedule or resorting to a rescue dose of another opioid, increasing the overall amount of opioids they are taking.

192. Nationwide, based on an analysis by the *Los Angeles Times,* more than 52% of patients taking OxyContin longer than three months are on doses greater than 60 milligrams per day, which converts to the 90 morphine milligram equivalents that the CDC Guideline urges prescribers to "avoid" or "carefully justify."[134]

193. Despite having knowledge that, for a substantial portion of patients, the 12-hour dosing is not effective, Purdue has remained committed to 12-hour dosing because it is key to

[134] Ryan *et al.*, *supra* note 131.

OxyContin's market dominance and comparatively high price. 12-hour dosing set OxyContin apart from its competitors and from less expensive, short-acting opioids.

194. The 12-hour dosing message was central to the conversations that Purdue sales representatives had directly with Illinois prescribers about OxyContin. [redacted]

195. In a 2004 letter to the FDA, Purdue acknowledged that it had not pursued approval to allow more frequent dosing in the label (*e.g.*, every 8 hours), and explained that "Purdue has always trained its sales force to promote q12h dosing only" because "[t]he 12 hour dosing schedule represents a significant competitive advantage of OxyContin over other products."[135]

196. Purdue's 12-hour dosing efficacy claims misrepresent the duration of pain relief from OxyContin and fuel the cycle of addiction with crashes and cravings. To fix a misleading marketing campaign, Purdue's solution was to make the drug more deadly by encouraging physicians to titrate doses up. Purdue had every opportunity to push appropriate dosing for OxyContin and chose not to do so, all to support its misleading claim that OxyContin was unique amongst opioids and therefore worth the price.

Purdue deceptively pushed prescribers to increase opioid doses

197. Because Purdue urged doctors to respond to evidence of addiction or the ineffectiveness of OxyContin's 12-hour dosing by increasing opioid dosage, it had to convince those doctors that the escalated doses were safe. It did so through deceptive marketing materials.

198. The ability to escalate doses was also critical to Purdue's efforts to market opioids for long-term use to treat chronic pain. Health care providers may not have chosen to initiate opioid

[135] April 14, 2004 Comments on Citizen Petition Docket #2004P-0043, at 12-13.

therapy at all if they did not feel comfortable prescribing increasingly higher doses of opioids to counter their patients' building of tolerance to the drugs' effects.

199. Purdue sponsored the American Pain Foundation's *Treatment Options: A Guide for People Living with Pain* (2007), which claims that some patients "need" a larger dose, regardless of the dose currently prescribed, and that opioids have "no ceiling dose."

200. Purdue also sponsored American Pain Foundation's *A Policymaker's Guide to Understanding Pain & Its Management*, which taught that dose escalations are "sometimes necessary," but did not disclose the risks from high-dose opioids.

201. Purdue sales representatives took the opportunity, when visiting with Illinois prescribers, to encourage increasing the doses of its opioids rather than prescribing them more frequently and to promote the lack of dose ceiling for its drugs, without disclosing the increased risk of addiction:

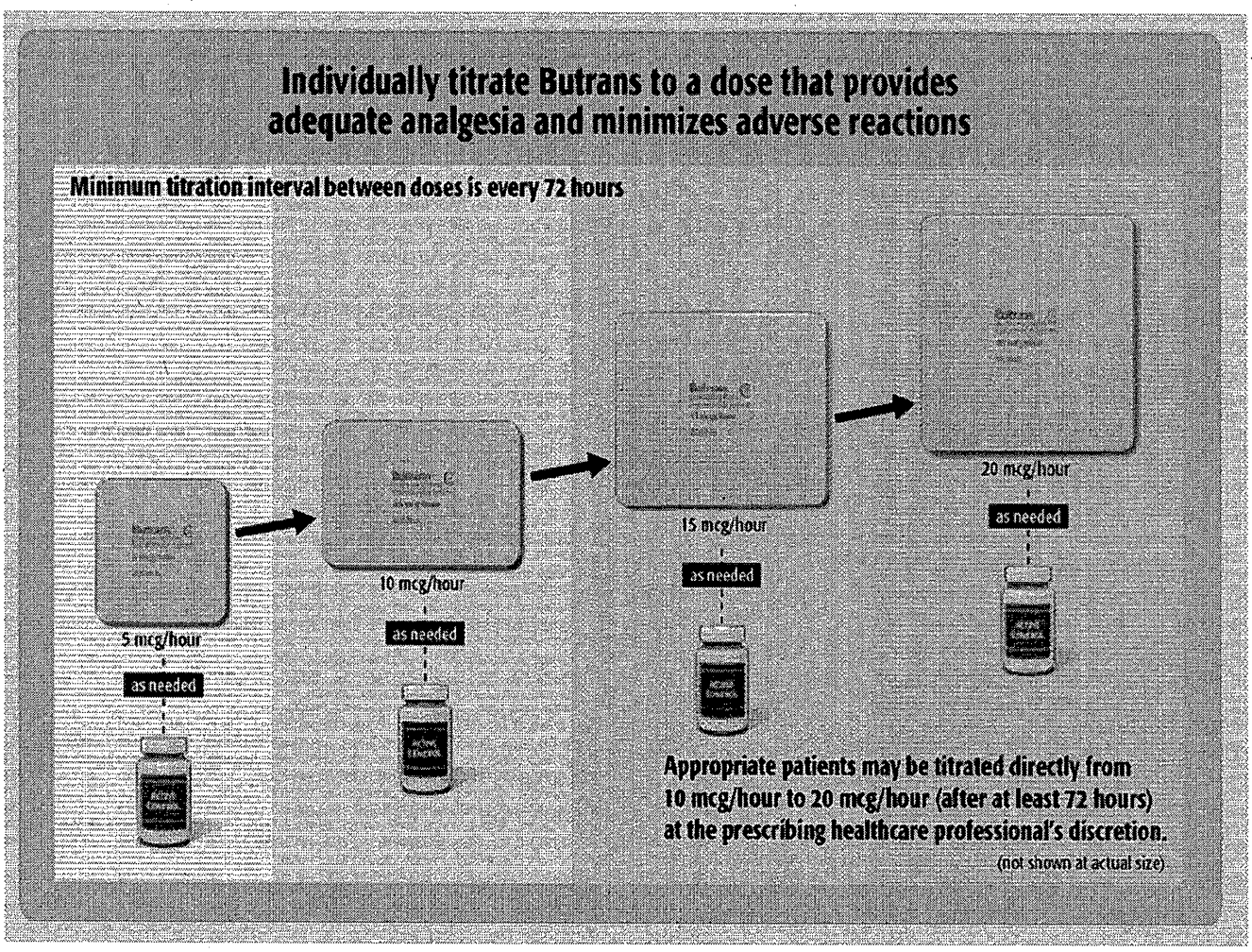
a. [redacted]

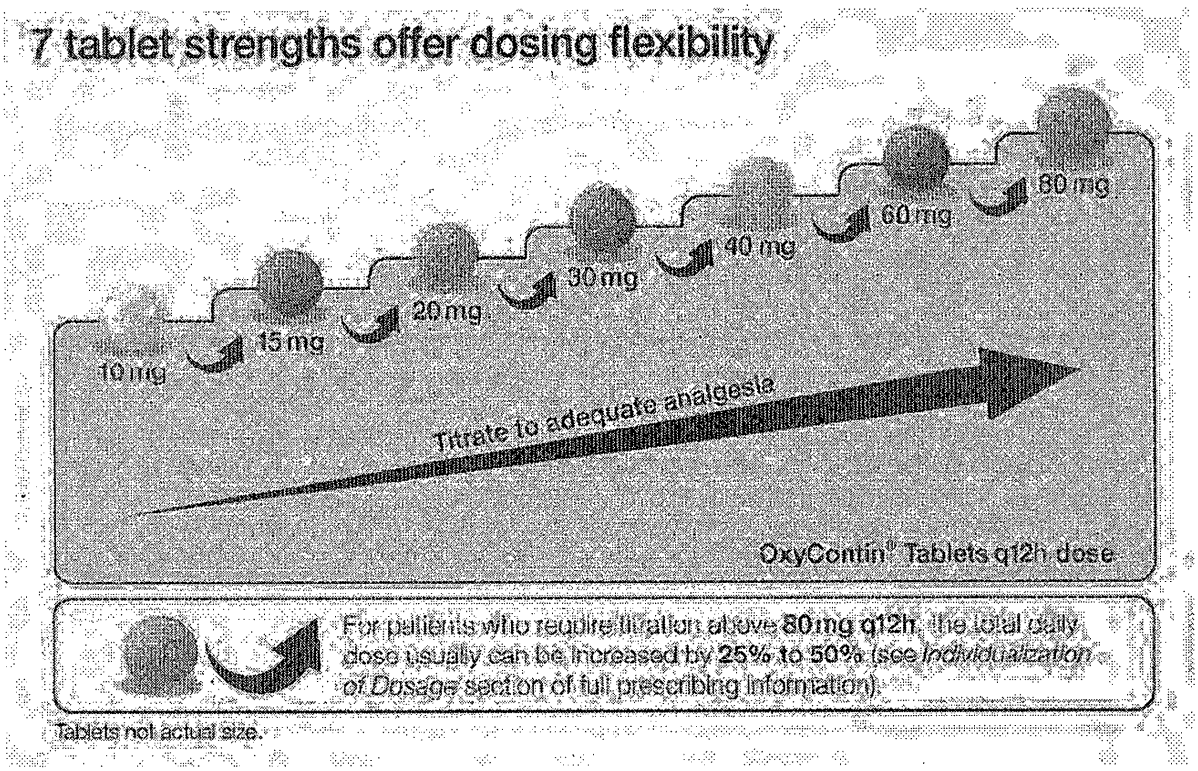
b. [redacted]

c. [redacted]

d. [redacted]

202. Purdue's visual aids prompt health care providers to titrate, or adjust, doses up, not down:





203. [redacted]

204. [redacted]

205. Purdue sales representatives were also instructed [redacted]

[redacted] By beginning sales pitches with the appropriate dose of branded opioids, Purdue sales representatives shifted the discussion from "should this patient be taking opioids chronically?" to "which Purdue opioid is easier for your patient to use long-term?"

206. In addition, Purdue strongly resisted tablet amount restrictions on OxyContin prescriptions. [redacted]

207. [redacted]

208. In reality and contrary to Purdue's claims, opioids are increasingly dangerous at higher doses. While 1 in every 550 patients on opioid treatment dies of opioid-related causes, that number increases to a staggering 1 in 32 for patients receiving 200 MMEs/day.[136]

209. In a national sample of Veterans Health Administration patients with chronic pain receiving opioids from 2004-2009, patients who died of opioid overdose were prescribed an average of 98 MME per day, while patients who did not were prescribed an average of 48 MME per day.[137]

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[136] Frieden, *supra* note 66.

[137] https://www.cdc.gov/drugoverdose/pdf/calculating_total_daily_dose-a.pdf (Last accessed March 22, 2019).

210. Overall, evidence has shown higher opioid dosages to be associated with increased risks of motor vehicle injury, opioid use disorder, and overdose, and that the increased risk rises in a dose-dependent manner.[138]

211. High dose opioids have continuously been a significant part of Purdue's business in Illinois—particularly for OxyContin. [redacted]

212. To put this in context, an OxyContin 40 mg tablet taken every 12 hours equates to 120 MMEs per day. 120 MMEs is 30 MMEs *over* the 90 MME daily threshold that the CDC states providers should avoid or carefully justify.

Purdue deceptively sought to keep patients on opioids for as long as possible

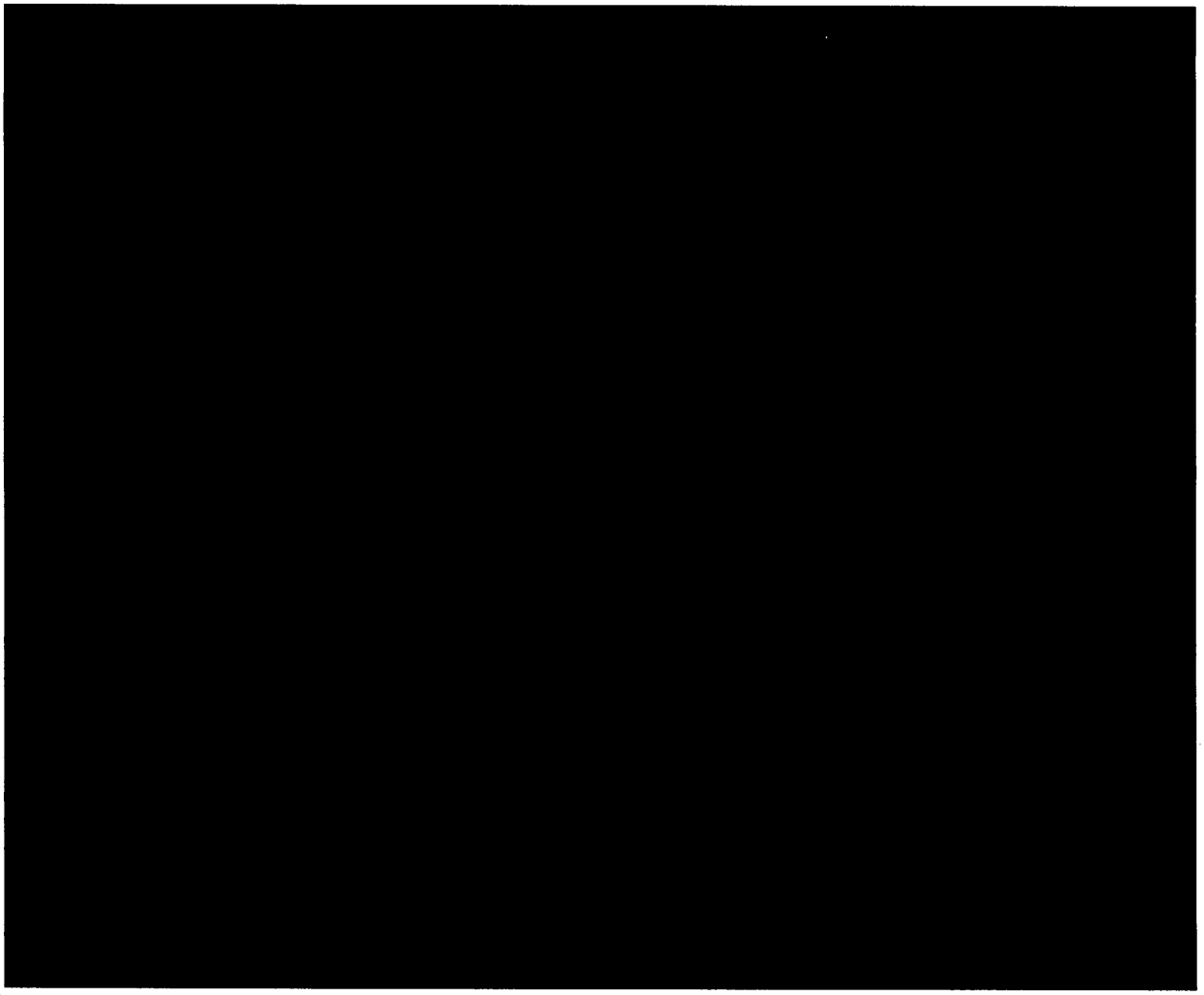
213. Purdue's misrepresentations regarding the risk of addiction, the signs of addiction, the ability of opioids to improve function and quality of life, and the safety of higher doses of opioids were all part of the bigger picture of keeping patients on Purdue's opioid products for longer and longer periods of time.

214. Purdue's marketing strategy and business model rely on the continuous, long-term use of its opioid products. [redacted]

215. Accordingly, Purdue instructed its sales representatives that one of their goals should be to [redacted]

216. [redacted]

[138] Dowell, *supra* note 28, at 22-24.



217. Purdue's "patient savings card" program was one method through which it was able to increase the number of long-term opioid users.

218. [redacted]

219. [redacted]

Purdue deceptively compared the risks and benefits of its products and those of competing opioids and alternative forms of pain treatment

220. As another element of its marketing plan, Purdue made deceptive and/or unsubstantiated claims that competing products were more dangerous than they actually were, less effective than they actually were, or that Purdue's products were equivalent to or superior to competing opioids and non-opioids.

221. Purdue cannot make comparisons between its drugs and other drugs or represent or suggest that Purdue's drug is safer or more effective than its competitor unless it has been demonstrated by substantial evidence or clinical trials. Yet Purdue's comparison claims were not supported by competent scientific evidence.

222. [redacted]

223. [redacted]

224. In spite of this, Purdue presented misleading comparisons between the risks and benefits of its extended-release opioid products and those of competing opioids and other non-opioid pain treatment methods.

225. [redacted]

[redacted]

226. However, Purdue sales representatives had been making those exact claims for years, and continued to do so, along with other misleading comparisons between Purdue's opioid products and those of competing extended-release and immediate-release opioids, as well as non-opioids, when conducting sales calls with Illinois prescribers.

Purdue's deceptive comparisons between its products and other opioids

227. Purdue made deceptive claims about its products as compared to other opioids, including that Purdue's opioid products were safer, more convenient for patients, and offered easier titration than competing opioids.

228. Purdue's internal documents trained its sales representatives to emphasize the convenience of Purdue's extended-release products when selling to prescribers. For instance, [redacted]

229. Purdue sales representatives deceptively made comparisons between Purdue's extended-release opioid products and immediate-release, or short-acting, opioid products, as well as competing extended-release opioids, when detailing Illinois doctors. For instance:

a. [redacted]

b. [redacted]

c.

d.

e.

f.

g.

h.

i. [redacted]

j. [redacted]

k. [redacted]

l. [redacted]

Purdue's deceptive comparison between its products and alternative forms of pain treatment

230. Purdue created and/or distributed several written materials to warn providers and managed care companies about the dangers of too much acetaminophen. One of these unbranded marketing pieced distributed by Purdue titled "Maximum Recommended Daily Doses of Opioid Analgesics Containing APAP (acetaminophen) or ASA (aspirin)" listed the maximum dosage of competing opioid products and therefore implied that high doses of OxyContin had no risk.

231. The Purdue sponsored American Pain Foundation's *Exit Wounds* (2009) emphasized "concern in the medical community about the growing rate of liver damage associated with large doses of acetaminophen." However, the pamphlet omits, for instance, warnings about potentially

fatal interactions between opioids and anti-anxiety medicines called benzodiazepines, commonly prescribed to veterans with post-traumatic stress disorder – the target audience for *Exit Wounds*.

232. Purdue sales representatives often highlighted the lack of acetaminophen in Purdue's extended-release opioid products when detailing Illinois prescribers:

a. [redacted]

b. [redacted]

233. Purdue also influenced and controlled marketing materials that inappropriately compared opioids to other non-opioid forms of treatment by omitting known risks of chronic opioid treatment and emphasizing or exaggerating risks of non-opioid products. These practices had the capacity to deceive prescribers and patients, who would then be more likely to choose opioids and would favor opioids over other therapies such as over-the-counter acetaminophen or over-the-counter or prescription NSAIDs.

234. Purdue sponsored the American Pain Foundation's *Treatment Options: A Guide for People Living with Pain* (2007), which claims that some opioids differ from NSAIDs in that they have "no ceiling dose as there is with the NSAIDs" and are therefore the most appropriate treatment for severe pain. *Treatment Options* attributed 10,000 to 20,000 deaths annually to NSAID overdose, when the true figure was closer to 3,200 at the time.[139] *Treatment Options* also warned that risks of NSAIDs increase if "taken for more than a period of months," but omitted any corresponding warning about the long-term risks of opioids.

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[139] Robert E. Tarone *et al.*, *Nonselective Nonaspirin Nonsteroidal Anti-Inflammatory Drugs and Gastrointestinal Bleeding: Relative and Absolute Risk Estimates from Recent Epidemiologic Studies,* 11 Am. J. of Therapeutics 17 (2004).

235. [redacted]

236. At Purdue's 2016 National Sales Meeting, [redacted]

237. This strategy is reflected in Purdue's sales representatives' interactions with Illinois prescribers. [redacted]

a. [redacted]

b. [redacted]

c. [redacted]

238. Purdue's campaign worked, and opioids replaced other, safer options in health care providers' pain treatment repertoires. For example, a study of 7.8 million doctor visits between 2000 and 2010 found that while prescriptions for NSAIDs and acetaminophen fell from 38% to

29%, opioid prescriptions increased from 11.3% to 19.6%, driven primarily by the decline in NSAID prescribing.[140]

Purdue targeted its deceptive claims at senior citizens

239. Purdue focused on marketing its opioids to the elderly.

240. [redacted]

Medicare is a government-run health insurance program available to seniors over the age of 65 and the disabled. Medicare Part D covers prescription drugs. [redacted]

241. Purdue misrepresented the safety of its opioid products in the elderly by emphasizing senior citizens as lower risk patients and omitting the material fact that there is a greater risk of respiratory depression from OxyContin and Butrans in elderly patients.

242. For instance, Purdue supported the American Geriatrics Society's 2009 Guidelines for the Pharmacological Management of Persistent Pain in Older Persons. The Guidelines misrepresented that the risk of addiction was "exceedingly low in older patients with no current or past history of substance abuse."

243. Purdue also targeted the above-described misrepresentations, including deceptive comparative and quality of life representations, specifically with regard to the treatment of senior citizens.

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[140] Matthew Daubresse *et al.*, *Ambulatory Diagnosis and Treatment of Non-Malignant Pain in the United States*, 2000-2010, 51 Med. Care 870 (2013). For back pain alone, the percentage of patients prescribed opioids increased from 19% to 29% between 1999 and 2010, even as the use of NSAIDS or acetaminophen declined from 39.9% to 24.5% of these visits; and referrals to physical therapy remained steady; *see also* John N. Mafi *et al.*, *Worsening Trends in the Management and Treatment of Back Pain,* 173 J. Am. Med. Ass'n Internal Med. 1573, 1573 (2013).

244. Purdue specifically targeted elderly patients and made these misrepresentations when directly marketing its drugs to Illinois prescribers. For instance:

a. [redacted]

b. [redacted]

c. [redacted]

d. [redacted]

e. [redacted]

f. [redacted]

245. In reality, elderly patients are at higher risk for the most dangerous side effect of opioids—respiratory depression. They also are likely to experience more severe consequences from falls (fractures and hospitalizations) caused by the cognitive impairment that is associated with opioid use. A 2010 paper reported that elderly patients who used opioids had a significantly higher rate of deaths, heart attacks, and strokes than users of NSAIDs.

Purdue Used Sophisticated Branded and Unbranded Marketing Targeted at Illinois Health Care Providers and Patients to Disseminate its Misleading Messages

246. Purdue pushed all of these deceptive messages in ways strategically designed to deceive health care providers and patients. Purdue sent its sales representatives to have one-on-one visits with health care providers to persuade them to prescribe more Purdue opioids. Purdue also authored and disseminated both its own branded materials, as well as unbranded materials from third-party groups that Purdue funded but which were designed to look independent.

247. [redacted]

248. [redacted]

Purdue engaged in deceptive in-person and direct marketing to Illinois health care providers and patients

249. Purdue marketed its brand-name opioids, such as OxyContin, MS Contin, Butrans, and Hysingla, directly to health care providers in Illinois through in-person visits from sales representatives, also known as "detailers."

250. [redacted]

251. Purdue's former Vice President for Marketing explained, in the context of marketing MS Contin, that,

> I know certainly the healthcare professionals I called on viewed us as a resource, as people that understood the product, understood its utilization. Understood the patient's types. *We were providing a lot of educational opportunities for prescribers, patient educational material, staff educational material.*
>
> *So we were viewed as [a] resource.* I don't know again specifically who or when someone might say, you are an expert. Certainly we were a resource and leaders in the market. And similar to other products that are leaders in market that have been involved with – you start to get viewed as a resource. And *someone they can look to for the information they need to make prescribing decisions.*

(Emphasis added.)

252. Purdue carefully trained its sales representatives to deliver company-approved messages designed to generate prescriptions of Purdue's drugs in particular and opioids in general. To ensure that sales representatives delivered the desired messages to prescribers, Purdue directed and monitored its sales representatives through detailed action plans, trainings, tests, scripts, role-plays, supervisor tag-alongs, and reviews of representatives' call notes from sales visits. Purdue likewise required its sales representatives to use sales aids reviewed, approved, and supplied by the company and forbade them from using promotional materials not approved by the company's marketing and compliance departments. Purdue further ensured marketing consistency nationwide through national and regional sales representative training.

253. [redacted]

254. In addition to "handling" the "objections" of health care providers who were not inclined to prescribe opioids, Purdue sought to become a "resource" for information to which health care providers looked in making prescribing decisions. They did so by delivering and discussing deceptive unbranded materials directly to Illinois prescribers to help "educate" them one-on-one. Purdue's call notes for Illinois prescribers include the following examples:

a. [redacted]

b. [redacted]

255. Purdue pursued a two-pronged strategy for targeting health care providers. Purdue targeted primary care physicians, physician assistants, and nurse practitioners, who were least likely to have the training and experience to evaluate Purdue's marketing claims. Purdue also promoted OxyContin, Butrans, and Hysingla to the highest opioid prescribers, who often worked at "pain clinics" and who accounted for an outsized portion of opioid prescriptions.

256. As the practice of medicine has changed, so too has Purdue's marketing strategy and efforts. As nurse practitioners and physician assistants became more active in prescribing opioids, Purdue shifted resources to follow them. As early as 2013, Purdue sought to identify key opinion leaders for these prescribers, expand its nurse educator program, and target marketing at them.

257. [redacted] Purdue responded by proposing increased marketing to nurses and physician assistants, including through peer-to-peer marketing, speaker programs, and targeted messages [redacted]

258. Purdue knew that its in-person marketing worked. The effect of sales calls on prescribing behavior are well-documented in the literature, including a 2009 study correlating the nearly ten-fold increase in OxyContin prescriptions between 1997 and 2002 to Purdue's doubling of its sales force and trebling of sales calls.[141]

259. Finally, both third-party materials and Purdue-branded educational resources containing deceptive information were targeted at patients. Purdue created and disseminated marketing materials directly to patients, such as patient brochures and branded public-facing websites like HysinglaER.com, encouraging consumers to seek out Purdue opioids from their health care providers.

260. Purdue also disseminated deceptive non-branded marketing materials directed toward patient consumers, such as the website *In The Face of Pain*, *Partners Against Pain* "Pain Management Kits," patient comfort assessment guides, and other resources guiding patients to use opioids.

[141] Art Van Zee, *The Promotion and Marketing of OxyContin: Commercial Triumph, Public Health Tragedy*, 99 Am. J. Pub. Health 221-227 (2009).

261. [redacted]

262. [redacted]

Illinois prescribers and their patients have been directly affected by Purdue's marketing

263. Purdue's marketing has been effective in changing the prescribing patterns of health care providers both nationally and in Illinois.

264. Purdue's misrepresentations encouraged health care providers to prescribe and patients to take increasing numbers of opioids for the treatment of chronic pain.

265. Purdue's sales representative trainings emphasized convincing prescribers to "convert" patients to Purdue's drugs, either from other opioid products or non-opioid drugs. [redacted]

266. [redacted]

Purdue therefore inserted its sales representatives directly into prescribers' decision-making process concerning the type and dose of opioid to prescribe.

267. [redacted]

142 [redacted]

[redacted]

268. Purdue's efforts in Illinois were rewarded with a substantial increase in opioid prescriptions during the same time period. [redacted]

269. The significant time and resources devoted to detailing prescribers in Illinois indicates that Purdue recognized the effectiveness of in-person marketing.

270. Purdue's significant influence on opioid prescribing habits is evident, by way of example, in the case of an Internal Medicine physician in Waukegan, Illinois. [redacted]

271. [redacted]

272. [redacted]

273. [redacted]

274. Purdue's efforts were fruitful. [redacted]

275. As a result of Purdue's aggressive tactics and the doctor's change in prescribing practices, this doctor started experiencing issues with patients showing signs of misuse. [redacted]

a. [redacted]

b. [redacted]

c. [redacted]

[redacted]

Despite these red flags, there is no indication that Purdue instructed its sales representatives to change or discontinue their detailing of this doctor.

276. On March 16, 2016, this doctor's Licensed Physician and Surgeon and Licensed Physician Controlled Substance licenses were placed on probation for failure to properly prescribe controlled substances. [redacted]

277. This is a clear example of Purdue's marketing strategy pushing to influence and, in fact, influencing prescribing activity, to the detriment of patients.

278. In addition, Purdue methodically tracks prescriptions and sales of its branded opioids in Illinois by prescriber, drug strength, pill quantity, days supplied and other factors. [redacted]

279. Using these granular sales data, Purdue undertook a business practice of aggressively marketing to top or "high decile" prescribers for Purdue branded opioids in Illinois. [redacted]

280. [redacted]

Purdue selectively supported and disseminated misleading materials from third-party groups

281. Purdue funded and disseminated materials from third-party groups, designed to look independent, which contained deceptive and misleading statements about opioids.

282. Promotion of opioids in general was important to Purdue's business plan and marketing strategy for several reasons.

283. First, by deceptively changing the medical community's and public's perception of opioids as a class of drugs, Purdue sought to change the perception of its own opioid products, which were part of that larger class. Although Purdue would not capture *all* the benefits of its investment in general opioid re-education, it would profit handsomely by increased prescriptions of its own brand-name drugs.

284. Second, once health care providers initially prescribed immediate-release opioids – often generics – to treat a patient's pain, Purdue sought to convince them to "convert" the patient from the generic immediate-release drug to one of Purdue's brand-name (and more expensive) extended-release drugs, such as OxyContin, Butrans, and Hysingla. [redacted]

285. Purdue has an active grant program supporting third-party organizations. [redacted]

a. [redacted]
b.
c.
d.

e. [redacted]
f.
g.
h.
i.
j.
k.
l.

286. Pharmaceutical companies, including Purdue, provided almost all of the funding for the American Pain Foundation, which provided publications to health care providers, patients, policymakers, and journalists.[143] The American Pain Foundation's materials contain misrepresentations about opioids.

287. [redacted]

288. In addition to selecting and funding third parties to conduct such campaigns, Purdue also incorporated apparently neutral entities in its direct marketing to Illinois prescribers.

289. In 2009, the American Academy of Pain Medicine and American Pain Society issued Clinical Guidelines (2009 APS Guidelines). These guidelines claimed that opioid treatment for chronic pain "can be an effective therapy for carefully selected and monitored patients with chronic noncancer pain." The guidelines cautioned, however, that to be safe and effective, such treatment required "clinical skills and knowledge in both the principles of opioid prescribing and

[143] Charles Ornstein & Tracy Weber, *The Champion of Painkillers,* ProPublica, Dec. 23, 2011, https://www.propublica.org/article/the-champion-of-painkillers (Last accessed March 28, 2019).

on the assessment and management of risks associated with opioid abuse, addiction, and diversion."[144]

290. Purdue incorporated and disseminated these guidelines without disclosing its contributions to both the American Academy of Pain Medicine and the American Pain Society. For example, Purdue's *Partners Against Pain*[145] website incorporated sections of a 2001 American Pain Society consensus statement about addiction to bolster Purdue's position that drug-seeking behavior in chronic pain patients should be interpreted as "pseudo addiction" rather than addiction.

291. In numerous instances, Purdue sales representatives referenced or discussed various iterations of the American Pain Society Guidelines or recommendations for opioid use during sales calls with Illinois prescribers.

292. [redacted]

293. [redacted]

[144] Roger Chou *et al.*, *Clinical Guidelines for Use of Chronic Opioid Therapy in Chronic Noncancer Pain,* 10 J. Pain 113 (2009). Of the 21 members of the APS panel, 6 disclosed payments from Purdue, and only 6 claimed no conflicts of interest. Dr. Russell Portenoy and Dr. Perry Fine were both on the panel.

[145] *Partners Against Pain* consists of both a website, styled as an "advocacy community" for better pain care, and medical education resources distributed to prescribers by Purdue's sales force.

294. Purdue funded and acted through these third-party groups because doctors were conditioned to trust them – more so than branded marketing material – when making prescribing decisions.

295. [redacted]

296. By using third-party materials and detailing visits to disseminate its messaging Purdue was able to exert significant, yet anonymous, influence over prescribers.

Purdue's Misconduct Stretches Back Two Decades and Continued Despite a Consent Judgment Regarding the Marketing of OxyContin

297. Purdue's marketing campaign to convince prescribers and patients that long-term opioid use would deliver better quality of life and functioning and that its risks could be safely managed is not new. Purdue's aggressive marketing extends back more than two decades. From the beginning, Purdue employed a wide variety of marketing strategies to accomplish its goal of recklessly increasing opioid sales.

298. In 1995, as Purdue prepared to launch OxyContin, it conducted market research and determined that the "biggest negative of [OxyContin] was the abuse potential." Beginning in 1995, Purdue employees set about marketing OxyContin as less addictive, less subject to abuse and diversion, and less likely to cause tolerance.[146] For example, Purdue created and maintained public-facing websites, such as "Partners Against Pain," as well as brochures and videotapes for patients in which Purdue asserted that the risk of addiction from OxyContin was small.[147]

[146] *United States v. Purdue Frederick Co., Inc.*, 495 F.Supp.2d 569, 571 (W.D. VA 2007); *United States vs. Purdue Frederick Co., Inc. et al.* Case 1:07-cr-00029-JPL, Dkt. 5-2, at 5-6.
[147] Van Zee, *supra* note 141.

299. From the beginning, much of Purdue's marketing was directed at prescribers. By 2000, Purdue had approximately 94,000 doctors on its physician call list.[148] Purdue also recruited and paid respected health care professionals as "speakers" who presented Purdue-approved programs to other prescribers at lunch and dinner events. From 1996 to 2001, Purdue held more than 40 national conferences and more than 5,000 physicians, pharmacists, and nurses attended these speaker conferences.[149] In addition to speaker programs, Purdue targeted doctors with "educational" programming and funded more than 20,000 pain-related educational programs through direct sponsorship or financial grants by July 2002.[150]

300. Purdue also paid for direct advertising to physicians in medical journals and distributed thousands of videos, many of which made the claim that addiction occurred in less than 1% of patients.[151] This claim came from a 1980 one-paragraph letter to the editor of the New England Journal of Medicine. It was not a study and did not support the assertion that addiction occurred in less than 1% of patients. Despite that, after Purdue began aggressively utilizing the letter as "evidence" that opioids were not addictive, citations to this article in medical literature exploded: the article was cited at least 608 times as of June 2017. More than 70% of these citations claimed that the letter was evidence that addiction was rare, 80% failed to note that the patients described in the letter were hospitalized when they received the opioid prescription, and some grossly misrepresented the letter's conclusions.[152]

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[148] *Id.*
[149] *Id.*
[150] *Id.*
[151] Purdue admitted it distributed 14,000 copies of *From One Pain Patient to Another: Advice from Patients Who Have Found Relief* for doctors to make available to patients, and 15,000 copies of *I Got My Life Back: Patients in Pain Tell Their Story.* Prescription Drugs: OxyContin Abuse and Diversion and Efforts to Address the Problem. Washington DC; General Accounting Office: December 2003 Publication GAO-04-110, 25-27.
[152] Pamela T.M. Leung *et al.*, Correspondence, *A 1980 Letter on the Risk of Opioid Addiction, 376 New Eng. J. Med. 2194 (2017).*

301. The impact of Purdue's efforts to disseminate this letter can be measured. The other eleven letters published contemporaneously were only cited a median number of eleven times.[153]

302. The marketing materials from the early 2000s had a long life. As illustrated by the longevity of the 1980 one-paragraph letter, misrepresentations that make it into scientific literature continue to be cited long after publication. Similarly, prescribers trained at Purdue Continuing Medical Education programs continue practicing. These early manipulations of prescribers provided fertile ground for Purdue's later, more nuanced misrepresentations like "pseudo addiction."

Purdue admitted its marketing conduct was unlawful in 2007 and promised to take corrective action

303. In 2007, The Purdue Fredrick Company and several Purdue Pharma executives entered a guilty plea to a criminal charge of misbranding and paid over $634 million in fines and sanctions related to the marketing campaign for OxyContin.[154]

304. At the same time, Illinois brought an action against Purdue related to the marketing campaign for OxyContin. The State alleged that Purdue aggressively promoted OxyContin as a first-line response to pain and a powerful and effective pain reliever,[155] while minimizing the risks of abuse, dependence, addiction, and diversion. Illinois further alleged that:

> Purdue could have used the prescribing data to readily identify potential sources of abuse and diversion…For years Purdue did not take those steps…Purdue sales representatives instead targeted the highest prescribers and encouraged them to prescribe more OxyContin, in larger doses, to more patients. Purdue's marketing practices thus exacerbate the abuse and diversion risks.[156]

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[153] *Id.*

[154] *United States vs. Purdue Frederick Co., Inc.*, 495 F.Supp.2d 569, 571 (W.D. VA 2007); *United States vs. Purdue Frederick Co., Inc. et al.* Case 1:07-cr-00029-JPL, Dkt. 5-2.

[155] *The People of the State of Illinois v. Purdue Pharma, L.P., et al.*, Cause No. 07CH 356, Complaint for Injunctive and Other Relief Under the Consumer Fraud and Deceptive Business Practices Act, at 1, filed May 8, 2007.

[156] *Id.* at 14.

305. Purdue entered into a Consent Judgment with Illinois in May 2007 to resolve these allegations. In that Consent Judgment Purdue agreed:

a. Not to market OxyContin with any claim that is false, misleading or deceptive;

b. Not to misrepresent the existence, non-existence, or findings of any medical or scientific evidence, including anecdotal evidence, relating to the off-label uses of OxyContin;

c. To establish, implement, and follow an OxyContin abuse and diversion detection program to internally report apparent patterns of excessive numbers of patients for a practice type, atypical patterns of prescribing techniques or locations, information that a health care professional or their patients are abusing or diverting medications, sudden unexplained changes in prescribing practices, disproportionate numbers of patients in a practice paying in cash, multiple allegations of overdose in a practice and to "take such further steps as may be appropriate based on the facts and circumstances"; and

d. To provide written, non-branded education information to all health care professionals related to detecting and preventing abuse and diversion of opioid analgesics.[157]

Despite its Promises of Reform, Purdue Continued its Unfair Practice of Marketing Opioids to, and Concealing from Oversight, Potentially Problematic Prescribers

306. Despite the numerous actions brought against Purdue for its deceptive marketing of OxyContin and its resulting obligations under the Consent Judgment, as described in detail above, Purdue continued to deceptively market OxyContin and its other opioid products.

307. Purdue also failed to appropriately monitor and report situations that gave rise to suspicion of abuse or diversion.

308. The 2007 Consent Judgment required Purdue, among other things, to:

establish, implement and follow an OxyContin abuse and diversion program consisting of internal procedures designed to identify potential abuse or diversion of OxyContin in certain settings (the "OxyContin Abuse and Diversion Detection Program"). The

[157] *The People of the State of Illinois v. Purdue Pharma, L.P. et al.*, Cause No. 07-CH 356, Consent Judgment, at 4-14, filed May 8, 2007.

> OxyContin Abuse and Diversion Detection Program will apply to Purdue employees and contract or third-party sales representatives, including Medical Liaisons, who contact practicing Health Care Professions in person or by telephone for the purpose of promoting OxyContin. That Program directs those persons to report to the Office of the General Counsel situations [suggestive of OxyContin abuse or diversion].[158]

309. The Consent Judgment set out a non-exhaustive list of examples of situations that raise an inference of abuse or diversion, and which needed to be reported by sales representatives and subsequently investigated. These situations include (a) excessive numbers of patients for the practice type, which could be indicated by long lines, "standing-room-only" capacity, and brief interactions between prescriber and patient; (b) "an atypical pattern of prescribing techniques or locations"; (c) credible information "that a [h]ealth [c]are [p]rofessional or their patients are abusing or diverting medications"; (d) unexplained and unjustified changes in prescribing or dispensing patterns; (e) a disproportionate number of patients paying for office visits or medications with cash; (f) "multiple allegations that individuals from a particular practice have overdosed"; or (g) "unauthorized individuals signing prescriptions or dispensing controlled substances."[159]

310. When the OxyContin Abuse and Diversion Detection (ADD) Program turned up information suggesting abuse or diversion, Purdue promised to:

> conduct an internal inquiry which will include but not be limited to a review of the [h]ealth [c]are [p]rofessional's prescribing history . . . and shall take such further steps as may be appropriate based on the facts and circumstances, which may include ceasing to promote Purdue products to the particular [h]ealth [c]are [p]rofessional, providing further education to the [h]ealth [c]are [p]rofessional about appropriate use of opioids, or providing notice of such potential abuse or diversion to appropriate medical, regulatory or law enforcement authorities.[160]

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[158] *Id.* at 8.
[159] *Id.* at 8-9.
[160] *Id.* at 9.

311. Even apart from the Consent Judgment, Purdue had an obligation to monitor and report suspicious conduct to the federal Drug Enforcement Administration ("DEA"). See 21 U.S.C. § 823(e); 21 C.F.R. 1301.74(b).[161]

312. However, despite Purdue's promise to reform pursuant to the terms of the Consent Decree, Purdue often failed to (a) detect or investigate potential abuse or diversion, and (b) take appropriate action to stop it.

313. For example, in the 10 years following entry of the Consent Judgment, the Consumer Protection Division of the Attorney General's Office has been unable to find evidence of a single instance in which Purdue provided notice of potential diversion or abuse to Illinois State authorities such as the Illinois Attorney General's Office.

314. Although Purdue was selling and marketing drugs that are highly addictive and for which diversion is a known problem, Purdue failed to investigate and take action in instances that reasonably would raise an inference of abuse or diversion – in other words, where it had information that its product was likely harming the public health. The following are instances where Purdue unfairly continued to market to opioid prescribers, offered by way of example only.

[redacted]

315. Purdue targeted [redacted], an orthopedic surgeon with practices in Arlington Heights, Illinois and Chicago, Illinois, with marketing including the following:

a. [redacted]

b. [redacted]

c. [redacted]

[161] For the avoidance of confusion, the State does not allege a cause of action under these or other federal laws.

d. [redacted]

e. [redacted]

316. [redacted]

a. [redacted]

b. [redacted]

c. [redacted]

317. [redacted]

318. [redacted]

a. [redacted]

b. [redacted]

c. [redacted]

d. [redacted]

e. [redacted]

f. [redacted]

g. [redacted]

319. [redacted]

[redacted]

a. [redacted]

b. [redacted]

c. [redacted]

d. [redacted]

e. [redacted]

f. [redacted]

g. [redacted]

h. [redacted]

These were triggers specifically identified in the Consent Judgment as requiring investigation and potential action.

320. [redacted]

321. [redacted]

a. [redacted]

b. [redacted]

c. [redacted]

322. [redacted]

323. Purdue's efforts to detail [redacted] were also fruitful for the company. [redacted]

324. In January of 2015, the State of Illinois Department of Financial and Professional Regulation ("IDFPR") reprimanded [redacted] and fined him $5,000 for failing to document the issuance of several prescriptions for controlled substances. [redacted]

325. Purdue targeted [redacted] a neurologist in Effingham, Illinois, with marketing including the following:

a. [redacted]

b. [redacted]

c. [redacted]

326. [redacted]

327. Purdue's efforts to detail [redacted] were fruitful for the company. [redacted]

328. Several of the recorded interactions with Purdue sales representatives should have alerted Purdue to a potential issue with [redacted] prescribing practices for opioids. For example:

a. [redacted]

b. [redacted]

c. [redacted]

Purdue did not discontinue sales calls or report [redacted] based on these interactions.

329. On March 26, 2014, federal law enforcement officials arrested [redacted] on a fifteen-count indictment, including ten counts of illegal distribution of Schedule II controlled substances like oxycodone, hydromorphone, and methadone.

330. [redacted] Physician and Surgeon and Physician Controlled Substance licenses were both suspended on June 6, 2014, after he surrendered his DEA registration for failing to comply with federal requirements pertaining to controlled substances.

331. As part of the federal criminal case against him, evidence was presented that a review of [redacted] patient files revealed that:

a. [redacted] routinely prescribed addictive opioids to patients who had a history of drug addiction and who were known to be simultaneously obtaining various prescriptions for controlled substances from multiple sources or providers;

b. [redacted] prescribed early refills up to several weeks before the refills were due to patients who repeatedly claimed that their medications had run out or were stolen;

c. [redacted] patients had irregular toxicology screens; and

d. [redacted] office received phone calls reporting that patients were actively abusing drugs.

332. [redacted] was found guilty on January 27, 2015 of seven counts of illegally dispensing Schedule II Controlled Substances to patients who suffered from drug addiction, and he was sentenced on November 5, 2015 to two years in federal prison.

[redacted]

333. Purdue targeted [redacted], a family medicine physician who practiced in Moline, Illinois, with marketing and sales calls.

334. [redacted]

335. [redacted]

a. [redacted]

b. [redacted]

336. [redacted]

a. [redacted]

b. [redacted]

c. [redacted]

d. [redacted]

e. [redacted]

337. [redacted]

a. [redacted]

b. [redacted]

c. [redacted]

d. [redacted]

338. [redacted]

a. [redacted]

b. [redacted]

c. [redacted]

d. [redacted]

339. The Illinois Department of Financial and Professional Regulation's Division of Professional Regulation issued a Notice of Preliminary Hearing and Complaint against [redacted] in August 2013. In the first of three counts, IDFPR alleged that between 2008 and 2011, [redacted] prescribed opioids to a patient identified as "H.K." and failed to properly assess H.K. for signs and symptoms of drug abuse and drug dependence. It also alleged that in May 2010, H.K. was self-injecting medications prescribed by [redacted], injecting his pregnant girlfriend with the medications, and selling the medications to local drug users, three of whom died.

340. [redacted]

341. As described above, Purdue had a responsibility under the law and the 2007 Consent Judgment to monitor prescribers and identify instances of possible abuse, diversion, or

inappropriate prescribing, as well as a responsibility to take appropriate steps to address those problems. It did not do so.

342. Even when Purdue recognized a problem so serious that it decided to stop detailing a doctor, it reported very few of those people to authorities. Purdue executives have confirmed that the company notified authorities about only eight percent of the doctors that it decided to stop detailing.

343. To make matters worse, when Purdue decided to notify authorities about a problematic prescriber, it did not always do so promptly. Years could pass between Purdue's decision to stop detailing a doctor and reporting of the doctor's suspicious conduct.

344. The consequences of Purdue's unfair and unreasonable reporting failures were profitable to the company and devastating for communities. Purdue allowed prescribers of great concern to continue to prescribe massive amounts of high-potency Purdue opioids long after the company concluded it would be inappropriate to send sales representatives to encourage them to sell even more Purdue drugs.

Opioids Have Severely Impacted Illinois

345. Like the rest of the country, Illinois is in the midst of an unprecedented opioid epidemic.

346. Opioid use, morbidity, and mortality have increased exponentially in the State of Illinois in the years since Purdue first began aggressively marketing opioids for long-term use. The total number of opioid prescriptions filled in Illinois increased by 25%, or nearly 2 million prescriptions, from 2008 to when it peaked in 2014.

347. Even as prescription rates have declined in recent years, the large number of opioid sales in Illinois continue to pose grave concerns. For example, in 2017, 2,386,820 Illinois patients received a total of 5,307,583 prescriptions, with an average supply of ninety-eight days of the

medication. In the first quarter of 2017 alone, almost 1.5 million opioid prescriptions were written in Illinois; that is approximately one prescription per eight and a half residents, or more than ten percent of the state's population.

348. Opioid-related overdose deaths in Illinois have increased proportionately with national rates. From 1999 to 2016, the rate increased from 3.9 to 15.3 deaths per 100,000 persons—equivalent to approximately 483 and 1,947 annual deaths statewide.[162]

349. Overdose deaths – specifically opioid overdose – have overtaken those causes that have traditionally had the highest rates of accidental death. In 2016, opioid-related overdoses claimed the lives of 1,946 Illinoisans. This is more than one and a half times the number of homicides and nearly twice the number of fatal car accidents.[163] The number of deaths then rose to 2,202 in 2017.

350. The 2,202 opioid overdose fatalities in 2017 represented a more than 100% increase since 2013.[164]

351. Opioid overdoses are a statewide problem affecting urban, suburban, and rural communities.

352. The scope of human suffering and economic cost of opioids on Illinois reverberates far beyond overdose mortality rate. The State spends significant public resources on medical services, law enforcement, corrections, worker's compensation, diversion programs, prosecution, probation, treatment, and child welfare.

353. Between Q1 2014 and Q3 2016, statewide hospitalization rates for all opioid overdoses increased 42%, opioid analgesic overdoses increased 45% and heroin overdoses increased

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[162] National Institute on Drug Abuse Illinois Opioid Summary, available at: https://www.drugabuse.gov/drugs-abuse/opioids/opioid-summaries-by-state/illinois-opioid-summary (Last accessed March 29, 2019).
[163] State of Illinois Comprehensive Opioid Data Report, *supra* note 37, at p. 3.
[164] Illinois Department of Public Health Opioid Data Dashboard, available at: https://idph.illinois.gov/OpioidDataDashboard/ (Last accessed March 22, 2019).

39%.[165] These numbers continue to rise at alarming rates, with the number of emergency department visits for suspected opioid overdoses increasing by 66% in Illinois between July 2016 and September 2017.[166]

354. Emergency medical service (EMS) providers are often the first responders on the scene of an opioid overdose. Under the Heroin Crisis Act, all EMS vehicles in Illinois must be equipped with naloxone, a drug that can quickly reverse an opioid overdose. 9,272 EMS naloxone administrations were reported to the Illinois Department of Public Health for 2015, a 32.6% increase over 2013. Further, in large part due to the presence of fentanyl and other synthetic opioids in substances being used, the number of EMS runs that required two administrations of naloxone increased by over 50% from 2013-2015, and the number of runs requiring three administrations increased over 75%.[167]

355. In 2017, Chicago Fire Department crews were dispatched to 9,158 opioid-related overdoses, with over 1,250 of those calls coming from just a four-block area on the city's West Side.[168] Local residents battle to keep the drug dealers away, but they are ever-present, even known to regularly host "serves" in a nearby alley, providing free samples to users.[169] The drug trade is so rampant that drug users will line up and wait outside in broad daylight to get into a building where heroin dealers operate.[170]

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[165] State of Illinois Comprehensive Opioid Data Report, *supra* note 37, at p. 12.
[166] Emergency Department Data Show Rapid Increases in Opioid Overdoses, CDC Press Release, Mar. 6, 2018, available at: https://www.cdc.gov/media/releases/2018/p0306-vs-opioids-overdoses.html (Last accessed March 29, 2019).
[167] State of Illinois, The Opioid Crisis in Illinois Data and the State's Response, *supra* note 47, at p. 3.
[168] Ali, Tanveer and Sam Charles, "A 4-block radius on the West Side is at the heart of Chicago's opioid epidemic," May 25, 2018, available at: https://chicago.suntimes.com/news/opioids-heroin-fentanyl-west-side-data/ (Last accessed March 29, 2019).
[169] *Id.*
[170] "West Side Drug Dealer Had Customers Lined Up Around Corner: Feds," June 25, 2015, available at: https://www.nbcchicago.com/news/local/West-Side-Drug-Dealer-Had-Customers-Lined-Up-Around-Corner-309764301.html (Last accessed March 29, 2019)

356. 19,289, or nearly 30%, of publicly-funded drug treatment admissions in Illinois in 2015 were for persons who indicated opioids as their primary substance of abuse.[171]

357. In 2016, 2,241 Illinois prisoners indicated opioids as their primary substance of misuse. In 2017, nine Illinois drug and mental health courts reported one-third of their participants had an opioid use-related diagnosis.[172]

358. Deceptive and unfair marketing of opioids by Purdue also has a significant detrimental impact on children in Illinois. In 2013-2014, 40,000 teens per year in Illinois reported non-medical use of prescriptions opioids.[173] Adolescent misuse of prescription opioids is very important, because it is the peak period in life when people first misuse opioids. The adolescent brain is still maturing and particularly susceptible to opioids. Even if opioid use does not lead to addiction or overdose deaths in youth and adolescents, research demonstrates the profound impacts of opioids on the developing brain. The overprescribing of opioids for chronic pain has given young children access to opioids, nearly all of which were prescribed for adults in their household or to the children by dentists.

359. Even infants have not been immune to the impact of opioid abuse and over-prescription. There has been a dramatic increase in the number of infants who are born addicted to opioids due to prenatal exposure and suffer from neonatal abstinence syndrome (NAS), which can occur in an infant exposed in utero to addictive, illegal or prescription drugs.

360. In 2016 alone, nearly 400 babies were born in Illinois suffering from NAS.[174]

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[171] State of Illinois, The Opioid Crisis in Illinois Data and the State's Response, supra note 47, at p. 8.
[172] Reichert, *supra* note 39, at p. 3.
[173] State of Illinois Opioid Action Plan, September 2017, at p. 17, available at: http://dph.illinois.gov/sites/default/files/publications/Illinois-Opioid-Action-Plan-Sept-6-2017-FINAL.pdf (Last accessed March 29, 2019).
[174] Neonatal Abstinence Syndrome, Illinois Department of Public Health, available at: http://www.dph.illinois.gov/topics-services/prevention-wellness/prescription-opioids-and-heroin/neonatal-abstinence-syndrome (Last accessed April 1, 2019).

361. There are substantial costs associated with these births, and the syndrome is particularly prevalent in infants covered by public insurance and who are uninsured. Babies born with NAS may experience a variety of withdrawal symptoms, medical complications and have prolonged hospital stays. In Illinois, in 2016, the median length of hospital stay after birth was eleven days longer for infants with NAS, compared to those without. The median hospital charges for infants with NAS were more than seven times higher than for infants without NAS, with the total charges for hospital care for infants born with NAS being nearly $18 million higher than what would have been expected if they had been born without NAS.[175]

362. Opioid use has had a significant impact on the nation's child welfare system, as parental substance abuse is a major risk factor for child fatalities, child maltreatment, and involvement with the child welfare system. In 2016, the number of new foster care cases involving parents who are using drugs hit the highest point in more than three decades,[176] a trend undoubtedly affecting Illinois' child welfare system.

363. The impacts of opioids on Illinois are inextricably linked with Purdue's marketing campaign designed to convince prescribers, patients, and the public that opioids were a drug that could be used long-term and at high doses with little risk of addiction or serious complications.

364. Despite evidence of the widespread impact opioids were having on Illinois and across the nation, Purdue carefully packaged and targeted its messages to convince prescribers that the risks of addiction were overstated and could be managed. Purdue knew its products were dangerous and were causing harm, yet it continued to massively push its product into more and more consumers' hands.

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[175] *Id.*

[176] Associated Press, "Opioid crisis straining foster systems as kids pried from homes," Dec. 12, 2017, available at: https://www.nbcnews.com/storyline/americas-heroin-epidemic/opioid-crisis-strains-foster-system-kids-pried-homes-n828831 (Last accessed March 29, 2019).

365. As a result of Purdue's efforts, opioid use has grown to epidemic proportions and the death rates, including in Illinois, continue to rise while Purdue continues to market and sell drugs that it knows are deadly.

366. The Attorney General asks this Court to stop Purdue's deceptive marketing and order legal and equitable remedies to begin addressing the opioid epidemic in our state.

APPLICABLE STATUTES

367. Section 2 of the Consumer Fraud Act provides:

> Unfair methods of competition and unfair or deceptive acts or practices, including but not limited to the use or employment of any deception fraud, false pretense, false promise, misrepresentation or the concealment, suppression or omission of any material fact, with intent that others rely upon the concealment, suppression or omission of such material fact, or the use or employment of any practice described in Section 2 of the "Uniform Deceptive Trade Practices Act", approved August 5, 1965, in the conduct of any trade or commerce are hereby declared unlawful whether any person has in fact been misled, deceived or damaged thereby. In construing this section consideration shall be given to the interpretations of the Federal Trade Commission and the federal courts relating to Section 5 (a) of the Federal Trade Commission Act

FIRST CAUSE OF ACTION

VIOLATIONS OF THE ILLINOIS CONSUMER FRAUD AND DECEPTIVE BUSINESS PRACTICES ACT, 815 ILCS 505/1-1, et seq.

368. The State incorporates Paragraphs 1 through 367 herein as if set forth in their entirety.

369. While engaged in trade or commerce, Purdue committed the following unfair and/or deceptive acts or practices declared unlawful under Section 2 of the Consumer Fraud Act, 815 ILCS 505/2:

a. Making misrepresentations and unsubstantiated claims, with the intent that prescribers and patients rely on those misrepresentations, about the risk of opioid addiction;

b. Making misrepresentations and unsubstantiated claims, with the intent that prescribers and patients rely on those misrepresentations, about the extent to which addiction risk can be managed and addiction prevented;

c. Making misrepresentations and unsubstantiated claims, with the intent that prescribers and patients rely on those misrepresentations, about the ability of abuse-deterrent formulations of Purdue's drugs to lower opioid abuse and addiction risk;

d. Misrepresenting, with the intent that prescribers and patients rely on its misrepresentations, the true risk of addiction of Purdue's drugs by deceptively using the terms addiction, dependence, tolerance, physical dependence, and "pseudo addiction";

e. Misrepresenting, with the intent that prescribers and patients rely on those misrepresentations, the symptoms of withdrawal, the challenges entailed in managing those symptoms, and the likelihood or ease with which patients could stop using opioids;

f. Making misrepresentations and unsubstantiated claims, with the intent that prescribers and patients rely on those misrepresentations, about opioids' generally and Purdue's products' ability to improve function and quality of life long-term;

g. Misrepresenting, with the intent that prescribers and patients rely on those misrepresentations, the duration of pain relief from OxyContin;

h. Making misrepresentations and unsubstantiated claims, with the intent that prescribers and patients rely on those misrepresentations, that increased doses of opioids do not pose significant health risks;

i. Making misrepresentations and unsubstantiated claims, with the intent that prescribers and patients rely on those misrepresentations, regarding the risks and benefits of its opioid products compared to those of other opioid products and alternative forms of pain treatment;

j. Making misrepresentations and unsubstantiated claims, with the intent that prescribers and patients rely on those misrepresentations, about the risks of opioid use by the elderly;

k. Unfairly using a marketing and sales scheme intended to overcome prescriber and patient concerns regarding opioid addiction, contrary to the public policy of combating opioid drug abuse;

l. Unfairly using a marketing and sales scheme intended to keep patients using its dangerous drugs for as long as possible, contrary to the public policy of combating opioid drug abuse;

m. Unfairly using a marketing and sales scheme intended to increase the doses of its dangerous drugs taken by patients, contrary to the public policy of combating opioid drug abuse;

n. Unfairly influencing health care providers' prescription decisions for particular patients in sales calls for which the patient was not present;

o. Unfairly targeting and encouraging health care providers with high rates of opioid prescription through in-person detailing, dissemination of educational materials and programs, and third-party materials containing misleading statements about the efficacy and risks of opioids. This targeted marketing sought to cause high volume prescribers to continue prescribing at those rates and encouraging additional prescriptions despite observing indications that the health care provider was not meeting the standard of care, and/or that opioids were being diverted or abused, thereby harming the public health;

p. Unfairly failing to report and/or concealing from relevant law enforcement and medical regulators and/or otherwise taking appropriate action in response to suspicious, excessive, and illegal opioid prescribing practices, while profiting from inflated prescriptions of OxyContin and other Purdue-branded opioids; and

q. Unfairly targeting the vulnerable populations of senior citizens and veterans for the sale of its dangerous products.

370. Purdue also specifically targeted its unfair and deceptive conduct toward senior citizens in Illinois.

SECOND CAUSE OF ACTION

PUBLIC NUISANCE

371. The State incorporates Paragraphs 1 through 370 above as if set forth in their entirety.

372. A public nuisance is something that negatively affects the public's health, safety, or morals, or causes substantial annoyance, inconvenience, or injury to the public.

373. Illinois residents have a public right to health, safety, peace, and comfort. Those rights are a matter of great interest and of legitimate concern to the State, which has a duty to protect the health, safety, and well-being of its residents. The Attorney General has the power and authority to bring suit to abate a public nuisance.

374. Purdue is required to abide by the Illinois Controlled Substance Act, in which the Illinois General Assembly specifically recognized, "the rising incidence in the abuse of drugs and other dangerous substances and its resultant damage to the peace, health, and welfare of the citizens of Illinois." 720 ILCS 570/100.

375. Purdue also has a duty under the Consumer Fraud Act to refrain from disseminating deceptive or misleading promotional material, a duty under the Consumer Fraud Act to disclose material facts, and a duty under the 2007 Consent Judgment to effectively establish, implement, and follow an abuse and diversion detection program. Purdue violated these duties.

376. As described in detail above, Purdue's deceptive and misleading marketing practices substantially and unreasonably interfered with the public rights to health, safety, comfort, and peace. For example, as a result of Purdue's conduct:

a. Opioid use, abuse, and overdose deaths have significantly increased throughout Illinois;

b. Buildings and public spaces have attracted drug dealers and addicts, rendering them and the surrounding private property less safe or unsafe. In addition, family medicine cabinets became outlets for diversion and abuse due to overprescribing, and the foreseeable failure to safely dispose of opioids;

c. The greater demand for emergency services, law enforcement, addiction treatment, and social services has placed an unreasonable burden on State and local resources;

d. Expanding the market for prescription opioids to primary care patients and chronic conditions has created an abundance of drugs available for criminal use and fueled a wave of addiction, abuse, and injury;

e. Additional illicit markets in other opiates have been created, particularly for heroin. Many users who were initially dependent on prescription opioids and then were unable to obtain or afford prescription opioids turned to heroin as an alternative, fueling a new heroin epidemic in the process;

f. Health care costs have increased for individuals, families, and the State; and

g. Health care providers who were profitable to Purdue but harmful to the public continued prescribing increasing numbers of opioids throughout the State in light of Purdue's failure to report suspicions of illicit prescribing to the State or law enforcement.

377. Purdue controlled and controls the "instrumentality" of the nuisance – its marketing of opioid medications, including the deceptive and misleading representations regarding particular opioid medications, and the deceptive and misleading marketing schemes Purdue used to disseminate messages about opioids in general, and failing to appropriately monitor and report the potential abuse and diversion of opioids.

378. Purdue's deceptive and unfair conduct was a direct and proximate cause of opioids becoming widely available, used, and all too often abused. Purdue's actions proximately caused prescribers' and patients' inability to assess and weigh the risks and benefits of opioids, resulting in pervasive overprescribing and abuse of these drugs. No third party broke the causal chain between Purdue's wrongful conduct and the resulting harm.

379. But for Purdue's 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. Purdue's actions have harmed and will continue to harm many residents throughout Illinois, including opioid users, their families, and their communities at large.

380. The intent of Purdue's promotion of extended-release opioids – and opioids generally – was to sell more of them. Purdue intended for health care providers to prescribe more opioids, for patients to fill those prescriptions, and then for people to continue filling opioid prescriptions, often at higher and higher doses.

381. The public nuisance and associated financial and economic losses resulting from Purdue's deceptive and unfair conduct were foreseeable to Purdue, which knew or should have known that its conduct would create a public health crisis. As alleged herein, Purdue engaged in

widespread deceptive and unfair promotion of opioids despite knowing that opioids carried serious risks of addiction, injury, overdose, and death. In addition to being unlawful, Purdue's conduct was also unreasonable and negligent in light of the lack of scientific support for Purdue's claims, and reckless and/or intentional in light of the known risks associated with opioids.

382. A reasonable pharmaceutical manufacturer in Purdue's position would have foreseen not only a vastly expanded market for opioids, but also the related likely and foreseeable result of Purdue's conduct – the widespread problems of opioid addiction and abuse. In fact, Purdue was on notice and aware of signs that health care providers were prescribing unreasonably higher numbers of opioids and that the broader use of opioids was causing just the kinds of injuries described in this Complaint, but it continued to make deceptive and misleading statements to promote opioids.

383. Purdue's deceptive business practices ultimately generated a new and very profitable circular market – providing both the supply of narcotics to prescribe and sell, as well as causing addiction which fueled the demand of users to buy more.

384. The injuries resulting from Purdue's deceptive and unfair conduct described above are severe, including opioid addiction, overdose, and death, as well as increased health care costs and loss of productivity. The State has suffered special injuries different from the general public, including the substantial costs associated with the investigation, monitoring, treatment, policing, and other remediation of the opioid epidemic.

385. Purdue acted without express authority of a statute or law when it engaged in the deceptive and unfair practices described herein.

386. Purdue's conduct was not insubstantial or fleeting; to the contrary, Purdue substantially and unreasonably interfered with public rights, and proximately caused and continues to cause significant injury to the public. Purdue's wrongful conduct is ongoing and persistent, and continues to cause tremendous injury to the public and the State to incur significant costs.

387. The public nuisance – i.e., the opioid epidemic – created, maintained, and perpetuated by Purdue can be abated, and further recurrence of such harm and inconvenience can be abated, by (a) ceasing any further marketing of Purdue's opioid products; (b) ceasing the further dissemination of any misleading information about opioids in general; (c) educating prescribers (especially primary care physicians, nurse practitioners, physician assistants and the most prolific prescribers of opioids) and patients regarding the true risks and benefits of opioids, including the risk of addiction; (d) educating young people in particular about the risks of addiction; (e) educating women in particular about the risks of opioid use during pregnancy, including neonatal abstinence syndrome; (f) creating a publicly-accessible repository for independent, peer-reviewed studies on the risks and benefits of opioids; (g) providing and expanding access to addiction treatment to patients who are already addicted to opioids; and (h) making overdose reversal drugs widely available so that overdoses are less frequently fatal, among other measures.

388. The State seeks an order that provides for abatement of the public nuisance Purdue has created, enjoins Purdue from further deceptive and unfair conduct, and awards the State the costs associated with abatement of the nuisance and harm to the State in an amount to be determined at trial.

PRAYER FOR RELIEF

Wherefore, the State prays for the following relief:

A. Finding that Defendants violated Section 2 of the Consumer Fraud Act, 815 ILCS 505/2,

by engaging in unlawful acts and practices including, but not limited to, the unlawful acts and practices alleged herein;

B. Permanently enjoining the Defendants from engaging in the unfair and/or deceptive acts or practices described herein;

C. Ordering Defendants to pay a civil penalty of $50,000 per deceptive or unfair act or practice, and an additional amount of $50,000 for each act or practice found to have been committed with the intent to defraud, all as provided in Section 7 of the Consumer Fraud Act, 815 ILCS 505/7;

D. Assessing an additional civil penalty in the amount of $10,000 per violation found by the Court to have been committed by the Defendants against a person 65 years of age and older as provided in Section 7(c) of the Consumer Fraud Act, 815 ILCS 505/7(c);

E. Disgorging all revenues, profits, and gains achieved in whole or in part through the deceptive and unfair acts or practices complained of herein;

F. Requiring full restitution be made to consumers who were harmed by Defendants' deceptive and unfair acts or practices;

G. Requiring the Defendants to pay all costs for the prosecution and investigation of this action, as provided by Section 10 of the Consumer Fraud Act, 815 ILCS 505/10;

H. An order requiring Defendants to abate the public nuisance that they created and compensate the State for costs associated with its abatement efforts; and

I. Providing such other and further relief as justice and equity may require.

THE PEOPLE OF THE STATE OF ILLINOIS, by KWAME RAOUL ATTORNEY GENERAL OF ILLINOIS

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