STATE OF VERMONT

SUPERIOR COURT
CHITTENDEN UNIT

CIVIL DIVISION
DOCKET NO. 757-9-18

STATE OF VERMONT,

Plaintiff,

v.

PURDUE PHARMA L.P., PURDUE PHARMA INC., and THE PURDUE FREDERICK COMPANY,

Defendants.



**COMPLAINT**

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# COMPLAINT

The Vermont Attorney General brings this suit against Purdue Pharma L.P., Purdue Pharma Inc., and The Purdue Frederick Company (collectively, "Purdue") for violations of Vermont's Consumer Protection Act and creating a public nuisance. Defendants have violated the Vermont Consumer Protection Act by engaging in unfair and deceptive trade practices, including making misleading marketing claims about their long-acting opioid products, during the period of April 2010 to present ("the Relevant Period"), and created a public nuisance in the State of Vermont through their deceptive marketing of opioids for the treatment of chronic pain, for which the Attorney General seeks civil penalties, injunctive relief, disgorgement, fees and costs, and other appropriate relief.

## INTRODUCTION

### A. Purdue Succeeded in Mainstreaming Opioids Prescribing

1. For 20 years, Purdue has been the leading force in the prescription opioid market, both nationwide and in Vermont. During this time, the pharmaceutical giant Purdue manufactured, sold, and aggressively marketed prescription opioids, including the brand-name drugs OxyContin, Butrans, and Hysingla ER.

2. Before the 1990s, opioids were not widely prescribed because it was correctly believed that their use involved serious risks—including addiction, withdrawal, and overdose—that were not justified by the benefits. Opioids typically were used only to treat short-term, acute pain (*e.g.*, trauma and post-surgical) or for palliative care (*e.g.*, end-of-life) because they were considered too addictive and debilitating for long-term use. This prevailing medical and popular understanding operated as an appropriate constraint on the market for prescription opioids.

3. Beginning in the late 1990s, Purdue set out to effect a sweeping change in the public and medical community's perception of opioids—by downplaying the risks and

aggressively encouraging much broader use. Purdue orchestrated and enacted a plan of massive expansion—designed to change opioids' limited use from acute and palliative care to become a wide-ranging and often front-line option for *long-term, chronic conditions* like back pain, migraines, and arthritis.

4. Purdue exploited a new emphasis in medicine on patient-centered care to advocate that pain was an undertreated priority. Purdue helped to institutionalize this patient-centric shift, and then Purdue capitalized on the platform it had created to push its message that health care providers should prescribe more opioids to treat this undertreated chronic pain. Purdue designed an array of deceptive messages that reduced concerns about opioids generally, and that promoted Purdue's opioids specifically as safe, effective, and appropriate for long-term use and for moderate pain conditions. Purdue's massive marketing scheme, which occurred alongside similar efforts of other industry players, was profoundly successful at shifting the medical and public consensus regarding the use of opioids.

5. Before the introduction of OxyContin in 1996, the opioid market was for post-surgical, end-of-life, or cancer pain. By 2012, opioids were among the most prescribed drugs; approximately 90% of prescription opioids were given for chronic pain conditions, and only 10% of prescription opioids were dispensed for post-surgical, palliative, and cancer pain treatments.[1] This was an almost complete reversal of long-standing medical practice.

6. According to the Centers for Disease Control and Prevention ("CDC"), nearly 62 million Americans received at least one opioid prescription in 2016.[2]

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[1] Laxmaiah Manchikanti *et al.*, *Opioid Epidemic in the United States*, 15 Pain Physician ES9-ES38, at ES27 (2012).

[2] Centers for Disease Control and Prevention, Annual Surveillance Report of Drug-Related Risks and Outcomes (2017), https://www.cdc.gov/drugoverdose/pdf/pubs/2017-cdc-drug-surveillance-report.pdf, at 7.

7. In 2007, Purdue and three of its executives pleaded guilty to federal criminal charges for deceptive conduct in the sale and marketing of opioids. Purdue paid more than $600 million to resolve the government enforcement actions. But by then, long-term opioid therapy for chronic pain had become established as a commonplace, often first-line, treatment.

8. Although Purdue made some concessionary adjustments to the marketing statements that had prompted its prosecution, it never stopped misrepresenting the risks and benefits of its blockbuster drug, OxyContin, and other opioids. Purdue failed to correct, and actually persisted in building upon and profiting from, its earlier deceptions and the platform of misunderstanding it had created. Even worse, Purdue began directing its deceptive marketing in pursuit of new target patients: specifically, it began focusing its efforts on the elderly and patients who had not previously used these powerful drugs (labeled by Purdue as the "opioid naïve").

9. Since 2007, Purdue, nationwide and in Vermont, has engaged in unfair, false, and misleading conduct, including from April 2010 to present ("the Relevant Period"), by continuing to: (a) omit or minimize the serious risk of addiction; (b) overstate the effectiveness of screening tools for preventing addiction, which gave prescribers unwarranted confidence that they could safely prescribe opioids; (c) deny or fail to disclose that the dangers of opioids increase as dose increases, which increase the risk of addiction and overdose; and (d) exaggerate the effectiveness of abuse-deterrent formulations at preventing abuse and addiction.

10. There is not now, and has never been, <u>any science</u> to support Purdue's distorted symphony of misrepresentations about the benefits and safety of long-term opioid use. Purdue falsely promoted long-term opioid use as an appropriate and effective therapy that would improve patients' function and quality of life. Year after year, Purdue promoted these

unsubstantiated claims to patients—via unbranded websites and other promotional materials—and to prescribers—through in-person sales calls, branded and unbranded marketing materials, speaker presentations, and other means. Purdue made these deceptive statements without disclosing the critical fact that there was no scientific evidence to support the safety or efficacy of opioid use for longer than 12 weeks. In fact, Purdue made the unconscionable decision not to pursue studies about the use of opioids for longer than 12 weeks. The Food and Drug Administration ("FDA") ordered Purdue and other manufacturers to undertake such studies in September 2013.[3]

11. At the same time, Purdue methodically minimized the very real risks of addiction in its sales calls and marketing materials, as alleged herein. These two pieces went hand-in-glove: (a) convincing the medical community and public to believe scientifically unsubstantiated statements about the safety and benefits of long-term opioid use, and (b) inappropriately minimizing the serious risks of addiction. These formed the lynchpins of Purdue's successful and deceptive scheme.

## B. The Proliferation of Prescription Opioids Has Been Devastating to Vermont

12. In 2010, 482,572 opioid prescriptions were dispensed in Vermont, a state with a population of just over 625,000.[4] That number continued to rise. In 2015, the number of opioid

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[3] Food and Drug Administration PMR 2065-5, Opioid Post-Marketing Requirement Consortium (available at https://www.fda.gov/Drugs/DrugSafety/InformationbyDrugClass/ucm363722.htm).

[4] Anne VanDonsel, Shayla Livingston, and John Searles (Vermont Department of Health), *Opioids in Vermont: Prevalence, Risk, and Impact* (October 27, 2016), http://www.healthvermont.gov/sites/default/files/documents/2016/12/ADAP_Opioids_Prevalence_Risk_Impact.pdf, at 30 ("Number of Prescriptions by Drug Type and Year"); Vermont Department of Health, *Special Report: Opioid Prescriptions and Benzodiazepines, 2014* (February 2016), http://www.healthvermont.gov/sites/default/files/documents/2016/12/ADAP_Opioids_Benzodiazepenes_Report.pdf, at 3.

prescriptions increased to 498,973[5]—the equivalent of giving a prescription to every 1.3 people living in Vermont, including infants.

13. There is no question that this volume of opioids leads to increased incidence of dependence and addiction. In a 2014 survey by the U.S. Department of Health and Human Services, more than three percent of Vermonters—approximately 18,000 people—reported a dependence on a controlled substance.[6] Vermont ranks as the 8th-highest state for drug dependence nationwide,[7] despite other favorable health indicators like better access to health care and insurance coverage as compared to other states.[8]

14. Opioids are killing Vermont citizens at a skyrocketing rate, and a common origin is prescription opioids. Drug-related fatalities involving opioids nearly doubled between 2012 and 2016.[9] While the national average of opioid-related overdose deaths in 2016 was 13.3 per 100,000 persons, the rate in Vermont was 18.4 – 38% higher than the national average.[10] And these overdose deaths have a broad impact. In a state like Vermont, there are no anonymous deaths.

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[5] *Id.*

[6] amfAR Opioid & Health Indicators Database, *Percent of people 12+ Reporting Drug Dependence*, http://opioid.amfar.org/indicator/drugdep.

[7] *Id.*

[8] *See State Health Assessment Plan - Healthy Vermonters 2020* (December 2012), http://www.healthvermont.gov/sites/default/files/documents/2016/11/Healthy%20Vermonters%202020%20Report.pdf, at 13, 5, 27.

[9] Vermont Department of Health, *Opioid-Related Fatalities Among Vermonters* (updated August 2018), http://www.healthvermont.gov/sites/default/files/documents/pdf/ADAP_Data_Brief_Opioid_Related_Fatalities.pdf.

[10] National Institute on Drug Abuse, *Vermont Opioid Summary* (March 2018), https://www.drugabuse.gov/drugs-abuse/opioids/opioid-summaries-by-state/vermont-opioid-summary.

15. The link between prescription opioids and "street drugs" like heroin and fentanyl fuels the opioid crisis. Many addicts begin with a legal opioid prescription from their doctor or by taking a pill from a prescription bottle belonging to a family member or friend.[11] Prescription opioid users also are far likelier to use illegal opioids like heroin and fentanyl. U.S. Centers for Disease Control and Prevention ("CDC") statistics show that people addicted to prescription opioids are 40x more likely also to be addicted to heroin. The same CDC report shows that nearly half (45%) of people who used heroin also were addicted to prescription opioid painkillers.[12] In 2017, the Vermont Department of Health reported that 80% of new heroin users also had a history of misusing prescription opioids.[13]

16. The heroin/fentanyl problem in Vermont is acute—fentanyl is involved in two-thirds of all opiate-related fatalities, and heroin is involved in one-third of all opiate-related fatalities.[14] The number of fatal overdoses involving fentanyl, in particular, has skyrocketed in recent years—a tenfold increase from 6 fatalities in 2012 to 67 fatalities in 2017.[15]

17. Beyond just addiction, there are additional and serious health dangers associated with illicit heroin and fentanyl use, including collapsed veins, bacterial infections of the blood

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[11] Nora Volkow and Francis Collins, National Institute on Drug Abuse, *"All Scientific Hands On Deck" to End the Opioid Crisis*, May 31, 2017, https://www.drugabuse.gov/about-nida/noras-blog/2017/05/all-scientific-hands-deck-to-end-opioid-crisis ("While there were nearly 20,000 overdoses in 2015 due to heroin or fentanyl, the trajectory of opioid addiction usually begins with prescription opioid misuse. Some people with opioid addiction began by taking diverted pills from friends and family members, but others began with an opioid prescription of their own").

[12] Centers for Disease Control and Prevention, *Today's Heroin Epidemic*, https://www.cdc.gov/vitalsigns/heroin/.

[13] Vermont Department of Health, *Opioid Misuse, Abuse & Dependence in Vermont Data Brief, April 2017*, http://www.healthvermont.gov/sites/default/files/documents/pdf/ADAP_data_brief_opiodmisuse.pdf.

[14] *Opioid-Related Fatalities Among Vermonters*, *supra* n.9, at 1.

[15] *Id.* at 5.

and heart, lung complications, and depression. When heroin is administered by injection, the sharing of needles or bodily fluids puts users at heightened risk for HIV and Hepatitis B and C—serious diseases that can be transmitted to sexual partners and children.[16] The concern about rising rates of HIV and Hepatitis C is very real in Vermont: in 2016, the CDC identified two Vermont counties—Essex and Windham—out of the more than 3,100 counties across the entire United States as among those in the 95th percentile (top 5% nationwide) at greatest risk for outbreaks of HIV and Hepatitis C.[17]

18. While heroin and fentanyl have contributed to the increasing number of opioid deaths in Vermont, the majority of opioid fatalities are causally linked to opioid prescriptions—which many heroin and fentanyl abusers have in their system at the time of their fatal overdose or have used at some point prior to their fatal overdose. A study by the Vermont Prescription Monitoring System found that 85% of opioid-related accidental fatalities in Vermont had received an opioid prescription within the last five years[18] and that 25% percent had received an opioid prescription within 30 days prior to their death.[19]

19. In Vermont, 90.6% of opioid-related fatalities in 2015 occurred in people who had controlled substance prescription histories. Of the decedents who had been given an opioid

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[16] National Institute on Drug Abuse, *What are the medical complications of chronic heroin use?* (March 28, 2018) at 11, https://www.drugabuse.gov/publications/research-reports/heroin/what-are-medical-complications-chronic-heroin-use.

[17] Michelle M. Van Handel et al., *County-level Vulnerability Assessment for Rapid Dissemination of HIV or HCV Infects among Persons who Inject Drugs, United States*, Journal of Acquired Immune Deficiency Syndromes, https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5479631/; American Foundation for AIDS Research, *Vermont Opioid Epidemic*, http://opioid.amfar.org/VT.

[18] Vermont Prescription Monitoring System, *Controlled Substance Prescription Histories for Opioid-Related Accidental Fatalities in 2015* at 3, http://www.healthvermont.gov/sites/default/files/documents/2017/01/HSRV_VPMS_10_28_16_opioid_related_accidental_fatality_brief.pdf.

[19] *Id.*

prescription during the year prior to their death, the average opioid prescription supply was 261 days.[20]

20. In the most recent years for which data from the Vermont Department of Health is available (2015, 2016 and 2017), prescription opioids have been involved in roughly one-third of opioid-related deaths in Vermont.[21]

21. The demand for opioid addiction treatment has risen dramatically. In 2006, 1,897 Vermonters were treated for opioid use in state-funded treatment facilities. By 2015, that number had more than tripled, to 6,084.[22]

22. The effects of the opioid epidemic are widely felt in Vermont. In a 2016 poll commissioned by Vermont Public Radio, 53% of respondents said that they or someone they knew had been personally affected by opiate addiction.[23]

**The devastating effects on infants and young children**

23. Opioid use disorder in pregnant women has become prevalent in Vermont, as opioid use has proliferated more broadly, with potentially devastating health consequences for them and their infants. The number of women with diagnosed opioid use disorder at the time of delivery has increased dramatically over time in Vermont: from 0.5 per 1,000 deliveries in 2001 to 48.6 per 1,000 deliveries in 2014—over seven times the national average, and the highest

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[20] *Opioids in Vermont: Prevalence, Risk, and Impact, supra* n.4, at 31 ("Prescription History of Individuals with Opioid-related Accidental Fatalities").

[21] *Opioid-Related Fatalities Among Vermonters, supra* n.9, at 1.

[22] Vermont Department of Health, *People Treated for Opiate Use in Vermont by Fiscal Year*, http://www.healthvermont.gov/sites/default/files/documents/2016/12/adap_TotalOpiatebyFY.pdf.

[23] Vermont Public Radio, *The VPR Poll: The Issues, The Races and The Full Results* (July 27, 2016), http://digital.vpr.net/post/vpr-poll-issues-races-and-full-results#stream/0.

among the 30 states that have compiled this data.[24] This widespread prevalence of opioid use disorder in pregnant Vermonters is a major public health concern, because of the serious potential adverse maternal and neonatal outcomes associated with opioid use during pregnancy: preterm labor, stillbirth, neonatal abstinence syndrome, and maternal mortality.[25]

24. The number of infants born in Vermont who are diagnosed with Neonatal Abstinence Syndrome ("NAS")—a condition in which a newborn baby suffers withdrawal symptoms—also far exceeds the national average. Based on available data from 2012, the Vermont Department of Health estimated that the rate of NAS in Vermont was five times higher than the national average, and the Vermont statistics have continued to rise.[26]

25. In 2008, there were 17.0 infants with NAS per 1,000 live births (to Vermont residents in Vermont hospitals). By comparison, in 2014, that number had more than doubled to 35.3 per 1,000 live births (to Vermont residents in Vermont hospitals).[27]

26. Infants exposed to opioids *in utero* also face serious health consequences. At least 60–80% of these babies will experience symptoms such as seizures, respiratory distress, diarrhea, hypertonia, feeding intolerance, tremors, and vomiting because of their exposure to opioids in the womb.[28]

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[24] *Opioid Use Disorder Documented at Delivery Hospitalization—United States, 1999-2014*, CDC Morbidity and Mortality Weekly Report (August 10, 2018), https://www.cdc.gov/mmwr/volumes/67/wr/mm6731a1.htm?s_cid=mm6731a1_e, at 847.

[25] *Id.* at 845.

[26] *Opioids in Vermont: Prevalence, Risk, and Impact*, *supra* n.4, at 44 ("Improved treatment and screening have helped to identify more infants exposed to opioids").

[27] Vermont Department of Health, *Neonates Exposed to Opioids in Vermont* (April 2017), http://www.healthvermont.gov/sites/default/files/documents/pdf/ADAP_Opioids_Neonate_Exposure.pdf, at 1.

[28] Stephen W. Patrick *et al.*, *Neonatal Abstinence Syndrome and Associated Health Care Expenditures*, Journal of the American Medical Association (2012), https://www.ncbi.nlm.nih.gov/pubmed/ 22546608.

27. Infants born with NAS require longer and costlier hospital stays than those who are born without exposure to opioids. In 2012, the average length of hospital stay for non-NAS infants born to Vermont residents in Vermont hospitals was 3.0 days, at a cost of $5,590. But Vermont infants with NAS faced hospital stays more than 2x longer and nearly 3x more expensive, averaging 7.4 days and $15,456 (respectively).[29]

28. More than 50% of Vermont children under the age of five who have been taken into the custody of the Vermont Department of Children and Families (DCF) have been removed from their homes because of opioid-related issues.[30] As reported in 2016, the reporting of incidences to DCF's Child Protection Line have increased by 30%—from 15,760 reports in 2012 to 20,583 in 2016—and during those same years, approximately 30% of the calls related to substance abuse.[31]

**The financial cost to our communities**

29. Opioid overprescribing, misuse, and prescription diversion are draining Vermont's health care system. For example, one study estimated the 2007 total health care spending associated with opioid abuse in Vermont as exceeding $38 million.[32] From 2007 to

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[29] Vermont Department of Health, *Neonates Exposed to Opioids in Vermont*, *supra* n.27, at 2.

[30] Vermont Opioid Coordination Council, *Initial Report of Recommended Strategies* (January 2018), http://www.healthvermont.gov/sites/default/files/documents/pdf/OCC%202018%20Report%202018-1-9.Final_.pdf, at 3 n.1.

[31] Howard Weiss-Tisman, *Opioid Abuse Continues to Strain Vermont's Child Welfare System*, Vermont Public Radio (December 5, 2017), http://digital.vpr.net/post/opioid-abuse-continues-strain-vermonts-child-welfare-system#stream/0; Vermont Dept. for Children and Families Family Services Div., *2016 Report on Child Protection in Vermont*, http://legislature.vermont.gov/assets/Legislative-Reports/Child-Protection-Report-2016.pdf.

[32] Matrix Global Advisors, *Health Care Costs from Opioid Abuse: A State-by-State Analysis* (April 2015), https://drugfree.org/wp-content/uploads/2015/04/Matrix_OpioidAbuse_040415.pdf, at 5.

2018, opioid prescribing rose dramatically, as did the numbers of persons using, misusing, and abusing both prescription and illegal opioids.

30. The health care costs associated with opioid overprescribing, addiction, and abuse are crushing. Vermont consumers—individuals, employers, and private insurers—have paid millions for opioid prescriptions. Vermont's opioid treatment programs cost more than $70 million between 2012 and 2017 alone.[33] Vermont consumers have likewise borne substantial healthcare costs due to this epidemic of addiction.

31. It is well-established that health care costs for persons addicted to opioids are much higher than health care costs for the general population. For example, overall health care costs are approximately 3x higher among patients receiving Medication Assisted Treatment for opioid addiction than is true for the general Medicaid population.[34] The average national private payer cost per person with opioid use disorder was $63,356 (in 2015).[35]

32. The prevalence of opioids in Vermont also places a greater burden on law enforcement – increased costs associated with investigating and prosecuting crimes related to opioid use and abuse, as well as increased costs for treating incarcerated residents for opioid use disorder.

33. The costs of incarceration—which include Medication Assisted Treatment for addiction and other related costs—are largely paid by the State. Crimes associated with

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[33] Harry Chen, MD (Commissioner, Vermont Dept. of Health), *Status of Opioid Treatment Efforts* – Health Reform Oversight Committee (October 25, 2016), http://www.leg.state.vt.us/jfo/healthcare/Health%20Reform%20Oversight%20Committee/2016_10_25/Status%20of%20Opioid%20Treatment%20Efforts%20-%20Chen.pdf, at 22.

[34] Vermont Department of Health, *The Opioid Addiction Treatment System* (January 13, 2013), http://www.leg.state.vt.us/reports/2013externalreports/285154.pdf, at 9.

[35] *Status of Opioid Treatment Efforts*, *supra* n.33.

prescription drugs—chiefly robbery and burglary—have risen.[36] Data collected by the Vermont Intelligence Center show that law enforcement consistently averages between one and two seizures of illicit opioids per day.[37] In a small state like Vermont, this steady drumbeat of opioid seizures has become a focal point of police time and attention.

34. Purdue's prescription opioids continue to be a central cause of the opioid crisis in Vermont, and Purdue also has retained a significant market share of the dollars spent by the State on opioid prescriptions. Using the Vermont State Employees' health plan data as just one example, Purdue's opioids alone account for more than 55% of the State of Vermont's total opioid prescription spending, from April 2010 to June 2018.

## C. Vermont Is Leading the Nation with Its Innovative and Effective Approach to Combatting the Opioid Crisis

35. In 2012, Vermont passed legislation[38] authorizing its Department of Health to establish a state-wide integrated care system for opioid addiction treatment, creating the treatment "Hubs" (for high intensity Medication Assisted Treatment and counseling) and "Spokes" (for treatment by a team consisting of Community Drug Addiction Treatment Act-waivered prescribers—which include physicians, nurse practitioners, and physician assistants—

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[36] Vermont Department of Health, *Issue Brief: Prescription Drug Misuse in Vermont,* at 12 (Feb. 12, 2013), http://thehungryheartmovie.org/wp-content/uploads/2013/09/SEOW_Rx_Issue_Brief_Final_02_12_13.pdf.

[37] *Opioid Seizures: Number of Opioid Seizures as Reported by Vermont Law Enforcement,* Vermont Intelligence Center (January 2017), last updated June 2015, last on website May 18, 2018 (available at https://webcache.googleusercontent.com/search?q=cache:u92N642SthsJ:https://app.resultsscorecard.com/perfmeasure/embed/101519+&cd=2&hl=en&ct=clnk&gl=us).

[38] Act No. 135 (available at https://legislature.vermont.gov/assets/Documents/2012/Docs/ACTS/ACT135/ACT135%20As%20Enacted.pdf).

supported by a treatment team consisting of a nurse and a credentialed substance abuse counselor for every 100 persons receiving MAT).[39]

36. The Hub-and-Spoke System is unique in its comprehensiveness and has been recognized nationally as "visionary."[40] Vermont's success is the result of state and local actors working cooperatively to design and implement a multi-faceted, cutting-edge approach to addressing opioid addiction that reaches even the most rural areas in the State.[41] Despite Vermont's success in developing and administering these programs, the problem of opiate addiction is overwhelming, and the demand for these treatment programs continues to increase. Vermont's Blueprint for Health reports that more than 6,000 Vermonters are participating in the Hub and Spoke treatment system through the State's Medicaid program,[42] and additional Vermonters are treated in the Hub & Spoke system through private insurance and Medicare. Demand for opioid treatment in Vermont has continued to rise.[43] Vermont has engaged in an ongoing effort to keep up with the need and reduce wait times for patients seeking treatment.[44]

37. Vermont has elected to invest its treatment funds in evidence-based approaches, and is the nation's most proactive state at providing buprenorphine (a key component of

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[39] Vermont Department of Health, *Public Health Strategies to Reduce Opioid Use Disorders*, March 2017 (available at http://www.healthvermont.gov/sites/default/files/documents/2017/03/ADAP_Opioid_Strategy_Brief.pdf).

[40] Vermont Opioid Coordination Council, *Initial Report of Recommended Strategies*, *supra* n. 30, at 3.

[41] Vermont Department of Health, *Public Health Strategies to Reduce Opioid Use Disorders*, *supra* n.39.

[42] Pat Bradley, *Vermont Governor Testifies in Washington on Opioid Treatment Programs* (Feb. 7, 2018), http://wamc.org/post/vermont-governor-testifies-washington-opioid-treatment-programs; State of Vermont, *Blueprint for Health*, http://blueprintforhealth.vermont.gov/about-blueprint/hub-and-spoke.

[43] Vermont Department of Health, *Public Health Strategies to Reduce Opioid Use Disorders*, *supra* n.39.

[44] Chen (Vermont Department of Health), *Status of Opioid Treatment Efforts*, *supra* n.33, at 11 ("Hub Census and Waitlist: September 26, 2016").

Medication Assisted Treatment) to patients in need. The State averages 204 buprenorphine prescriptions per 1,000 persons, which is 524% higher than the national average of 39 per 1,000.[45] Vermont also leads the nation in funding access to buprenorphine for its citizens. Medicaid funding is used by patients filling over 68% of the total buprenorphine prescriptions in Vermont—nearly 3x the national average of 24.2%.[46]

38. Vermont also has elevated its outreach to high-risk patients for comprehensive, specialty support. Pregnant women are eligible for not simply treatment, but also for supportive programming, including housing and transportation, which can vastly improve health outcomes for mothers and infants.[47] The State has been providing up to 120 days of addiction treatment to inmates and has pioneered efforts to divert low-level drug offenders from prosecution and incarceration if they agree to treatment shortly after arrest. As of July 1, 2018, all Vermont inmates who enter the correctional system on Medication-Assisted Treatment and/or are diagnosed with opioid use disorder will continue to be provided with Medication-Assisted Treatment while incarcerated, for as long as treatment is medically necessary.[48]

39. In December 2013, the Vermont Department of Health launched an overdose reversal pilot project to distribute naloxone to people at risk for overdose, along with their family

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[45] IMS Institute for Healthcare Informatics, *Use of Opioid Recovery Medications* (September 2016), https://www.iqvia.com/-/media/iqvia/pdfs/institute-reports/use-of-opioid-recovery-medications.pdf, at 5.

[46] *Id.*

[47] Vermont Department of Health, *Public Health Strategies to Reduce Opioid Use Disorders, supra* n.39, at 7.

[48] S. 166, An act relating to the provision of medication-assisted treatment for inmates, https://legislature.vermont.gov/assets/Documents/2018/WorkGroups/House%20Corrections%20and%20Institutions/Bills/S.166/S.166~Ed%20Paquin%20~As%20Introduced,%201-31-2018~3-29-2018.pdf.

members and others most likely to be present in the event of an overdose.[49] To date, more than 17,000 kits have been distributed at 30 sites in Vermont—all free of charge to the recipients. [50]

40. In August 2016, the Vermont Commissioner of Health issued a statewide, standing order authorizing every pharmacy to dispense naloxone to anyone—without a prescription.[51]

41. Statewide rules and protocols for Emergency Medical Services (EMS) personnel were changed in 2013 to allow EMT providers at all license levels to administer nasal naloxone. Additional legislation passed in 2016 allowed VDH to provide all EMS agencies and law enforcement entities with naloxone at no charge.[52]

42. In June 2013, the Vermont Legislature passed Act 75 which, among other things, mandated every health care provider who prescribes or dispenses any Schedule II, III, or IV controlled substances to register for and use the Vermont Prescription Monitoring System (VPMS).[53] This law was amended in 2016, through Act 173, to increase the mandatory reporting frequency for dispensers from at least once per week to daily.[54] Today, when a prescription is

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[49] Vermont Department of Health, *Naloxone Pilot Project – Data Brief* (April 18, 2014), https://legislature.vermont.gov/assets/Documents/2014/WorkGroups/House%20Human%20Services/Bills/S.295/Witness%20Testimony/S.295~Barbara%20Cimaglio~Naloxone%20Pilot%20Project%20%E2%80%93%20Data%20Brief~4-24-2014.pdf.

[50] Vermont Opioid Coordination Council, *Initial Report of Recommended Strategies, supra* n.30, at 30; Naloxone Distribution and Administration in Vermont – Data Brief, updated May 2018, http://www.healthvermont.gov/sites/default/files/documents/pdf/ADAP_Naloxone_Data_Brief_0.pdf.

[51] Vermont Department of Health, *Public Health Strategies to Reduce Opioid Use Disorders* (March 2017), supra n.39.

[52] *Id.*

[53] Act No. 75. An act relating to strengthening Vermont's response to opioid addiction and methamphetamine abuse. (H. 522) (2013), http://www.leg.state.vt.us/docs/2014/Acts/Act075.PDF.

[54] Act. No. 173, An act relating to combating opioid abuse in Vermont. (S. 243) (2016), https://legislature.vermont.gov/assets/Documents/2016/Docs/ACTS/ACT173/ACT173%20As%20Enacted.

dispensed to a patient, information about the drug, recipient, prescriber, and pharmacy is uploaded into VPMS within 24 hours so that this data can be tracked and monitored, which improves a prescriber's ability to detect abuse and diversion. The Vermont Department of Health works to ensure compliance with data uploading and data quality.[55]

43. Act 75 also required professional licensing authorities for healthcare providers to develop evidence-based standards to guide them in the prescription of Schedule II, III, and IV controlled substances for the treatment of chronic pain, which was later supplemented by Act 173 to include development of guidelines for treatment of acute pain. Act 173 also created the Controlled Substances and Pain Management Advisory Council to advise the Department of Health on the drafting of guidelines for prescribing opioids for acute and chronic pain. Rules for responsible prescribing of opioids for chronic and acute pain were finalized in December 2016. The rules provide information to prescribers on appropriate treatment of pain and guidance on how to reduce the likelihood of drug dependence. Importantly, the rules require prescribers to consider non-opioid alternatives before prescribing opioids and to re-evaluate treatment at least every 90 days, if not more frequently.[56]

44. Finally, the State has undertaken many initiatives to increase public awareness and education about the dangers of opioids. The Vermont Department of Health launched Vermont's Most Dangerous Leftovers campaign in 2014, to increase awareness of the safe use, safe storage, and proper disposal of prescription drugs, including promoting the "Vermont 2-1-1" informational telephone line as a source to find local drug disposal sites. The Department of

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[55] Vermont Department of Health, *Public Health Strategies to Reduce Opioid Use Disorders*, supra n.39.

[56] Vermont Department of Health, Rule Governing the Prescribing of Opioids for Pain, July 1, 2017, R. §§ 6.2, 6.2.1, 6.2.1.1, 6.2.2.

Health also produced Public Service Announcements to promote the safe use, safe storage, and safe disposal of prescription drugs and promote naloxone to prevent overdose deaths.[57]

45. Additionally, the Vermont Department of Health launched ParentUpVT.org, which provides strategies and actions for parents and caregivers to help prevent drug use among youth. And the State is establishing educational campaigns to increase the perception of risk associated with prescription pain reliever misuse and increase awareness on the responsible use of prescription pain relievers.[58]

46. Yet, much more remains to be done. The cost and effort of remediating the opioid crisis require tremendous resources and persistence. For decades, Purdue cultivated the demand for its opioids and opioids generally, and profited from their overprescribing, misuse, and abuse. The State has filed this lawsuit to expose Purdue's misconduct and legal culpability in Vermont—because the public deserves to know how it has been deceived, and because Purdue must be held accountable so that it is required to pay its share of the extraordinary costs required to abate this crisis.

47. Purdue's success in promoting opioids is particularly astonishing in light of the efforts Vermont had made to curb the influence of drug manufacturers on prescribing. In 2009, Vermont passed a law banning gifts from manufacturers of prescription drugs and products to health care professionals and providers. *See* Vt. Stat. Ann. tit. 18 § 4631a. These prohibitions include a ban on any payment, food, entertainment, travel, subscription, service, or anything else of value with limited exceptions for things like research grants and teaching honoraria that must

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[57] Vermont Department of Health, *Public Health Strategies to Reduce Opioid Use Disorders*, supra n.39.

[58] *Id.*

be disclosed to the Attorney General's Office.[59] But Purdue did not rely exclusively on in-person visits and gifts to persuade doctors. Purdue used front groups disguised as independent patient advocacy organizations, paid spokespeople disguised as experts, and biased studies disguised as legitimate academic research to reach doctors and patients. All of this conduct needs to be exposed.

48. Even today, Purdue seeks to obscure its culpability for this crisis, as set forth in Section D. Purdue distances itself from its past misconduct, and attempts to portray itself as a responsible corporate citizen by falsely portraying the opioid epidemic as mainly a problem of illicit drug diversion and abuse. But the genesis of this crisis can be placed squarely on Purdue's doorstep. Purdue's efforts to change the medical consensus and public perception about the inherent dangers of opioids were tremendous in their scope, strategy, and success. Purdue has been the epitome of greed and deception for more than 20 years.

49. Purdue's unfair and deceptive conduct, which fomented and perpetuates the opioid crisis, has violated and continues to violate Vermont law. To redress and punish Purdue's conduct, the Attorney General of Vermont seeks an Order requiring Purdue to permanently cease its unlawful promotion of opioids, correct its past and current misrepresentations, abate the public nuisance its deceptive marketing has created, and pay civil penalties for its continuous, pervasive, deceptive and unfair business practices in connection with the marketing of opioids.

## PARTIES

### A. Plaintiffs

50. The Attorney General is authorized to represent the State in all civil matters at common law and as allowed by statute. Vt. Stat. Ann. tit. 3, § 152. The Attorney General is

[59] 18 V.S.A. § 4631a.

charged with the responsibility of enforcing the Consumer Protection Act ("CPA") and all regulations promulgated thereunder, Vt. Stat. Ann. tit. 9, § 2458.

51. The State also has standing *parens patriae* to protect the health and well-being, both physical and economic, of its residents. Opioid use and abuse have affected a substantial segment of the population of Vermont.

**B. Defendants**

52. Purdue Pharma L.P. is a Delaware limited partnership. Purdue Pharma Inc. is a New York corporation that is the general partner of Purdue Pharma L.P. The Purdue Frederick Company is a New York corporation. Defendants operate as an integrated enterprise with its principal place of business at One Stamford Forum, 201 Tresser Boulevard, Stamford, Connecticut 06901.

53. Purdue manufactures, promotes, sells, and distributes the opioids OxyContin, MS Contin, Dilaudid, Dilaudid HP, Butrans, and Hysingla ER in the United States and Vermont. OxyContin is Purdue's best-selling opioid. Purdue has generated sales estimated at more than $35 billion since it launched OxyContin in 1995.[60]

**JURISDICTION AND VENUE**

54. The Court has personal jurisdiction over Purdue because it has regularly transacted business in Vermont, purposely directed business activities into Vermont, maintained employees who operated in Vermont, and engaged in unlawful practices in Vermont against Vermont consumers.

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[60] 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/#4921c27475e0; Chase Peterson-Withorn, "Fortune of Family Behind OxyContin Drops Amid Declining Prescriptions," *Forbes* (June 29, 2016), https://www.forbes.com/sites/chasewithorn/2016/06/29/fortune-of-family-behind-oxycontin-drops-amid-declining-prescriptions/#7142049f6341.

55. Defendants Purdue Pharma L.P. and Purdue Pharma Inc. are registered to do business in Vermont with Corporation Service Company as their registered agent located at 100 North Main St., Suite 2, Barre, VT, 05641.

56. Purdue has generated millions of dollars of revenue through sales of its opioid pain medications in Vermont. Until recently, Purdue also consistently maintained a sales force in the State. During the Relevant Period, at least 19 different Purdue sales representatives and sales managers have had a sales territory in or including Vermont. In that period, Purdue's Vermont sales force made more than 5,300 sales visits regarding OxyContin and other Purdue opioids to Vermont health care providers.

57. As alleged herein, Purdue has deceptively and otherwise unlawfully marketed its opioids in Vermont, through both conduct within the State and other business activities directed into the State. This conduct includes (a) directly conveying promotional messages to Vermont health care providers through the sales force, and (b) funding, developing, influencing, adopting, and/or disseminating or making available publications regarding opioids—such as promotional materials, continuing medical education, and prescribing guidelines—to Vermont health care providers and consumers.

58. Venue in this Court is proper, pursuant to Vt. Stat. Ann. tit. 9, § 2458(a), because Purdue does business in Chittenden County. Among other things, Purdue made nearly 2,000 sales visits regarding opioids to health care providers in Chittenden County during the Relevant Period.

## GENERAL ALLEGATIONS COMMON TO ALL COUNTS

### A. Cementing the Foundation: From the Late 1990s to 2007, Purdue Engaged in a Campaign of Deception to Create and Sustain a Market for Its Opioids

*The success of Purdue's opioid enterprise was due to a bold master plan. Purdue offered a product—opioids—that had been previously viewed by the medical community and the public*

*as dangerous. A healthy aversion to opioid use existed. That was true until Purdue built a campaign to mainstream opioid use for long-term pain patients, co-opted the science and understanding of opioids by disseminating false and deceptive information about studies and testing, and blanketed the medical community with disinformation, incentives, and false evidence about opioids—and particularly, about its flagship product, 12-hour extended release OxyContin. This reprehensible and illegal conduct led to investigations by federal and state governments, including Vermont, forcing Purdue to enter into criminal and civil settlements in 2007 to the tune of $635 million dollars.*

59. Beginning in 1996, Purdue presented OxyContin—and later its other opioids—as the solution to the problem of chronic pain. (As used in this Complaint, "chronic pain" means non-cancer pain lasting twelve weeks or longer.) Through marketing that was as pervasive as it was deceptive, Purdue convinced health care providers that the risks of long-term opioid use were overblown and also that the alleged benefits—reduced pain, improved function, and quality of life—were proven, even though Purdue had no evidence to support these assertions.[61] By the mid-2000s, Purdue had succeeded in drastically changing medical and public opinion about opioids. Purdue's marketing convinced prescribers, educators, and patients that opioids were safe and effective for long-term use and also that they were an appropriate, first-line treatment for routine chronic pain conditions.

**1. Purdue Mainstreamed Opioids for Chronic Pain**

60. Purdue marketed its opioids directly to health care providers and patients, nationwide and in Vermont. Purdue's sales representatives, also known as "detailers," made thousands of in-person sales calls to Vermont healthcare providers in which they misleadingly portrayed opioids as safe, effective, and appropriate for the treatment of chronic pain. In Vermont especially, Purdue targeted generalists—primary care physicians, nurse practitioners,

[61] Centers for Disease Control and Prevention, *Guideline for Prescribing Opioids for Chronic Pain* (2016), https://www.cdc.gov/drugoverdose/prescribing/guideline.html (hereafter, "CDC Guideline"), at 2, 20, 25. (confirming, based on existing research and evidence, that opioid use presents a "serious risk" of addiction, use for three months or more "substantially increases" that risk, and there never has been "good evidence that opioids improve pain or function with long-term use").

and physician assistants—as opposed to other healthcare professionals with specialized training and knowledge about the use and risks of opioids. Purdue's deceptive marketing created a cadre of primary care doctors, nurse practitioners and physicians' assistants who were "educated" by Purdue's sales representatives and marketing literature to look for pain and to treat it with opioids. This, in turn, created a patient population that came to expect and specifically request opioids.

61. Purdue misrepresented key facts about the safety of its opioids – in particular, the risk of addiction. Purdue admitted, in 2007, that its sales representatives, as a matter of course:

- falsely told health care providers that OxyContin had a less euphoric effect, and less abuse potential, than short-acting opioids;[62]
- falsely told prescribers that OxyContin—the first "extended-release," a/k/a "long-acting" ("ER/LA") opioid—had fewer "peak and trough" effects than short-acting opioids, also known as immediate release ("IR") opioids;[63]
- falsely told prescribers that patients could discontinue OxyContin therapy abruptly without experiencing withdrawal symptoms; and
- falsely told prescribers that OxyContin was more difficult to abuse intravenously than generic oxycodone.[64]

62. In addition to making deceptive claims through its sales force, Purdue also widely advertised OxyContin, including in print ads in medical journals and in videos distributed directly to prescribers. These ad campaigns deceptively underplayed the risks and overemphasized benefits of chronic opioid therapy. For example, in 1998 and 2000, Purdue

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[62] Agreed Statement of Facts, *U.S. v. The Purdue Frederick Company, Inc.*, May 9, 2007, at 6; Press Release, U.S. Attorney's Office, Western District of Virginia, The Purdue Frederick Company, Inc. and Top Executives Plead Guilty to Misbranding OxyContin, Will Pay Over $600 Million (May 10, 2007), https://media.defense.gov/2007/May/10/2001711223/-1/-1/1/purdue_frederick_1.pdf, at 3.

[63] *Id.* at 6.

[64] *Id.* at 6.

distributed to doctors thousands of copies of videos, titled "I Got My Life Back," which made the unsubstantiated claim that opioid addiction occurred in less than 1% of patients.[65] In 2003, FDA warned Purdue about advertisements Purdue paid to run in the *Journal of the American Medical Association*, expressing concern that they would lead to ill-considered prescribing of OxyContin because the body of the ad text nowhere referred to the "serious, potentially fatal risks associated with OxyContin."[66] In 2005, Purdue also paid to run an advertisement that ran in pain journals that misleadingly implied long-term improvement in patients' pain, function and quality of life, touting OxyContin as an "around-the-clock analgesic . . . for an extended period of time" and featuring a man and a boy fishing under the tagline "There Can Be Life With Relief."

63. Purdue's advertising also included the claim that OxyContin provides "Consistent Plasma Levels Over 12 Hours."[67] That claim was accompanied by a chart, shown below, that depicted plasma levels on a logarithmic scale. However, this presentation visually distorted and obscured the steep decline in OxyContin's efficacy over 12 hours, by depicting 10 milligrams in a way that it appeared to be half of 100 milligrams in the table's y-axis, falsely making the absorption rate appear more steady or consistent over 12 hours:

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[65] United States General Accounting Office Report to Congressional Requesters, *Prescription Drugs: OxyContin Abuse and Diversion and Efforts to Address the Problem*, December 2003, https://www.gao.gov/products/GAO-04-110, at 27.

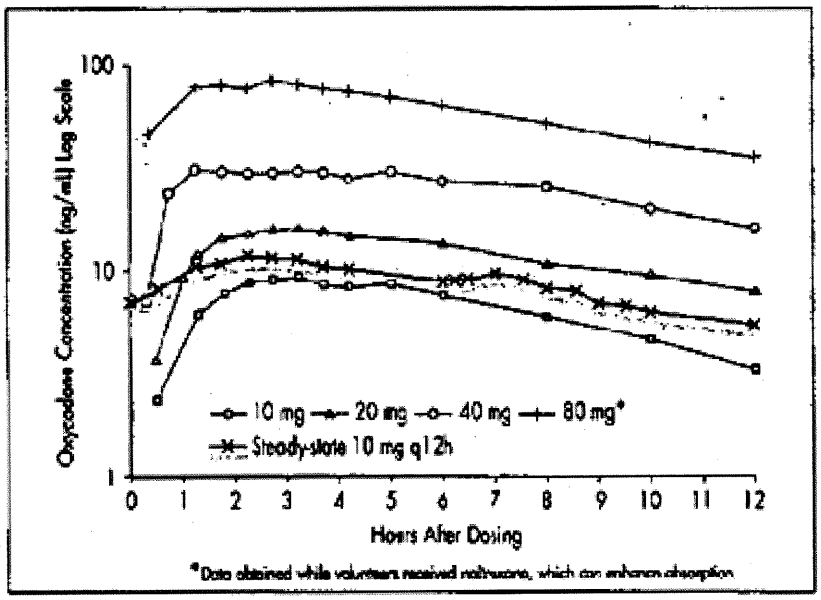
[66] Letter from Thomas Abrams, Dir. FDA Div. of Drug Mktg., Advert. and Commc'n, to Michael Friedman, Exec. Vice President and Chief Operating Officer, Purdue Pharma L.P. (Jan. 17, 2003).

[67] Jim Edwards, *How Purdue Used Misleading Charts to Hide OxyContin's Addictive Power*, CBSNews.com (Sept. 28, 2011), http://www.cbsnews.com/news/how-purdue-used-misleading-charts-to-hide-oxycontins-addictive-power/.

**For moderate to severe pain when a continuous, around-the-clock analgesic is needed for an extended period of time**

# Consistent Plasma Levels Over 12 Hours

**Plasma concentrations (ng/mL) over time of various dosage strengths**




- **OxyContin® 80 and 160 mg Tablets FOR USE ONLY IN OPIOID-TOLERANT PATIENTS requiring minimum daily oxycodone equivalent dosages of 160 mg and 320 mg, respectively. These tablet strengths may cause fatal respiratory depression when administered to patients not previously exposed to opioids**

*Steady state achieved within 24 to 36 hours*

In fact, OxyContin works by releasing a greater proportion of oxycodone (about 40%) into the body when administered, followed by a steep decline over the subsequent hours.[68]

**2. Purdue's Pervasive and Deceptive Unbranded Marketing**

64. In addition to its branded marketing efforts that showcased specific Purdue opioids, Purdue also undertook or financially supported a number of "unbranded" marketing initiatives that were designed to promote opioids generally, and to convey Purdue's key messages about opioids without properly disclosing that Purdue created, funded, directed, or was in any way involved with these endeavors. Purdue intended patients and prescribers to read

[68] New Zealand Ministry of Medicine Data Sheet (http://www.medsafe.govt.nz/Profs/Datasheet/o/OxyContintab.pdf); *How Purdue Used Misleading Charts to Hide OxyContin's Addictive Power*, supra n.67.

these materials and to perceive (incorrectly) that the materials were published by neutral researchers, clinicians, and legitimate patient advocacy groups.

65. As part of its unbranded marketing scheme, Purdue recruited and paid physicians to make presentations on opioids to their peers at lunch and dinner events. It funded the biased research that formed the basis of these presentations and sponsored Continuing Medical Education programs ("CMEs") that misleadingly portrayed the risks and benefits of chronic opioid therapy. Purdue collaborated with professional associations and pain advocacy organizations, such as the American Pain Foundation, to develop and disseminate pro-opioid educational materials and guidelines for prescribing opioids.

66. Purdue had a particularly close relationship with the American Pain Foundation ("APF"), which was highly dependent on pharmaceutical company funding and produced numerous publications touting the use of opioids to treat chronic pain. Purdue was APF's second-biggest donor, with donations totaling $3.6 million between 1999 and 2012. As early as 2001, Purdue grant letters informed APF that the contributions reflected Purdue's effort to "strategically align our investments in nonprofit organizations that share our business interests," making clear that funding depended on APF continuing to support Purdue's objectives. Purdue also engaged APF as a paid consultant on various initiatives.

67. Purdue created a range of unbranded materials—from websites to glossy pamphlets—that were copyrighted by Purdue but on their face implied that the recommendations and research contained therein were the work of independent organizations with names like *Partners Against Pain*. Purdue ensured that these unbranded materials supported Purdue's branded marketing efforts to promote the use of opioids.

68. Among these tactics, all of which originated in the late 1990s and early 2000s, three stand out for their lasting influence on opioid prescribing nationwide and in Vermont: Purdue's capture, for its own ends, of healthcare providers' increased focus on pain treatment; Purdue's efforts to seed the scientific literature on chronic opioid therapy; and Purdue's corrupting influence on authoritative treatment guidelines issued by professional associations.

**a. *Co-opting the Medical Community's Focus on Pain***

69. As Purdue marketed OxyContin in the late 1990s, it both capitalized on and co-opted a movement in the medical community to make pain identification and treatment a priority for all patients. Purdue provided financial support to the organizations and people leading the movement, and in turn they promoted the aggressive treatment of chronic pain, especially with opioids.

70. Purdue already had laid the groundwork for this strategy by financially supporting researchers who were willing to advocate for the expanded use of opioids without adequate scientific support. Chief among these was Dr. Russell Portenoy, who wrote a seminal 1986 paper supporting chronic opioid therapy while receiving Purdue funding and serving as Purdue's consultant. Dr. Portenoy concluded—based on a review of just 38 patients—that "opioid maintenance therapy can be a safe, salutary and more humane alternative" to not treating patients with chronic pain.[69]

71. Beginning in 1995, the American Pain Society ("APS"), of which Dr. Portenoy later would become president, launched a national campaign to make pain a "vital sign"—an indicator doctors should monitor alongside blood pressure, temperature, heartbeat, and breathing.

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[69] Russell K. Portenoy & Kathleen M. Foley, *Chronic use of opioid analgesics in non-malignant pain: report of 38 cases*, 25(2) Pain 171-86 (May 1986).

Purdue provided substantial funding to APS both to promote pain awareness generally and, on information and belief, to support the group's "Pain as the 5th Vital Sign" campaign. The Veterans Health Administration adopted this concept in its facilities nationwide in 1999, and "Pain as the 5th Vital Sign" spread from there to the private sector.

72. Coming on the heels of the APS campaign was the work of the Joint Commission on the Accreditation of Healthcare Organizations ("JCAHO"), which accredits hospitals across the United States. In 2001, JCAHO issued pain treatment standards that called for assessment of pain in all patients and in each physician-patient interaction, and made accreditation decisions contingent on institutions having policies in place to accomplish these goals. JCAHO worked closely with Purdue to promote the pain standards and licensed Purdue—exclusively—to distribute certain educational videos about how to comply with the new pain management standards.[70] Purdue also sponsored various guides for implementing the JCAHO standards, such as *Pain Assessment and Management: An Organizational Approach.* This book promoted the use of opioids, claiming that "[s]ome clinicians have inaccurate and exaggerated concerns about addiction, tolerance, respiratory depression, and other opioid side effects . . . . despite the fact there is no evidence that addiction is a significant issue when persons are given opioids for pain control." (Emphasis added.) JCAHO distributed the book to hospital officials and physicians nationwide at a series of Purdue-sponsored "leadership summits" on pain management.[71]

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[70] United States General Accounting Office, *Prescription Drugs: OxyContin Abuse and Diversion and Efforts to Address the Problem*, supra n. 65, at 23.

[71] American Pain Society Press Release, 10-May-2000, *National summit on pain management to discuss new standards for pain assessment and treatment*, https://www.eurekalert.org/pub_releases/2000-05/PN-Nsop-1005100.php; United States General Accounting Office, *Prescription Drugs: OxyContin Abuse and Diversion and Efforts to Address the Problem*, supra n. 65, at 23.

73. Both the APS "Pain as the 5th Vital Sign" campaign and the JCAHO pain standards have been widely integrated into medical practice. Although the JCAHO standards were developed to apply strictly in hospital settings, they influenced the entire medical profession through hospital-based residency training.

74. Vermont health care providers interviewed by the State recall learning about "Pain as the Fifth Vital Sign" and the importance of treating pain, through training and medical literature, during the 1990s and early 2000s. Many of these providers credit such initiatives with driving an increased focus on treatment of pain and increased use of opioids.

### b. *Seeding the Science Regarding the Efficacy and Risks of Opioids with Flawed and Biased Research*

75. Rather than rigorously test the safety and efficacy of opioids for long-term use, Purdue created scientific support for its marketing claims by sponsoring studies that were methodologically flawed, biased, and drew inappropriate conclusions from prior evidence. These studies, once published, formed a seemingly objective, research-based foundation for liberalized opioid prescribing and were cited in subsequent studies, resulting in a body of literature on which physicians relied.

76. Some of these methodologically flawed studies claimed that the risk of psychological dependence or addiction is low in opioid use, absent a patient history of substance abuse.[72] One such study making this claim, published in the journal *Pain* in 2003 and widely referenced since (with more than 600 citations in Google Scholar),[73] ignored existing research

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[72] Seddon R. Savage *et al.*, *Definitions related to the medical use of opioids: Evolution towards universal agreement*, 26 J. Pain and Symptom Mgmt. 1:655-667 (2003); Watson, C. Peter N., *et al.*, *Controlled-release oxycodone relieves neuropathic pain: a randomized controlled trial in painful diabetic neuropathy*, 105 Pain 71 (2003).

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

showing actual addiction rates between 8% and 13%,[74] and instead relied heavily on a 1980 letter to the editor—not a peer-reviewed study or in-depth article, but a letter—in the *New England Journal of Medicine*. That letter, J. Porter & H. Jick, "Addiction Rare in Patients Treated with Narcotics," 302(2) New Eng. J. Med. 123 (1980) ("Porter-Jick Letter"), is reproduced below:

**ADDICTION RARE IN PATIENTS TREATED WITH NARCOTICS**

*To the Editor:* Recently, we examined our current files to determine the incidence of narcotic addiction in 39,946 hospitalized medical patients[1] who were monitored consecutively. Although there were 11,882 patients who received at least one narcotic preparation, there were only four cases of reasonably well documented addiction in patients who had no history of addiction. The addiction was considered major in only one instance. The drugs implicated were meperidine in two patients,[2] Percodan in one, and hydromorphone in one. We conclude that despite widespread use of narcotic drugs in hospitals, the development of addiction is rare in medical patients with no history of addiction.

JANE PORTER
HERSHEL JICK, M.D.
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Boston University Medical Center
Waltham, MA 02154

1. Jick H, Miettinen OS, Shapiro S, Lewis GP, Siskind Y, Slone D. Comprehensive drug surveillance. JAMA. 1970; 213:1455-60.
2. Miller RR, Jick H. Clinical effects of meperidine in hospitalized medical patients. J Clin Pharmacol. 1978; 18:180-8.

77. The Porter-Jick Letter does not reflect any study, but simply describes a review of the charts of hospitalized patients who had received opioids. Both the authors of the letter[75] and

[74] *See, e.g.*, Lawrence Robbins, *Long-Acting Opioids for Severe Chronic Daily Headache*, 10(2) Headache Q. 135 (1999); Lawrence Robbins, *Works in Progress: Oxycodone CR, a Long-Acting Opioid, for Severe Chronic Daily Headache*, 19 Headache Q. 305 (1999).

[75] NPR, *Doctor Who Wrote 1980 Letter on Painkillers Regrets That It Fed The Opioid Crisis* (June 16, 2017), http://www.npr.org/sections/health-shots/2017/06/16/533060031/doctor-who-wrote-1980-letter-on-painkillers-regrets-that-it-fed-the-opioid-crisis.

the *New England Journal of Medicine*[76] have repudiated the misuse of the Porter-Jick letter, but it became a mainstay in scientific literature, with more than 1,000 citations in Google Scholar.[77]

78. Purdue also sponsored flawed studies that were published in the *Journal of Rheumatology*[78] and the *Clinical Journal of Pain*[79] in 1999. Both studies concluded that long-term opioid therapy rarely resulted in addiction despite short trial periods and high drop-out rates.

### c. *Funding and Influencing Professional Associations*

79. Treatment guidelines were particularly important to Purdue in securing acceptance for chronic opioid therapy. Treatment guidelines inform doctors' prescribing practices, are cited throughout the scientific literature, and are referenced by third-party payors when determining which prescriptions should be covered by insurance. Purdue financed and collaborated with three groups, in particular, on guidelines that have been, and continue to be, broadly influential in Vermont and nationwide: the American Academy of Pain Medicine (AAPM), the American Pain Society (APS), and the Federation of State Medical Boards (FSMB).

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[76] http://www.nejm.org/doi/10.1056/NEJM198001103020221.

[77] Purdue has also relied upon the Porter-Jick letter in its marketing efforts. Purdue, for example, has cited it in support of Purdue's patently false marketing claim that "less than 1%" of opioid patients become addicted, most prominently in its 1998 "I Got My Life Back" video. Yet Purdue failed to disclose both the nature of the citation (a letter, not a study) and any of its serious limitations. *See* OxyContin Promotional Video, "I got my life back," Purdue Pharma L.P. (1998), https://www.youtube.com/watch?v=Er78Dj5hyeI.

[78] Jacques R. Caldwell *et al.*, *Treatment of Osteoarthritis Pain with Controlled Release Oxycodone or Fixed Combination Oxycodone Plus Acetaminophen Added to Nonsteroidal Antiinflammatory Drugs: A Double Blind, Randomized, Multicenter, Placebo Controlled Trial*, 26:4 Journal of Rheumatology 862-868 (1999)."

[79] Martin E. Hale *et al.*, *Efficacy and Safety of Controlled-Release Versus Immediate-Release Oxycodone: Randomized, Double-Blind Evaluation in Patients with Chronic Back Pain*, 15(3) Clinical J. Pain 179-183 (Sept. 1999).

**AAPM/APS Guidelines**

80. The American Academy of Pain Medicine and American Pain Soiety each received substantial funding from Purdue. From 2009 to 2012, Purdue gave APS nearly $500,000, and AAPM more than $400,000. An internal Purdue request to its CEO for approval of "2009 funds for AAPM and APS proposals" described each group as "one of our top tiered organizations."

81. In 1997, AAPM and APS issued a consensus statement, "The Use of Opioids for the Treatment of Chronic Pain," that endorsed using opioids to treat chronic pain and claimed that the risk of patients becoming addicted to opioids was low. The co-author of the statement, Dr. David Haddox, was, at the time, a paid speaker for Purdue. He later became a senior executive for the company. Dr. Portenoy was the sole consultant. The consensus statement remained on AAPM's website until 2011. The statement was taken down from AAPM's website only after a doctor complained, though it lingers on the Internet elsewhere.[80]

82. AAPM and APS also issued a 2001 set of recommendations, titled "Definitions Related to the Use of Opioids for the Treatment of Pain," which advanced the unsubstantiated (and since discredited) concept of "pseudoaddiction." The term, coined by Dr. Haddox in a 1989 journal article, reflects the idea that signs of addiction may actually be the manifestation of undertreated pain and will resolve once the pain is effectively treated—*i.e.*, with more or higher doses of opioids.[81] The 2001 AAPM/APS recommendations asserted that "clock-watch[ing]," "drug seeking," and "[e]ven such behaviors as illicit drug use and deception can occur in the

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[80] Available for purchase at http://journals.lww.com/clinicalpain/toc/1997/03000.

[81] David E.Weismann & J. David Haddox, *Opioid pseudoaddiction—an iatrogenic syndrome*, 36 Pain 363-366 (1989).

patient's efforts to obtain [pain] relief." The lack of evidentiary support for this definition has since been exposed and the treatment approach has been definitively discredited.[82]

83. In 2009, AAPM and APS issued comprehensive opioid prescribing guidelines ("2009 AAPM/APS Guidelines"), drafted by a 21-member panel, that promoted opioids as "safe and effective" for treating chronic pain. The panel made "strong recommendation[s]" regarding management of chronic opioid therapy, even while acknowledging "low quality evidence," to support its positions, and it concluded that the risk of addiction is manageable for patients, even patients with a prior history of drug abuse. Six of the panel members, including Dr. Portenoy, received financial backing from Purdue, and another eight received funding from other opioid manufacturers.[83]

84. The 2009 AAPM/APS Guidelines were reprinted in the *Journal of Pain* and widely distributed nationally.[84] The guidelines have been a particularly effective channel of deception and have influenced not only treating physicians, but also the body of scientific evidence on opioids. According to Google Scholar, they have now been cited nearly 1,700 times in academic literature.

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[82] The CDC Guideline makes clear that the scientific literature does not support the concept of pseudoaddiction, explaining that "[p]atients who do not experience clinically meaningful pain relief early in treatment . . . are unlikely to experience pain relief with longer-term use," (CDC Guideline, supra n.61, at 13) and that physicians should "reassess[] pain and function within 1 month" to decide whether to "minimize risks of long-term opioid use by discontinuing opioids" because the patient is "not receiving a clear benefit" (CDC Guideline, supra n.61, at 25).

[83] *See* John Fauber, *Chronic Pain Fuels Boom in Opioids*, Milwaukee Journal Sentinel (Feb. 19, 2012), https://www.medpagetoday.com/neurology/painmanagement/31254.

[84] Roger Chou *et al.*, *Opioid Treatment Guidelines, Clinical Guidelines for the Use of Chronic Opioid Therapy in Chronic Noncancer Pain*, The Journal of Pain, Vol 10, No 2 (February), 2009: pp 113-130.

**FSMB Guidelines**

85. The Federation of State Medical Boards ("FSMB") is an association of the various state medical boards in the United States. The state boards that comprise the FSMB membership, including Vermont's, have the power to license doctors, investigate complaints, and discipline physicians. The FSMB has financed opioid- and pain-specific programs through grants from pharmaceutical manufacturers, including more than $800,000 from Purdue between 2001 and 2008.

86. In 1998, the FSMB developed its *Model Guidelines for the Use of Controlled Substances for the Treatment of Pain* ("FSMB Guidelines"), which the FSMB acknowledged were produced "in collaboration with" pharmaceutical companies and allied groups such as the American Pain Society (a professional society that received funding from Purdue). The FSMB Guidelines stated that opioids "may be essential" for treatment of both acute and chronic pain, but failed to mention risks of respiratory depression and overdose death; addressed addiction only to define the term as separate from physical dependence; and stated that an "inadequate understanding" of addiction can lead to "inadequate pain control."

87. A 2004 iteration of the FSMB Guidelines and the 2007 book adapted from them, *Responsible Opioid Prescribing*, repeated the 1998 version's claims. The book also stated that opioids would improve patients' function and included the now-discredited concept of pseudoaddiction, suggesting that signs of addiction may actually reflect undertreated pain that should be addressed with more opioids.

88. *Responsible Opioid Prescribing* was sponsored by Purdue, among other opioid manufacturers, and Purdue had editorial input into its contents. In particular, Purdue's David Haddox, the inventor of the term "pseudoaddiction," made edits to the book to ensure that pseudoaddiction was presented as an accepted medical concept.

89. Through at least 2015, the FSMB website described the book as the "leading continuing medical education (CME) activity for prescribers of opioid medications." Purdue provided an "educational grant" of $100,000 in 2007—sponsored internally by David Haddox—to support FSMB's distribution of *Responsible Opioid Prescribing* to physicians nationwide through state medical boards.

90. The FSMB Guidelines and *Responsible Opioid Prescribing* were widely distributed in Vermont. The Vermont Board of Medical Practice's first Policy for the Use of Controlled Substances for the Treatment of Pain, published in January 2006, was largely based on the 2004 FSMB model Guidelines.[85] FSMB (with the help of Purdue's grant funding) distributed *Responsible Opioid Prescribing* to 4,412 Vermont prescribers, through the Vermont Board of Medical Practice and other channels. Vermont prescribers interviewed by the State recalled receiving, reviewing, and relying upon the book into the Relevant Period.

## B. Even after the 2007 Vermont Consent Judgment, Purdue's Marketing in Vermont Continued to Misrepresent the Risks and Benefits of Opioids

*Notwithstanding its settlement with the federal government and Vermont, Purdue persisted in misrepresenting the risks and benefits of opioids. Rather than correcting its prior misrepresentations, Purdue built upon them. It stayed largely silent about the serious risks of opioids and continued to miseducate the medical community and public about the benefits and risks of using opioids for chronic pain.*

91. In 2007, Purdue entered into consent decrees with the federal government and numerous states, including Vermont, to resolve investigations into its marketing of OxyContin. As reported by USDOJ, those investigations centered on misrepresentations that OxyContin was less addictive and had less abuse potential than IR opioids, and that patients taking OxyContin

[85] Vermont Board of Medical Practice, *Policy on the Use of Opioid Analgesics in the Treatment of Chronic Pain* (2014), http://www.healthvermont.gov/sites/default/files/documents/2016/12/ADAP_Opioid_Pain_Treatment_Policy_0.pdf, at 1.

could discontinue the drug without withdrawal symptoms. Prospectively, the decrees required Purdue more generally to discontinue all deceptive marketing, including any misrepresentations regarding OxyContin's potential for abuse, addiction, or physical dependence, and to provide a fair balance of risk and benefit information as required by FDA regulations. Specifically, the Vermont Consent Judgment required that all material used in promoting OxyContin be "not inconsistent with the Package Insert, contain only information that is truthful, balanced, accurately communicated, and not minimize the risk of abuse, addiction or physical dependence associated with the use of OxyContin." The Vermont Consent Judgment also required Purdue to disseminate "written, non-branded educational information related to detecting and preventing abuse and diversion of opioid analgesics," the intended purpose of which was to enlist Purdue's considerable financial resources to set the record straight on the abuse and diversion potential of opioids. Instead, Purdue seized a new opportunity to continue deceiving the public regarding the broader risks of dependence and addiction.

92. Notwithstanding its legal commitments to the State of Vermont, Purdue failed to correct its misrepresentations or actually reform its conduct. Purdue built upon its decades-long foundation of deceptive messaging that had established chronic opioid therapy as commonplace and generated billions of dollars in profit for Purdue. Throughout the Relevant Period, Purdue continued to omit discussion of the serious risks of opioids and lack of evidence supporting long-term opioid use—thereby failing to correct its prior deceptions—and to affirmatively under-represent the serious risks and over-represent the benefits of opioids for the treatment of chronic pain.

93. Purdue accomplished much of this through its sales force: the messages they verbally conveyed to healthcare providers, and the materials they showed or distributed to

prescribers, or directed prescribers to review online. Since the launch of OxyContin, Purdue has relied heavily on its sales representatives to market its opioids directly to prescribers, and that practice continues. For example, of the $167 million Purdue spent on promoting opioids nationwide in 2016, $156 million—93.4%—was spent on detailing. By establishing personal relationships with doctors, Purdue's sales representatives were able to disseminate their misrepresentations in targeted, one-on-one settings.

94. At least 26 different Purdue sales representatives have detailed Vermont prescribers since 2006. Purdue set goals that each sales representative should make seven to eight in-person sales calls to prescribers per day. Purdue's own records indicate that its representatives detailed at least 645 Vermont prescribers (a very significant percentage of the several thousand physicians, nurse practitioners, and physician's assistants practicing in the State) between 2006 and 2017. Many of these prescribers were visited repeatedly. Indeed, in that same period, Purdue sales representatives made in excess of 11,000 unique sales visits in Vermont. Purdue assessed sales representatives' performance based on their ability to drive prescribing of its opioids; for example, one former Purdue detailer in Vermont had a sales goal of 1,100 OxyContin prescriptions per month.

95. The content of these sales calls was documented in "call notes," which Purdue expected to be detailed, thorough, and accurate. According to internal sales training documents, sales representatives were instructed to "[p]repare a concise call note that captures the key points of the dialogue between the Representative and the Customer," "ensure that call reporting clearly reflects the sales presentation," "[r]e-read every word of your call report to make sure that it is clear and accurate," "[a]lways review a call note before saving the record to ensure that it

accurately reflects the important events that took place during the call," and complete the call note shortly after the sales call to ensure accuracy.

96. Purdue developed sophisticated plans to select prescribers for sales visits based on their prescribing habits. It purchased and closely analyzed prescription sales data that allowed the company to track prescribing of its opioids and those of its competitors. According to a former Purdue employee who trained and supervised Vermont sales representatives, any prescribing of an opioid—whether Purdue's or a competitor's—could land a prescriber on a detailing target list.

97. Purdue employed the same marketing tactics and messages in Vermont as it did nationwide, using uniform marketing materials and national and regional sales training. Purdue carefully trained its sales representatives to deliver company-approved sales messages. The company exactingly directed and monitored its sales representatives—through detailed action plans, trainings, tests, scripts, role-plays, supervisor tag-alongs, and review of representatives' "call notes" from each visit—to ensure that individual detailers actually delivered the company's desired messages. Purdue likewise required its sales representatives to deploy sales aids reviewed, approved, and supplied by the company.

## C. Purdue's Material Misrepresentations and Omissions: 2010 - present

*Purdue continued to build upon the foundation of deception it had laid in Vermont and nationally. Using unbranded marketing, Purdue carried on its prior deceptions by misleading Vermont prescribers and consumers about the risks and benefits of opioids for long-term pain. Purdue also pushed its sales force to target general practitioners in the State's medical community. Purdue exploited these practitioners' lack of specialized training in pain management to bias them into prescribing their drugs, by misleading them about the effectiveness of their drugs, and failing to discuss with them the dangerous risks of addiction. Purdue also pursued new targets to expand their market: patients who were not taking opioids (the opioid naïve) and the elderly. The Company aggressively marketed low dose OxyContin (10 and 15mg), including for the opioid naïve and elderly—knowing that these doses were no better than a placebo for pain management and carried serious side effects.*

98. Through its sales force and deceptive promotional materials, Purdue continued to misrepresent the risks and benefits of its opioids to Vermont prescribers from the beginning of the Relevant Period until February 2018, when Purdue announced that it would stop promoting its opioid drugs to prescribers. Purdue also expanded the market for its drugs through unfair and deceptive conduct.

99. Purdue faced special challenges in Vermont during this time period, because the State passed legislation that barred pharmaceutical companies from giving gifts—including meals—to healthcare providers and required drug manufacturers to report permissible expenditures like research grants and teaching honoraria. Without the ability to give prescribers access to free meals and other goodies—and with the added requirement that any permissible expenditure would need to be disclosed annually to the Vermont Attorney General in a public report—in-person sales meetings became less reliable for Purdue.

100. In 2013, the year after the Vermont Gift Ban law took effect, Purdue detailer visits to Vermont prescribers plummeted from 1,381 to 384. And yet, Purdue benefitted nevertheless: Vermont prescribers were left to rely on Purdue's older, branded and unbranded marketing materials, which contained some of the worst and most harmful deceptions about opioid therapy for chronic pain, and unbranded websites that Purdue continued to fund and support, like *Partners Against Pain*, *In the Face of Pain*, and the sites of other advocacy and professional groups that were supported by Purdue.

101. Purdue's marketing strategy to increase opioid prescriptions during the Relevant Period focused on two distinct patient groups: keeping existing patients with "continuing" opioid prescriptions, which constituted over 80% of Purdue's sales, and identifying and gaining new patients who were not yet on opioid therapy or were new to the Purdue brand. To maintain

and expand "continuing" prescription patients, Purdue built on its prior deceptions and persisted in (1) misleading prescribers and the public about the benefits of opioids and of its specific opioid products, especially for long-term use, while (2) minimizing the serious risks associated with these drugs, including addiction and overdose. To expand its reach and generate new prescriptions, Purdue took additional steps to (3) expand the market for its opioids.

102. Overall, Purdue's marketing strategy created the impression that opioids were an ordinary and appropriate treatment for many kinds of people, that opioids generally (and OxyContin, specifically) provided meaningful benefits that justified their use, and that the risks of these drugs were minimal (and outweighed by the benefits).

**1. Purdue Misled Prescribers and Consumers About the Benefits of Opioids**

103. Purdue's efforts to promote the benefits of its opioid products were a critical part of Purdue's overall marketing efforts, because the risks of these drugs are so substantial—Purdue needed to persuade prescribers and consumers of the benefits, so that the risks would seem acceptable in comparison. In reality, for many Vermont consumers, Purdue's opioid products exposed them to significant risk of addiction, overdose, and other health problems, while providing no meaningful health benefits.

104. Purdue's deceptive marketing about the benefits of its products focused on (a) reinforcing the supposed benefits of long-term opioid use, in general, and (b) promoting the benefits of OxyContin's unique 12-hour dosing, which differentiated it from its competitors. These marketing messages lacked scientific support and were, in many cases, false.

***a. Peddling the Benefits of Long-Term Opioid Therapy Without Evidence***

105. To convince Vermont prescribers and patients that opioids should be used to treat chronic pain, despite the unavoidable risk of addiction, Purdue had to persuade them that there was a significant upside to long-term opioid use. But as the 2016 CDC Guideline made clear,

there was "insufficient evidence to determine the long-term benefits of opioid therapy for chronic pain." (Emphasis added.) In fact, the CDC found that "[n]o evidence shows a long-term benefit of opioids in pain and function versus no opioids for chronic pain with outcomes examined at least 1 year later (with most placebo-controlled randomized trials ≤ 6 weeks in duration)" and that other treatments were more or equally beneficial and less harmful than long-term opioid use.[86] (Emphasis added.) FDA similarly recognized the lack of scientific support for long-term opioid use, stating in 2013 that it was "not aware of adequate and well-controlled studies of opioid use longer than 12 weeks."[87] Thus, Purdue's ongoing representations, to prescribers and consumers, regarding the benefits of long-term opioid therapy have continued to be misleading and deceptive.

**The Medical Consensus**

106. It is well established—and has been throughout the Relevant Period—that long-term opioid use harms, rather than helps, patient health and wellbeing. Purdue's marketing scheme runs contrary to the real science on the known risks and unproven benefits of long-term opioid use.

107. The available evidence indicates opioids are not effective to treat chronic pain, and may worsen patients' health. As early as 2006, numerous peer-reviewed studies conducted by independent researchers have concluded that: (1) "[f]or functional outcomes, . . . other [non-addictive] analgesics were significantly more effective than were opioids,"[88] (2) increasing

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[86] CDC Guideline, supra n. 61, at 9, 15.

[87] Letter from Janet Woodcock, M.D., Dir., FDA Ctr. for Drug Evaluation and Research, to Andrew Kolodny, M.D., President, Physicians for Responsible Opioid Prescribing (Sept. 10, 2013) https://www.regulations.gov/document?D=FDA-2012-P-0818-0793, at 10.

[88] Andrea D. Furlan *et al.*, *Opioids for chronic noncancer pain: a meta-analysis of effectiveness and side effects*, 174(11) Can. Med. Ass'n J. 1589-1594 (2006).

duration of opioid use is strongly associated with an increasing prevalence of mental health conditions (depression, anxiety, post-traumatic stress disorder, or substance abuse), increased psychological distress, and greater healthcare utilization,[89] and (3) "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."[90] Most recently, the 2016 CDC *Guideline for Prescribing Opioids for Chronic Pain—United States* ("CDC Guideline"), approved by FDA, concluded that "there is no good evidence that opioids improve pain or function with long-term use."[91] (Emphasis added.) The CDC reinforced this conclusion throughout the CDC Guideline, finding that (a) "[n]o evidence shows a long-term benefit of opioids in pain and function versus no opioids for chronic pain with outcomes examined at least 1 year later";[92] (b) "[a]lthough opioids can reduce pain during short-term use, the clinical evidence review found insufficient evidence to determine whether pain relief is sustained and whether function or quality of life improves with long-term opioid therapy";[93] and (c) "evidence is limited or insufficient for improved pain or function with long-term use of opioids for several chronic pain conditions for which opioids are commonly prescribed, such as low back pain, headache, and fibromyalgia."[94] The CDC also noted that the risks of addiction and death "can

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[89] Richard A. Deyo *et al.*, *Opioids for Back Pain Patients: Primary Care Prescribing Patterns and Use of Services*, 24 J. Am. Bd. Fam. Prac. 717-27 (2011).

[90] Andrea Rubenstein, *Are we making pain patients worse?*, Sonoma Medicine (Fall 2009).

[91] CDC Guideline, supra n.61, at 20.

[92] *Id.* at 15.

[93] *Id.* at 18.

[94] *Id.* at 18-19.

cause distress and inability to fulfill major role obligations."[95] As a matter of common sense (and medical evidence), drugs that can kill patients or commit them to a life spent cycling through periods of addiction, abuse, and recovery do not improve their function and quality of life.

108. Purdue long has been aware of the disconnect between the academic literature, which has never assessed efficacy beyond 12 weeks, and the prescribing reality—which Purdue was instrumental in shaping—that many patients use OxyContin and other opioids for many months or years. For example, a 2011 internal email among Purdue researchers discussed the need for "new research studies of not less than 12 months duration to determine the long-term effectiveness of opioids for chronic non-cancer pain"—an acknowledgement that such evidence did not exist.

**Material Misrepresentations and Omissions Regarding Long-Term Use of Opioids**

109. The FDA-approved labeling of Purdue's ER/LA opioids does not address long-term use (*i.e.*, beyond 12 weeks). Relied upon in the first OxyContin label—and still, to this day, the only clinical study Purdue has cited for OxyContin's efficacy in adults—is a two-week study of a scant 133 patients. Yet, Purdue marketed OxyContin with the expectation that health care providers—believing the drug to be appropriate for long-term use—would prescribe it to their chronic pain patients over periods of months or years. The State of Vermont did not uncover, in its review of call notes reflecting thousands of sales visits to prescribers, that detailers disclosed Purdue's lack of evidence supporting the use of opioids for more than 90 days.

110. Routine, chronic pain conditions—like osteoarthritis and lower back pain—continued to be a focus of Purdue's marketing efforts for OxyContin and Butrans. In more

[95] *Id.* at 20.

recent years, sales representatives have used "patient vignettes" or "patient profiles"—brief summaries of the background and medical needs of fictional patients—to illustrate the kinds of patients who should be identified as "good" (according to Purdue) candidates for drugs like OxyContin and Butrans. These vignettes typically featured chronic, long-term health problems as indications appropriate for opioid use. For example, the "Carol" and "Maggie" patient profiles, used to market OxyContin, featured osteoarthritis of the hip and chronic low back pain. The "Scott" and "Pam" patient profiles, used to market Butrans, both featured chronic low back pain due to osteoarthritis. Purdue provided its sales representatives with these and other patient profiles, along with training on their use, and Vermont sales representatives used them in sales calls to Vermont healthcare providers during the Relevant Period.

111. In Vermont, Purdue sales representatives positioned Purdue's opioid products—namely OxyContin and Butrans—*specifically for* long-term pain relief, to encourage healthcare providers to convert patients from short-acting opioids or other pain relievers to Purdue's extended-release opioid products. For example, sales representatives asked prescribers how long they typically wait before transitioning patients from short-acting opioids to an extended-release product, like OxyContin. During one Vermont sales call, for example, the sales representative initiated this discussion, and the prescriber agreed that "he would think about some patients who have been on an IRO [immediate release opioid] way too long."

112. Upon information and belief, sales representatives in Vermont also delivered a national "insight message" crafted by Purdue specifically for use in sales calls—that "according to IMS, a 3rd party prescription data source, 41% of IR hydrocodone/APAP combination prescriptions were associated with a length of therapy lasting 90 days or longer. Of these prescriptions lasting at least 90 days, the average number of days until a patient was converted to

an extended- release opioid was 287." This message implied that long-term use was inappropriate for short-acting opioids, but not so for extended-release opioids, and that such patients should be transitioned to an extended-release opioid like OxyContin.

113. Purdue also reinforced the appropriateness of OxyContin for long-term use through written materials it distributed in Vermont. For example, Purdue's OxyContin *Conversion and Titration Guide*, which sales representatives widely referred to during sales visits and distributed in Vermont, implied that use could continue safely for years. A 2007 version of that guide recommended that "the need for around-the-clock opioid therapy should be reassessed periodically (*e.g.*, every 6 to 12 months) as appropriate for patients on chronic therapy," but did not disclose the absence of evidence supporting safety and efficacy of use for 6 to 12 months. Later versions of this *Guide* omit the parenthetical "(*e.g.*, every 6 to 12 months)" and simply state that prescribers should "periodically reassess the continued need for opioid analgesics." However, Purdue continued to train sales representatives to tell prescribers to periodically reassess "every 6 to 12 months," when prescribing OxyContin, even after this language had been removed from the printed marketing materials, but they did not train representatives to disclose that Purdue had no studies supporting efficacy of use beyond 12 weeks.

114. Purdue and Purdue-sponsored materials distributed nationally reinforce the message that opioids offer benefits to the patient with use that lasts months or even years. The APF-published *Exit Wounds*, a book written as a personal narrative of one veteran recovering from war injuries, asserted unequivocally that "[w]hen used correctly, opioid pain medications increase [a person's] level of functioning" and that opioids "can really help improve your functioning in daily life." APF promoted this book until at least 2011.

115. Purdue also sponsored APF's *A Policymaker's Guide to Understanding Pain & Its Management*, a 2011 publication that falsely claimed that "multiple clinical studies have shown that long-acting opioids, in particular, are effective in improving [d]aily function . . . [and] quality of life for people with chronic pain." *A Policymaker's Guide* cited a single study for this claim – which, upon examination, expressly noted the absence of long-term studies and actually found that "[f]or functional outcomes, . . . other analgesics were significantly more effective than were opioids."[96]

116. Purdue provided substantial funding to, and closely collaborated with, APF in creating *A Policymaker's Guide*. Purdue provided a grant for its development and distribution and kept abreast of the content of the guide as it was formulated. On information and belief, based on Purdue's close relationship with APF and the periodic reports APF provided to Purdue about the project, Purdue had editorial input into *A Policymaker's Guide*.

117. FDA has said for years that opioid manufacturers should not make claims regarding functional improvement and ability to perform daily activities, and FDA has warned Purdue competitors in public letters that such claims lacked substantial scientific evidence.[97]

118. These unsubstantiated and deceptive statements regarding the benefits of long-term opioid therapy misled prescribers and patients into believing that there were advantages to continuing opioid use over many months or even years.

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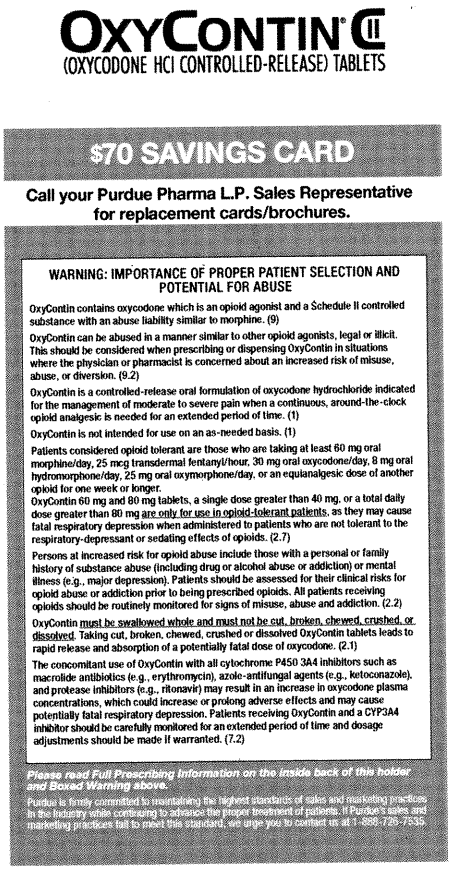
[96] Andrea D. Furlan *et al.*, *Opioids for chronic noncancer pain: a meta-analysis of effectiveness and side effects*, 174(11) Can. Med. Ass'n J. 1589-1594 (2006).

[97] Warning Letter from Thomas Abrams, Dir., FDA Div. of Mktg., Adver., & Commc'ns, to Doug Boothe, CEO, Actavis Elizabeth LLC (Feb. 18, 2010), https://www.fdanews.com/ext/resources/files/archives/a/ActavisElizabethLLC.pdf; Warning Letter from Thomas Abrams, Dir., FDA Div. of Mktg., Adver., & Commc'ns, to Brian A. Markison, Chairman, President and Chief Executive Officer, King Pharmaceuticals, Inc. (March 24, 2008).

## Use of Savings Cards to Encourage Long-Term Use of Opioids

119. Purdue's distribution of Savings Cards for OxyContin and Butrans was part of a deliberate marketing strategy to encourage and increase long-term use of these drugs, well beyond the duration of treatment for which Purdue had scientific support.

120. Purdue promoted "Savings Cards" in Vermont to provide patients with a Purdue-funded discount on their out-of-pocket cost for OxyContin and encourage long-term use of OxyContin:




121. Purdue trained sales representatives to discuss Savings Cards on every sales call. The company also carefully tracked redemption of Savings Cards and evaluated sales representatives on the number of Savings Cards redeemed in their districts.

122. The purpose behind Purdue's emphasis on Savings Cards was to boost the "continuing prescriptions" group of patients—which constituted 80% of its OxyContin sales—beyond 90 days of use. In a 2012 sales training document, Purdue explained that "market research has shown that ~60% more patients stay on therapy >90 days if a savings card is redeemed." Purdue had no research showing the benefits of OxyContin for these longer durations of treatment.

123. Purdue also used Savings Cards to encourage initiation of new patients on its opioids, lowering the barrier of entry by making the drugs cheaper to try. In a 2012 sales training presentation, Purdue described its rationale for subsidizing a $0 (*i.e.*, free) copayment through Savings Cards for new Butrans patients: that a Savings Card was "effectively acting as a sample."

124. Sales representatives routinely distributed OxyContin Savings Cards during their sales visits to Vermont prescribers and pharmacies. Some Vermont healthcare providers declined Savings Cards, expressly referencing the prescriber's concerns about OxyContin use.

125. But Purdue continued to distribute the Savings Cards through marketing efforts in Vermont pharmacies, instructing pharmacists to inform opioid patients about available discounts for OxyContin that would bring the out-of-pocket price down significantly. In 2012, Purdue introduced what it described in internal documents as "new channels" to broaden access to Patient Savings Card Program: "Relay Health," which provided automatic rebates at pharmacies, and downloadable savings cards on PurdueHCP.com. This training document identified the Savings Cards as being downloadable by "HCP"—or healthcare providers, but Purdue sales representatives seem to have encouraged pharmacists to tell *patients* to download the cards directly, as a workaround when prescribers chose not to offer them. In one 2012 sales call to a

pharmacy, the Purdue detailer advised the pharmacy techs about how patients can go online to obtain savings cards "[s]ince the p[re]scribers in town are changing policies about cards."

126. Purdue has long been aware of the State of Vermont's concern that offering free or heavily subsidized opioids to consumers was an unfair business practice. In the 2007 Consent Judgment, Purdue expressly agreed to stop distributing samples of OxyContin in Vermont. Nonetheless, Purdue used the promotion of Savings Cards to eliminate or steeply discount patient co-payments—effectively making these drugs free to patients—as a way to drive long-term use.

**b.** ***Misrepresenting OxyContin's Supposed 12-Hour Dosing***

127. Purdue's key point of differentiation between OxyContin and other opioid pain relievers on the market is its extended-release formulation and "Q12"—or every 12 hour—dosing. However, Purdue consistently overstated the efficacy of this dosing interval while omitting the serious risks associated with it, compared to other alternative pain relievers.

128. Purdue sought FDA approval for OxyContin's 12-hour dosing schedule to maintain a competitive business advantage over more-frequently dosed (*e.g.*, every 8 hours, or as needed) opioids, despite knowing that OxyContin does not provide pain relief for 12 hours in many patients, a phenomenon known as "end of dose failure." Internal Purdue marketing documents indicate that 12-hour dosing was considered key to differentiating the drug from the competition—generic, short-acting opioids that require patients to wake in the middle of the night to take the next dose.[98]

[98] Memo to OxyContin Launch Team (April 4, 1995), available at http://documents.latimes.com/oxycontin-launch-1995/.

129. To convince prescribers and patients to use OxyContin, Purdue misleadingly promoted the drug as providing 12 continuous hours of pain relief with each dose. Purdue relied on labeling that it sought from FDA, and for which the company is legally responsible, directing 12-hour dosing. However, Purdue went well beyond the label's limited instructions to take OxyContin every 12 hours by affirmatively advertising that OxyContin lasts for 12 hours—and by failing to disclose that OxyContin does not provide 12 hours of pain relief to many patients.

130. From the outset, Purdue leveraged 12-hour dosing to promote OxyContin as providing continuous, round-the-clock pain relief with the convenience of not having to wake to take a third or fourth pill. The 1996 press release for OxyContin touted 12-hour dosing as providing "smooth and sustained pain control all day and all night."[99] But FDA has never approved such a marketing claim. To the contrary, FDA found in 2008, in response to a citizen petition by the Connecticut Attorney General, that a "substantial proportion" of chronic pain patients taking OxyContin experienced "end of dose failure."[100]

131. Sales representatives frequently referenced "Q12" dosing as a benefit of OxyContin during sales visits in Vermont. These misrepresentations continued into the Relevant Period in Vermont. Purdue trained its sales representatives to deliver the message of "[p]roven relief with Q12h dosing" to prescribers during sales calls.

132. Twelve-hour dosing is also featured in most OxyContin promotional pieces. A 2012 version of the *Conversion and Titration Guide*, for example, contains the tag line:

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[99] Purdue Pharma L.P., *New Hope for Millions of Americans Suffering from Persistent Pain*, PR Newswire (May 31, 1996), https://assets.documentcloud.org/documents/2815975/Pressreleaseversionone.pdf.

[100] FDA response letter from Janet Woodcock, Dir., Ctr. for Drug Evaluation and Research, to Richard Blumenthal, Conn. Att'y Gen. (Sept. 8, 2008), http://www.purduepharma.com/wp-content/pdfs/fda_response_blumenthal_oxycontin.pdf, at 5.

"Because each patient's treatment is personal / Individualize the dose / Q12 OxyContin Tablets." And a 2014 visual aid used by sales representatives repeatedly refers not merely to OxyContin, but to *"[E]very 12-hour OxyContin"* and *"Every-12-Hour OxyContin Tablets."* None of these pieces discloses that the pain relief from each 12-hour dose will last well short of 12 hours for many patients, leaving prescribers and patients unprepared for end-of-dose failure and the craving for more opioids that the failure creates.

133. Purdue has known, since the launch of OxyContin, that the drug often wears off well short of 12 hours. According to a 2016 *Los Angeles Times* investigation, Purdue's own early studies showed many patients asking for more medication before their next scheduled dose. In one clinical trial, one-third of patients dropped out because the treatment was ineffective. Researchers changed the rules to allow patients to take supplemental short-acting opioids—"rescue medication"—in between OxyContin doses. In another study, most patients used rescue medication, and 95% resorted to it at least once.[101] Prescribers, including prescribers in Vermont, likewise have observed and complained to Purdue sales representatives that OxyContin does not supply 12 hours of pain relief in a significant number of the prescribers' patients. And it was well-known to Purdue that OxyContin was routinely prescribed (including in Vermont) every 8 hours—rather than every 12 hours, as directed. One former Purdue employee, who trained and supervised sales representatives in Vermont, said Purdue knew providers frequently prescribed OxyContin for every 8 hours, tracked statistics on such prescribing, and sought to change it: "We talked about that in almost every meeting, how we were going to try and get people to buy [the 12-hour dosing]."

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[101] Harriet Ryan, Lisa Girion & Scott Glover, *'You Want a Description of Hell?' OxyContin's 12-Hour Problem*, Los Angeles Times (May 5, 2016), http://www.latimes.com/projects/oxycontin-part1/.

134. Purdue's solution to the end-of-dose failure experienced by many patients was to advise prescribers to maintain the 12-hour dosing schedule but to increase the dose of OxyContin. Purdue's sales representatives routinely told doctors in Vermont that, if the Q12 dose didn't last the full 12 hours, the doctor should increase—or "titrate"—the dose, rather than increasing the frequency of dosing. The OxyContin label and the *Conversion and Titration Guide* also advise prescribers that they can increase the dosage to achieve adequate pain relief "as clinical need dictates, while maintaining every 12-hour dosing." Increased opioid dosing poses greater risks, as discussed in Section C(2)(d). However, Purdue's advice to "titrate up" when a patient experienced end-of-dose failure was not accompanied by appropriate warnings regarding the increased risk of addiction associated with higher doses.

135. Purdue's misrepresentations regarding 12-hour dosing—which Purdue has made since 1996 and continued to make at least until 2018, when it stopped promotion of opioids to prescribers through sales representatives—are particularly dangerous because the inadequate dosing helps fuel addiction. End-of-dose failure causes patients to experience the early stages of psychological and physical withdrawal symptoms on a daily basis, followed by a euphoric rush when they take their next dose—leading to a cycle that fuels a craving for OxyContin. For this reason, Dr. Theodore Cicero, a neuropharmacologist at the Washington University School of Medicine in St. Louis, has called OxyContin's 12-hour dosing "the perfect recipe for addiction."[102]

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[102] Harriet Ryan, Lisa Girion & Scott Glover, *'You Want a Description of Hell?' OxyContin's 12-Hour Problem*, Los Angeles Times (May 5, 2016), http://www.latimes.com/ projects/oxycontin-partl.

### 2. Purdue Built on Prior Deceptions to Mislead Prescribers and Consumers about the Known, Serious Risk of Addiction

136. To convince Vermont prescribers and patients that opioids were safe, Purdue built upon its extensive and effective foundation of deceptive marketing and continued to minimize and omit discussion of the risks of long-term opioid use, particularly the risk of addiction. This strategy has been crucial to Purdue's business model, because the vast majority of Purdue's OxyContin sales are for patients who are continuing users of the drug (as opposed to new prescriptions). Deceptively minimizing the risk of addiction also was critical to Purdue's efforts to encourage new prescriptions, as prescribers and consumers have become more aware of the opioid epidemic over the last ten years.

137. Purdue trained its sales representatives to deflect questions about addiction into discussions of how to identify "appropriate patients," and to draw distinctions between "physical dependence" and "addiction" to allay prescribers' concerns about addiction risks.

138. Purdue's misrepresentations and omissions, described further below, have reinforced each other to create the dangerously misleading impressions that:

(a) Purdue's ER/LA opioids present a reduced risk of addiction, and even patients who present symptoms of addiction may simply be physically dependent on the drug or have undertreated pain that should be treated with more opioids;

(b) patients at greatest risk of addiction can be identified and vetted out, allowing doctors to confidently prescribe opioids to all other patients and even prescribe to high-risk patients, provided they are closely managed;

(c) the abuse-deterrent formulations of Purdue's opioids both prevent abuse and are inherently less addictive; and

(d) physicians can prescribe steadily higher doses of opioids without added risk.

Each of these misrepresentations has been debunked by FDA and the CDC.

139. These deceptive messages were often delivered in combination and had a cumulative impact.

### a. *Perpetuating the Fiction of "Pseudoaddiction" and Trivializing Addiction Risk*

140. Purdue's sales representatives regularly omitted from their visits to Vermont prescribers any discussion of the addiction risks that are plainly associated with long-term use of opioids. Given that Purdue made admitted misrepresentations between 1996 and 2007, these material omissions were particularly damaging. Purdue did not train its sales force to correct the company's historic, deeply misleading—but highly profitable—message that patients who receive chronic opioid therapy for legitimate pain conditions face only a very small risk of becoming addicted.

141. The messages delivered in Vermont by detailers to prescribers were, as Purdue intended, passed on to patients. Patients receiving substance abuse treatment and whose addiction began with prescriptions for chronic pain often report that they were not warned of the risk they might become addicted to opioids. This is confirmed by national research: A 2015 survey of more than 1,000 opioid patients found that 40% were not told opioids were potentially addictive.[103]

**"Pseudoaddiction"**

142. Purdue represented to Vermont prescribers that red-flag signs of addiction may simply be indicators of medically undertreated pain that should be treated with higher doses. This concept was dubbed "pseudoaddiction" in earlier marketing, and the term persisted in marketing to Vermont prescribers until at least 2014. Even after Purdue stopped calling it "pseudoaddiction," Purdue continued to advance this unsubstantiated and misleading concept.

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

Purdue consistently used this concept to suggest to prescribers that they should prescribe higher doses of opioids when presented with patients who quite clearly exhibit drug-seeking behaviors.

143. As discussed in Section A above, the concept of "pseudoaddiction" was developed by Dr. Haddox, a paid Purdue speaker in the 1990s who went on to become a high-level Purdue executive. Purdue ensured that the term and concept of "pseudoaddiction" appeared in *Responsible Opioid Prescribing*, a reference book that was distributed through the Vermont Board of Medical Practice to prescribers in Vermont. The concept has since been discredited. Nonetheless, Vermont prescribers interviewed during the State's investigation of Purdue's deceptive marketing scheme stated that they currently have in their possession, continue to reference, and rely upon copies of this book.

144. Purdue was aware of growing concerns in the regulatory and medical community that the concept of "pseudoaddiction" was misleading. In 2012, U.S. Senators Baucus and Grassley requested documents and communications about *Responsible Opioid Prescribing* as part of an investigation into whether pharmaceutical companies encouraged and funded efforts by non-profit organizations to promote misleading information about opioids. In 2014, Purdue circulated internally a news article about how *Responsible Opioid Prescribing* and its author had contributed to the rate of deaths and addictions by downplaying the risks of opioids. The notation from James Heim, Senior Director, Public Affairs, on an email accompanying this article said only: "FYI, no action required."

145. Rather than take steps to correct the fundamentally misleading information about "pseudoaddiction" in *Responsible Opioid Prescribing* – which remains in circulation and use by Vermont prescribers to this day – Purdue reinforced the message with its own marketing materials during the Relevant Period through its distribution of a pamphlet entitled "*Providing*

*Relief, Preventing Abuse*." This pamphlet was distributed for the purpose of fulfilling Purdue's obligation under the 2007 Vermont Consent Judgment to provide "written, non-branded educational information related to detecting and preventing abuse and diversion of opioid analgesics," and it was broadly disseminated in Vermont. But rather than provide accurate, non-deceptive information about the risk of abuse and diversion, this pamphlet reinforced the misleading message that drug-seeking behaviors—commonly understood to be symptoms of addiction—are instead signs of benign "pseudoaddiction."

146. The term "pseudoaddiction" persisted in *Providing Relief, Preventing Abuse* through several versions that were distributed in Vermont until February 2014. Subsequent editions of *Providing Relief, Preventing Abuse* omitted the term "pseudoaddiction" but continued to include a description of the phenomenon without using the word, saying "[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."

147. Internal Purdue documents show that the company had engaged in a long-standing debate since at least 2009 about whether to include the term and concept of "pseudoaddiction" in the *Providing Relief, Preventing Abuse* pamphlet, with some senior level employees—including Purdue's Senior Manager for Medical Services—recommending its removal. Nonetheless, the term "pseudoaddiction" was not removed from the pamphlet until its 3rd Edition, distributed in February 2014, and the deceptive and scientifically-debunked concept—that drug-seeking conduct should be interpreted as untreated pain, not addiction—continued to be included in that and subsequent versions.

148. Purdue promoted the concept of "pseudoaddiction" through other extensive, unbranded marketing that it funded or controlled. *Partners Against Pain* is a Purdue marketing imprint consisting of both medical education resources, distributed to prescribers (including Vermont prescribers) by the sales force, and a now-defunct website that, before Purdue shut it down in 2016, was styled as an "advocacy community" for better pain care. *Partners Against Pain* existed since at least the early 2000s and served as a vehicle for Purdue to downplay the risks of addiction from long-term opioid use. Through at least 2013, the *Partners Against Pain* website relied on and directed users to the 2001 Guideline from American Academy of Pain Medicine and American Pain Society, which endorsed the concept of "pseudoaddiction."

149. A *Partners Against Pain* "Pain Management Kit" that debuted in 2009 likewise advocated the "pseudoaddiction" concept, referring prescribers to the 2001 AAPM/APS "Definitions Related to the Use of Opioids for the Treatment of Pain." The kit also introduced another resource—a set of drug abuse screening tools (discussed in Section C(2)(b))—by stating that "[b]ehaviors that are suggestive of drug abuse exist on a continuum, and pain-relief seeking behavior can be mistaken for drug-seeking behavior." Purdue sales representatives have regularly directed Vermont prescribers to the *Partners Against Pain* website and distributed the Pain Management Kit to Vermont prescribers, and Vermont prescribers have used the *Partners Against Pain* website as a prescribing resource.

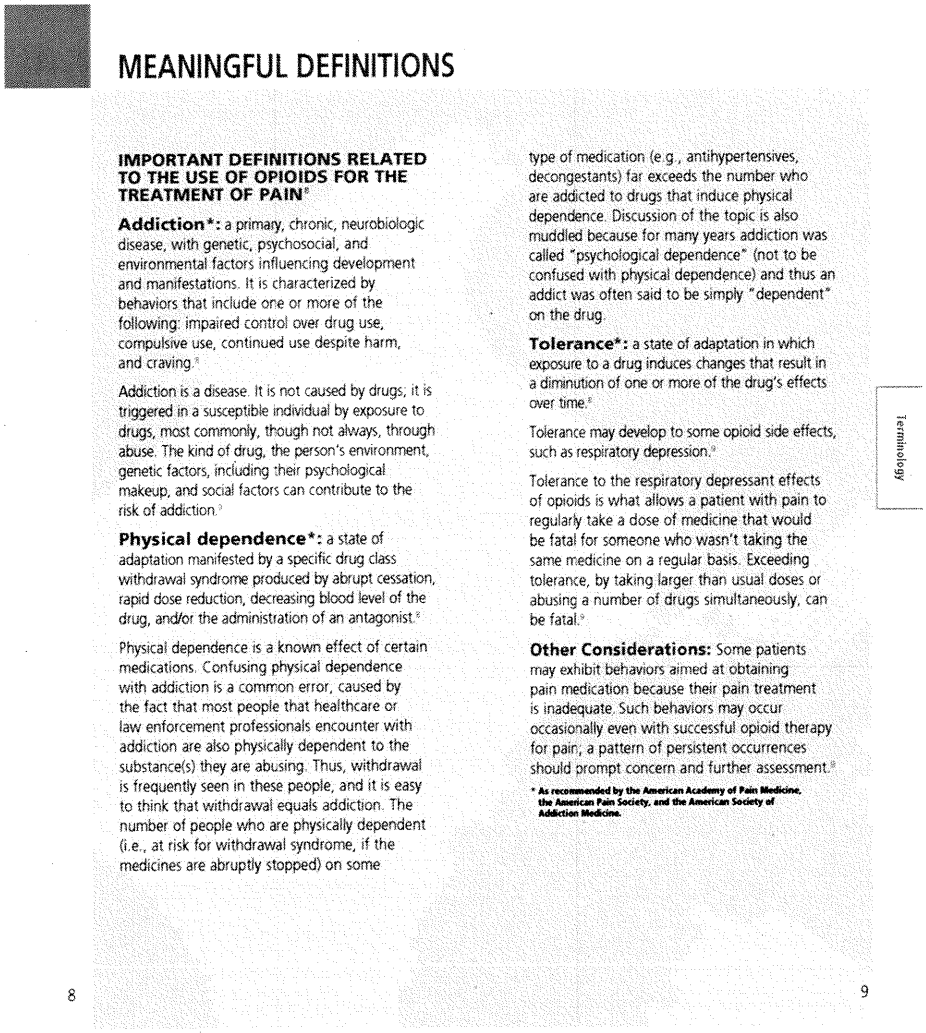
**Distinction between "Physical Dependence" and Addiction**

150. Purdue also attempted to assuage prescribers' concerns about its products by distinguishing between "addiction" (dependence that results in compulsive drug use despite harmful consequences) and "physical dependence" (the body's need for higher doses of the opioid over time and withdrawal symptoms if opioids are discontinued). Purdue described "physical dependence" as a normal consequence of extended opioid use, but failed to disclose

the serious risks and problems associated with physical dependence. Purdue misled prescribers when it drew a distinction between "physical dependence" and "addiction" without fully explaining the risks associated with both conditions—deliberately creating the impression that the negative consequences prescribers (and patients) were worried about would only occur in the context of "addiction."

151. Purdue's omissions about the risks of physical dependence are all the more glaring because the risks are expressly included in the label. The 2013 version of the OxyContin label describes the risk that a patient will experience withdrawal symptoms if OxyContin is discontinued or reduced in dose. The label also states that infants born to mothers physically dependent on opioids will be physically dependent and may experience withdrawal themselves.

152. This misleading and incomplete message minimizing the risks of "physical dependence" was delivered through both sales calls and in written advertising materials. Purdue sales representatives were trained to differentiate between "physical dependence" and "addiction," and sales representatives delivered this message in sales calls to prescribers. Promotional materials and other publications Purdue disseminated or made available in Vermont have included similar, mutually reinforcing messages minimizing the risk of addiction by distinguishing it from "physical dependence."



## MEANINGFUL DEFINITIONS

**IMPORTANT DEFINITIONS RELATED TO THE USE OF OPIOIDS FOR THE TREATMENT OF PAIN**[8]

**Addiction*:** a primary, chronic, neurobiologic disease, with genetic, psychosocial, and environmental factors influencing development and manifestations. It is characterized by behaviors that include one or more of the following: impaired control over drug use, compulsive use, continued use despite harm, and craving.[8]

Addiction is a disease. It is not caused by drugs; it is triggered in a susceptible individual by exposure to drugs, most commonly, though not always, through abuse. The kind of drug, the person's environment, genetic factors, including their psychological makeup, and social factors can contribute to the risk of addiction.[3]

**Physical dependence*:** a state of adaptation manifested by a specific drug class withdrawal syndrome produced by abrupt cessation, rapid dose reduction, decreasing blood level of the drug, and/or the administration of an antagonist.[8]

Physical dependence is a known effect of certain medications. Confusing physical dependence with addiction is a common error, caused by the fact that most people that healthcare or law enforcement professionals encounter with addiction are also physically dependent to the substance(s) they are abusing. Thus, withdrawal is frequently seen in these people, and it is easy to think that withdrawal equals addiction. The number of people who are physically dependent (i.e., at risk for withdrawal syndrome, if the medicines are abruptly stopped) on some type of medication (e.g., antihypertensives, decongestants) far exceeds the number who are addicted to drugs that induce physical dependence. Discussion of the topic is also muddled because for many years addiction was called "psychological dependence" (not to be confused with physical dependence) and thus an addict was often said to be simply "dependent" on the drug.

**Tolerance*:** a state of adaptation in which exposure to a drug induces changes that result in a diminution of one or more of the drug's effects over time.[8]

Tolerance may develop to some opioid side effects, such as respiratory depression.[9]

Tolerance to the respiratory depressant effects of opioids is what allows a patient with pain to regularly take a dose of medicine that would be fatal for someone who wasn't taking the same medicine on a regular basis. Exceeding tolerance, by taking larger than usual doses or abusing a number of drugs simultaneously, can be fatal.[9]

**Other Considerations:** Some 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.[8]

* As recommended by the American Academy of Pain Medicine, the American Pain Society, and the American Society of Addiction Medicine.

Terminology

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153. The *Providing Relief, Preventing Abuse* pamphlet included similar deceptions. It downplayed "physical dependence" as "a known effect of certain medications," citing benign blood pressure medications and decongestants as analogous examples. It also asserted that "physical dependence" and "addiction" are commonly confused.

154. Purdue's distinction between "physical dependence" and "addiction" was especially deceptive in the context of increasing public awareness of the risks of opioid addiction, because it implied that "physical dependence" was less harmful than "addiction." These messages also implied that physical dependence on OxyContin was no more problematic

than physical dependence on blood pressure medication. *Providing Relief, Preventing Abuse* also showed graphic pictures of the stigmata of injecting or snorting opioids—skin popping, track marks, and perforated nasal septa, to illustrate "potential signs consistent with drug abuse." In fact, opioid addicts who resort to these extremes are uncommon; the far more typical reality is patients becoming addicted through oral use. These depictions deceptively reassured doctors that, as long as they do not observe physical signs of snorting or injecting, they need not worry that their patients are abusing or addicted to opioids.

155. Purdue's *Partners Against Pain* website likewise offered misleading and deceptively reassuring distinctions between addiction and physical dependence, presenting addiction as a neurobiological disease and physical dependence as a benign "state of adaptation."

156. In disseminating such messages, Purdue was attempting to remove the stigma of "addiction" that had become linked to its products. This failed to acknowledge the very serious reality that Vermont consumers faced: that no matter what definitions and labels are applied, patients taking opioids are at serious risk of becoming "hooked," needing ever-increasing doses to avoid withdrawal symptoms, and being unable to stop taking opioids.

**Other Unbranded Marketing Minimizing the Risk of Addiction**

157. Purdue disseminated or supported the dissemination of unbranded marketing materials that also minimized the risk of addiction associated with opioids generally.

158. Purdue maintained an online "interactive toolkit" for patients, caregivers, and prescribers—*In the Face of Pain* (www.inthefaceofpain.com)—that deceptively downplayed the risks of chronic opioid therapy. *In the Face of Pain*, which Purdue deactivated in October 2015 following an investigation by the New York Attorney General, was another example of "unbranded" marketing. Although it featured the Purdue copyright at the bottom of each page, the site did not refer to Purdue products in particular and cultivated the impression that it was

neutral and unbiased.[104] As of 2010, the "In the Face of Pain Toolkit" was also available on the *Partners Against Pain* website, which detailers frequently referenced during Vermont sales calls.

159. *In the Face of Pain* asserted that policies limiting access to opioids are "at odds with best medical practices" and encouraged patients to be "persistent" in finding doctors who will treat their pain. As of 2015, while a document linked from the *In the Face of Pain* website briefly mentioned opioid abuse, the site itself did not—even once—mention the risk of addiction, a risk so significant that it requires a black box warning on all opioid drug labels. At the same time, the website contained testimonials from several dozen physician "advocates" speaking positively about opioids. The website failed to disclose that, from 2008 to 2013, Purdue paid 11 of these advocates a total of $231,000.[105]

160. Purdue also continued working closely with allies, such as the American Pain Foundation—a group that, as discussed above, was heavily dependent on funding from Purdue and other pharmaceutical companies—to disseminate misleading, unbranded messages about the risks of opioids.

161. APF's *Exit Wounds* described opioids as the "'gold standard' of pain medications" and minimized the risk of addiction. It emphasized that physical dependence often is mistaken for addiction and claimed 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."

162. APF's *A Policymaker's Guide to Understanding Pain & Its Management* claimed pain generally had been "undertreated" due to "[m]isconceptions about opioid addiction" and

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[104] *In the Matter of Purdue Pharma L.P.*, Assurance No. 15-151, Assurance of Discontinuance (signed August 19, 2015).

[105] *Id.*

asserted, without basis, that "less than 1 percent of children treated with opioids become addicted." In addition to mischaracterizing the risk of addiction, *A Policymaker's Guide* perpetuated the misleading concept of pseudoaddiction, stating that "[p]seudo-addiction describes patient behaviors that may occur when pain is undertreated" and that "[p]seudo-addiction can be distinguished from true addiction in that this behavior ceases when pain is effectively treated"—*i.e.*, with more opioids.

**The True Risks of Opioids**

163. Purdue's claims regarding addiction are contrary to longstanding scientific evidence, and its failures to address the risk of addiction when promoting the use of these drugs are material omissions, given both the magnitude of the risk and the grave consequences of addiction. As confirmed by the CDC in its 2016 Guideline, "extensive evidence" of the "possible harms of opioids (including opioid use disorder [an alternative term for opioid addiction])" exists. The Guideline points out that "[o]pioid pain medication use presents serious risks, including . . . opioid use disorder" and that "continuing opioid therapy for 3 months substantially increases risk for opioid use disorder." (Emphasis added.)

164. Studies have shown that at least 8-12%, and as many as 30% or even 40%, of long-term users of opioids experience problems with addiction.[106] In requiring a new black-box warning on the labels of all IR opioids in March 2016, similar to the warning already required for ER/LA opioids, FDA emphasized the known, "serious risks of misuse, abuse, [and] addiction . . .

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[106] Joseph A. Boscarino *et al.*, *Risk factors for drug dependence among out-patients on opioid therapy in a large US health-care system*, 105(10) Addiction 1776-82 (Oct. 2010); Joseph A. Boscarino *et al.*, *Prevalence of Prescription Opioid-Use Disorder Among Chronic Pain Patients: Comparison of the DSM5 vs. DSM-4 Diagnostic Criteria*, 30(3) J. of Addictive Diseases 185-94 (July-Sept. 2011); Vowles, Kevin E. *et al.*, *Rates of opioid misuse, abuse, and addiction in chronic pain: a systematic review and data synthesis*, Pain 156.4 (2015): 569-576.

. across all prescription opioid products."[107] That same month, after a "systematic review of the best available evidence" by a panel excluding experts with conflicts of interest, the CDC published its *Guideline for Prescribing Opioids for Chronic Pain.*[108] The CDC found that "[o]pioid pain medication use presents serious risks, including overdose and opioid use disorder."[109] The CDC also emphasized that "continuing opioid therapy for 3 months substantially increases risk for opioid use disorder."[110]

**b. *Overstating the Efficacy of Screening Tools***

165. Purdue deceptively promoted screening tools—such as drug testing, pill counts, and patient contracts—as reliable ways to prevent addiction and safely prescribe long-term opioids. While screening tools may help doctors identify the most susceptible patients and identify diversion, and patient contracts convey the gravity of risks and establish protocols to stop diversion, they cannot prevent dependence or addiction from occurring.[111] These misrepresentations provided false assurances to healthcare providers and patients that addiction was avoidable and largely the result of other prescribers' failure to rigorously manage and weed out problem patients who could have been easily identified with screening tools.

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[107] Food and Drug Administration, *FDA announces enhanced warnings for immediate-release opioid pain medications related to risks of misuse, abuse, addiction, overdose and death* (Mar. 22, 2016), http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm491739.htm.

[108] CDC Guideline, supra n.61, at 2.

[109] CDC Guideline, supra n.61, at 2.

[110] CDC Guideline, supra n.61, at 25.

[111] The CDC Guideline confirms the lack of substantial scientific evidence to support Purdue's claims regarding the utility of screening tools and patient management strategies in managing addiction risk. There are no studies assessing the effectiveness of screening tools, patient contracts, urine drug testing, or pill counts—all which were widely promoted by Purdue and believed by doctors in Vermont—"for improving outcomes related to overdose, addiction, abuse, or misuse." CDC Guideline, supra n.61, at 11. In fact, the CDC Guideline recognizes that risk screening tools "show insufficient accuracy for classification of patients as at low or high risk for [opioid] abuse or misuse" and counsels that doctors "should not overestimate the ability of these tools to rule out risks from long-term opioid therapy." *Id.* at 28. (Emphasis added.)

166. Purdue conveyed these messages during in-person sales calls in Vermont. For example, when one prescriber discussed with the Purdue sales representative the increasingly aggressive behavior of his opioid patients and his fears for his staff's safety, the representative emphasized the importance of continuing to prescribe OxyContin for "appropriate patients": *e.g.*, ones who attended scheduled appointments, signed and abided by patient contracts, and complied with urine screens and pill checks.

167. Purdue also promoted the "Opioid Risk Tool" created by opioid advocate Dr. Lynn Webster, who received research funding from Purdue, as part of its *Partners Against Pain* "Pain Management Kit." This "Opioid Risk Tool" is a five-question, one-minute screening tool that relies on honest patient self-reporting (particularly unlikely given the sensitive topic and the nature of addiction) to purportedly allow doctors to manage the risk that their patients will become addicted to or abuse opioids. Sales representatives distributed the kit in CD ROM format to prescribers in Vermont, and frequently directed prescribers to the *Partners Against Pain* site throughout the Relevant Period.

168. Purdue promoted screening tools as a reliable means to manage addiction risk in CME and scientific conferences available to Vermont prescribers. In 2011, Purdue sponsored a CME taught by Dr. Lynn Webster via webinar titled "Managing Patient's Opioid Use: Balancing the Need and Risk." This presentation deceptively instructed prescribers that screening tools, patient agreements, and urine tests prevented "overuse of prescriptions" and "overdose deaths." Purdue also funded a 2012 symposium called "Chronic Pain Management and Opioid Use: Easing Fears, Managing Risks, and Improving Outcomes," which taught doctors that, through the use of screening tools, more frequent refills, and other techniques, even high-risk patients showing signs of addictive behavior could be safely treated with opioids.

### c. *Exaggerating the Efficacy of Abuse-Deterrent Properties*

169. Since 2010, Purdue deceptively marketed its abuse-deterrent opioids—a reformulated version of OxyContin and Hysingla ER—to Vermont prescribers in a manner that falsely implies that these abuse-deterrent drugs can curb abuse and even addiction. In truth, all these reformulations do is make it harder to crush the pill. This does nothing to protect against the most common form of abuse, which is via oral ingestion.

170. Oral abuse of prescription opioids includes not only taking the drugs without a prescription, but also taking higher or more frequent doses than prescribed. Rather than focus on the oral abuse associated with the widespread prescribing of OxyContin for chronic pain, Purdue tied abuse and addiction to less common illegal product diversion and abuse via snorting or injecting the drug. Purdue's proffered solution—introduced as an abuse-deterrent formulation in 2010—was a new pill coating and other elements to make its opioids more difficult to crush or inject (*i.e.,* making it tamper resistant). Purdue misleadingly assured prescribers that they could prescribe Purdue's opioids without contributing to the epidemic of misuse and abuse.

171. FDA approved the reformulated OxyContin in 2010.[112] In its medical review of Purdue's application, however, 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 HCI is still relatively easily extracted."[113] (Emphasis added.)

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[112] Center for Drug Evaluation and Research Approval Package for NDA 22-272, Apr. 5, 2010, https://www.accessdata.fda.gov/drugsatfda_docs/nda/2010/ 022272s000Approv.pdf.

[113] Center for Drug Evaluation and Research, NDA 22-272, *Summary Review for Regulatory Action* (Dec. 30, 2009), https://www.accessdata.fda.gov/drugsatfda_docs/nda/2010/022272s000MedR.pdf, at 7.

172. Purdue regularly cites its introduction of abuse-deterrent opioids as evidence of its commitment to addressing the opioid crisis, as described in Section C(2)(c). In fact, the tamper-resistant reformulation, and the change in labeling, made Purdue richer by solving an inconvenient business problem: how to keep the money flowing after April 2013, when OxyContin's patent was set to expire. Generic versions of OxyContin had become available in February 2011, threatening to erode Purdue's share of the long-acting opioid market and decrease the price Purdue could charge. However, Purdue convinced FDA in April 2013 that original OxyContin—which Purdue had designed and promoted for years—should be removed from the market as unsafe because it lacked abuse-deterrent properties. The impact was that generic equivalents of the old formulation could not be sold, once again securing brand exclusivity for OxyContin and Purdue through at least 2017.

173. Purdue also uses the abuse-deterrent properties of its opioids as a primary selling point to differentiate its products from its competitors, including generic short-acting opioids. As recently as 2015, internal sales training documents characterize the "abuse-deterrence labeling" as one of four "Strategic Pillars" for achieving OxyContin sales goals, directing Purdue employees to "[e]levate the importance of abuse deterrence as a key driver for [extended-release opioid] prescribing."

174. However, Purdue knew or should have known that its abuse-deterrent drugs still are regularly tampered with and abused. In online forums such as bluelight.org and Reddit, drug abusers discuss a variety of ways to tamper with OxyContin and Hysingla ER, including by grinding the pills, microwaving then freezing them, or dissolving them in soda or lemon juice. Indeed, a citizen petition submitted by another pharmaceutical firm in 2016 challenged Purdue's abuse-deterrent labeling based on the firm's ability to easily process OxyContin for snorting or

injection.[114] And a 2015 study by researchers at Washington University in St. Louis found that many addicts continued to abuse reformulated OxyContin. Of the survey respondents who continued to abuse the drug, most either continued with or switched to oral abuse, while roughly one-third found various methods to continue snorting or injecting it.[115]

175. There remains no substantial scientific evidence that Purdue's abuse-deterrent opioids actually reduce opioid abuse. As the CDC Guideline states, "[n]o studies" support the notion that "abuse-deterrent technologies [are] a risk mitigation strategy for deterring or preventing abuse," and the technologies—even when they work—"do not prevent opioid abuse through oral intake, the most common route of opioid abuse, and can still be abused by non-oral routes."

176. Because of their questionable benefits, any discussion of abuse-deterrent technologies has a high potential to mislead practitioners and patients and create a false sense of security about prescribing opioids, particularly for long-term use. In a 2014 survey of 1,000 primary care physicians, nearly 50% reported that they believed abuse-deterrent formulations of opioids are inherently less addictive.[116] One-third of the doctors in that same study had the mistaken impression that most prescription pill abuse is by means other than swallowing the pills.

177. Purdue's deceptive marketing of the benefits of its abuse-deterrent formulations was particularly dangerous because it persuaded doctors—who might otherwise have curtailed

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[114] Citizen Petition to FDA by Pharmaceutical Manufacturing Research Services, Inc., Feb. 19, 2016, Docket No. FDA-2016-P-0645.

[115] Theodore J. Cicero & Matthew J. Ellis, *Abuse-Deterrent Formulations and the Prescription Opioid Abuse Epidemic in the United States: Lessons Learned from OxyContin*, 72(5) JAMA Psychiatry 424-430 (May 2015).

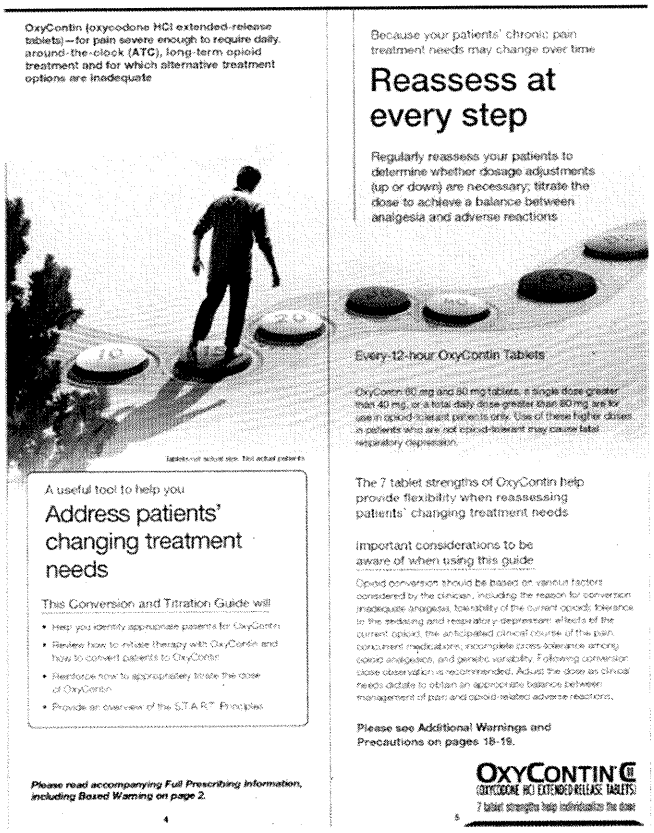
[116] Catherine S. Hwang *et al.*, *Primary Care Physicians' Knowledge and Attitudes Regarding Prescription Opioid Abuse and Diversion*, 32(4) Clinical J. Pain 279-284 (Apr. 2016).

their opioid prescribing—to continue prescribing Purdue's opioids based on misleading assurances and deceptive implications that they are safer. It also allows prescribers and patients to discount evidence of opioid addiction and attribute it to other opioids that don't have tamper-resistant properties—*i.e.*, to believe that while patients might abuse or overdose on non-abuse-deterrent opioids, Purdue's opioids do not carry that risk.

**d. *Failing to Disclose the Increased Risk of Higher Doses***

178. Purdue also misled Vermont prescribers and consumers by stating that opioids can be taken at ever-increasing doses for better pain relief without any maximum dosage cap, without disclosing that higher doses carry greater risk of addiction and overdose. Further, as described in more detail in Section C(1)(b), Purdue encouraged physicians to increase the dose of OxyContin rather than prescribe it more than 2x daily, despite knowing that higher doses posed greater risks and that OxyContin often did not provide 12 hours of pain relief.

179. The ability to escalate doses ("titrating up") was critical to Purdue's efforts to market opioids for long-term use to treat chronic pain. Unless doctors felt comfortable prescribing increasingly higher doses of opioids to counter tolerance to the drugs' effects, they may not have chosen to initiate opioid therapy at all. Numerous Purdue marketing materials depict the seven OxyContin tablet strengths—in a line or even a series of steps—and instruct prescribers that they can titrate, *i.e.*, increase the dose, "as clinical need dictates." Purdue's *Conversion and Titration Guide*—frequently distributed to prescribers in Vermont during the Relevant Period—reiterated the message that there was "no defined maximum daily dose" for OxyContin.




180. Through at least June 2015, Purdue's *In the Face of Pain* website promoted the notion that if a doctor did not prescribe, in the patient's opinion, a sufficiently high dose of opioids, the patient should find another doctor who would.

181. *A Policymaker's Guide* asserted that dose escalations—even when unlimited—are "sometimes necessary." The publication did not disclose the risks from high doses of opioids.

182. Purdue also was deceptive in the way it compared the risks of opioids to the risks of other pain relievers, like non-steroidal anti-inflammatory drugs ("NSAIDs" like Advil) and acetaminophen (Tylenol). The company sponsored a 2013 CME titled "Overview of Management Options" that highlighted the evidence of adverse effects from high doses of NSAIDs but did not discuss the increased risk from using high doses of opioids. The CME was edited by Dr. Russell Portenoy, who received research support, honoraria, and consulting fees from Purdue. Issued by the American Medical Association in 2013, the CME remains available

from the American Medical Association ("AMA") online.[117] Purdue also sponsored a pain pamphlet for physician assistants that similarly emphasized the risk of liver damage from acetaminophen at higher doses, while omitting any comparable discussion of the risks of opioids at high doses.

183. Even where Purdue marketing materials acknowledged that certain risks rose with the dose, they failed to disclose the increased risk of addiction. For example, the *Conversion and Titration Guide* stated that "the ceiling to analgesic effectiveness is imposed only by side effects, the more serious of which may include somnolence and respiratory depression."

184. There is no substantial scientific evidence that doses of opioids can be continuously titrated upward without significant added risk. On the contrary, the risk of addiction, overdose, and death are increased when patients are prescribed higher doses of prescription opioids.[118] Patients receiving high doses of opioids as part of long-term opioid therapy are 3x to 9x more likely to suffer overdose than those on low doses.[119] For example, in 2015 in Vermont, over 80% of individuals with opioid prescription histories who suffered opioid-related accidental fatalities had received high dose (at least 90 MME) analgesics in the five years prior to death.[120]

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[117] American Medical Association, *Pain Management – Overview of Management Options*, https://cme.ama-assn.org/activity/1296783/detail.aspx (last visited 8/3/18).

[118] National Institute on Drug Abuse, *Improving Opioid Prescribing*, last updated March 2017, https://www.drugabuse.gov/publications/improving-opioid-prescribing/improving-opioid-prescribing; Centers for Disease Control and Prevention, *Calculating Total Daily Dose of Opioids for Safer Dosage*, last visited Aug. 6, 2018, https://www.cdc.gov/drugoverdose/pdf/calculating_total_daily_dose-a.pdf.

[119] Kate M. Dunn *et al.*, *Opioid prescriptions for chronic pain and overdose: a cohort study*, 152(2) Annals of Internal Med. 85-92 (Jan. 19, 2010). Most overdoses were medically serious and 12% were fatal.

[120] *Opioids in Vermont: Prevalence, Risk, and Impact*, supra n.4, at 31.

185. As compared to non-opioid pain remedies, patients develop a tolerance to opioids' analgesic effects more quickly than they develop a tolerance to opioids' depressive effects on respiration. Accordingly, the practice of continuously escalating doses to match pain tolerance can, in fact, lead to accidental overdose even where opioids are taken as recommended.[121]

186. As confirmed by the CDC in its Guideline, research published over the past decade has consistently found that the "[b]enefits of high-dose opioids for chronic pain are not established," while the risks for serious harms are clear and dose-dependent. More specifically, the CDC explains—citing research dating back to 2010—that "there is now an established body of scientific evidence showing that overdose risk is increased at higher opioid doses." The CDC also states that there are "increased risks for opioid use disorder, respiratory depression, and death at higher dosages."

187. The CDC Guideline reinforces earlier findings announced by FDA. In 2013, FDA acknowledged "that the available data do suggest a relationship between increasing opioid dose and risk of certain adverse events." For example, FDA noted that studies "appear to credibly suggest a positive association between high-dose opioid use and the risk of overdose and/or overdose mortality."[122]

188. Because of these risks, the CDC Guideline advises doctors to "avoid increasing doses" above 90 morphine milligram equivalents (MME) per day. Yet, many patients continue to receive dangerously high doses of opioids, and every dosage of OxyContin available on the market imposes increased risks (compared to lower-dose analgesics) on patients. Of the seven

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[121] *See* Laxmaiah Manchikanti *et al.*, *Opioid Epidemic in the United States*, supra n.1 (60% of opioid overdoses prescribed were within guidelines).

[122] Letter from Janet Woodcock, M.D., Dir., FDA Ctr. for Drug Evaluation and Research, to Andrew Kolodny, M.D., President, Physicians for Responsible Opioid Prescribing, supra n.87.

available OxyContin tablet strengths, the three strongest all exceed the CDC guideline limit when taken (as directed) twice daily: 40-mg (120 MME per day), 60-mg (180 MME per day), and 80-mg (240 MME per day). Patients on the twice-daily 80-mg dose receive nearly 3x the recommended ceiling of 90 MME. Even patients taking 30-mg of OxyContin twice daily reach the CDC daily maximum of 90 MME. Moreover, the CDC has made it clear that even much lower daily doses—exceeding just 20 MME per day—put patients at increased risk.[123] The lowest strength of OxyContin—the 10-mg tablet strength—exceeds this amount when taken twice daily as prescribed.[124] However, despite the known and growing body of research on the risks of these high-dose opioids during the Relevant Period, Purdue marketed OxyContin, and advocated for doctors to prescribe higher and higher doses to patients, without providing adequate disclosures of the risks these drugs posed.

### 3. Purdue Expanded the Market for its Opioids through Unfair and Deceptive Practices

189. As discussed above, a key component of Purdue's marketing efforts during the Relevant Period focused on expanding the market for its opioid drugs—specifically, OxyContin and Butrans—to generate new prescriptions. Purdue used a variety of strategies to increase the pool of potential customers: (a) focusing the in-person marketing efforts of its sales force on medical generalists, the highest prescribers of opioids in Vermont during the Relevant Period; (b) deceptively marketing OxyContin at low (and ineffective) doses, to overcome barriers to prescribing; (c) targeting elderly and opioid-naïve (not previously treated with opioids) patients; and (d) targeting unbranded marketing at the general public, to stoke demand.

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[123] Centers for Disease Control and Prevention, *Calculating Total Daily Dose of Opioids for Safer Dosage*, https://www.cdc.gov/drugoverdose/pdf/calculating_total_daily_dose-a.pdf.

[124] *Id.*

### a. *Focusing Its Sales Team on High Prescribing Medical Generalists*

190. The overwhelming majority of Purdue's marketing efforts in Vermont focused on prescribers who were generalists—primary care physicians and internists, physician assistants, and nurse practitioners—with less specialized background and experience with opioid therapy and long-term pain management:

**Purdue's VT Detailer Visits, by Specialty (2010-2015):**

| Specialty | # of Detailer Visits | Percentage of Total Visits |
|---|---|---|
| GENERAL PRACTICE & FAMILY MEDICINE | 1,243 | 34.71% |
| INTERNAL MEDICINE | 984 | 27.48% |
| NURSE PRACTITIONER | 364 | 10.16% |
| PAIN MEDICINE | 31 | 0.87% |
| PHYSICIAN ASSISTANT | 520 | 14.52% |
| OTHER SPECIALTIES | 439 | 12.26% |
| Total | 3,581 | |

Purdue's emphasis on generalists was based on—and also likely drove—the large percentage of OxyContin being prescribed by generalists in the State. The overwhelming majority of OxyContin prescriptions during the same time period were written by the same types of prescribers:

**OxyContin Prescriptions in VT, by Specialty:**

| Specialty | # of Prescriptions | Percentage of Total |
|---|---|---|
| GENERAL PRACTICE & FAMILY MEDICINE | 31,049 | 41.75% |
| INTERNAL MEDICINE | 19,081 | 25.66% |
| NURSE PRACTITIONER | 7,109 | 9.56% |
| PAIN MEDICINE | 8 | 0.01% |
| PHYSICIAN ASSISTANT | 7,678 | 10.33% |
| OTHER SPECIALTIES | 9,438 | 12.69% |
| Total | 74,363 | |

191. Vermont prescribing data are consistent with national prescribing data that Purdue tracked and analyzed. For example, in an internal 2015-2016 "Brand Strategy" presentation for OxyContin, Purdue highlighted the fact that primary care prescribers (including nurse practitioners and physician assistants) write 82% of all OxyContin prescriptions.

192. Internal Purdue documents show that this focus on generalists was not coincidence: it was a deliberate marketing strategy. Internal documents show that part of that strategy was to overcome prescriber concerns about their lack of experience treating chronic pain.

193. When primary care physicians began prescribing less OxyContin, Purdue shifted its marketing focus to nurse practitioners and physician assistants. A Purdue Annual Marketing Plan from 2013, for example, states that "[w]hile [primary care physicians] remain the largest group of prescribers of OxyContin, they are also one of the fastest-declining groups. The only specialties still growing are [nurse practitioners] and [physician assistants], which make up the fastest-growing group in both the [extended-release opioid] market and the industry in general." Purdue also believed that nurse practitioners and physician assistants were particularly susceptible to marketing messages, saying "NPs and PAs desperately seek information, typically from sales representatives." Purdue also sought to influence nurse practitioners and physician assistants through their peers, outlining a strategy in 2012 to "[s]trengthen relations with NP & PA thought leaders" as part of an overall effort to enhance Purdue's reach with Key Opinion Leaders.

194. Purdue's marketing to nurse practitioners and physician assistants over the Relevant Period was effective. The percentage of OxyContin prescriptions in Vermont written

by nurse practitioners doubled between 2010 and 2015. The percentage of OxyContin prescriptions in Vermont written by physician assistants nearly tripled over the same time period.

195. Purdue's purposeful targeting of generalists with its deceptive marketing messages was particularly insidious, because of the asymmetry between Purdue's resources and knowledge and those of a practicing doctor. Purdue is an expert in pharmacology, employing numerous scientists and doctors who work full-time on developing, studying, and understanding its pharmaceutical products. Moreover, Purdue operates in a heavily regulated field, in which misrepresenting the benefits and risks of its drugs is illegal. Prescribers generally do not have extensive specialized training in pharmacology. They relied on Purdue to tell the truth when it provided them with information about Purdue's drugs.

**b. *Pitching OxyContin at (Ineffective) Low Doses***

196. Purdue has also deceptively marketed OxyContin at the lower doses—10- and 15-mg—for which the Company has offered no evidence of efficacy. The apparent purpose of these efforts was to overcome barriers to prescribing, such as doctors' and patients' well-founded concerns about the health and addiction risks of the drug.

197. Despite the fact that Purdue built a multi-billion dollar empire based largely on the sale of OxyContin, the actual label for the drug lists only one study showing its efficacy in adults. The results of this study, as printed on the label, state that, "OxyContin 20 mg, but not 10 mg, was statistically significant in pain reduction compared with placebo."[125] (Emphasis added.) Yet, Purdue aggressively marketed OxyContin in both the 10- and 15-mg doses, without informing prescribers of the lack of evidence to support these prescriptions.

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[125] OxyContin ER Full Prescribing Information (last revised 12/2016), https://www.accessdata.fda.gov/drugsatfda_docs/label/2016/022272s034lbl.pdf.

198. Even Purdue's own study showed the 10-mg dose to be no better than placebo for reducing pain. Moreover, 10-mg of OxyContin is—overall—indisputably more harmful than a placebo because of its potential for diversion, its dangerous side effects, and its ability to cause physical dependence—information that Purdue has known since at least 2000. Most patients taking these low and ineffective doses of OxyContin inevitably need to "titrate up" to a higher dose of OxyContin to attain adequate pain relief, as discussed in Section C(2)(d) above.

199. Call notes show that Vermont sales representatives regularly promoted the 10- and 15-mg doses of OxyContin, encouraged their prescription, and worked with prescribers to identify candidates for starting OxyContin on these doses. Purdue trained sales representatives to promote these doses, particularly when they encountered a reluctant prescriber. Purdue specifically evaluated its sales representatives on their ability to increase the number of 10- and 15-mg doses of OxyContin prescribed in their territory. One nurse practitioner interviewed during the State's investigation described the marketing messages about these low doses as prompting a "paradigm shift" in her mind regarding OxyContin prescribing.

200. In its sales training materials, Purdue specifically identified "chronic moderate to severe pain patients" who were opioid-naïve as "appropriate" candidates for the 10-mg dose. These sales messages presumed that the dose would need to be increased over time for these patients, telling sales representatives to "probe to reinforce individualized titration." However, nowhere in these sales messages did Purdue acknowledge that its own research found the 10-mg dose to be no better than placebo at controlling pain.

201. Sales training materials included affirmative misrepresentations about the 10- and 15-mg doses, which detailers across the country—including in Vermont—were instructed to repeat to healthcare providers. A Training Bulletin titled "New to Brand 'The New OxyContin

Patient'" lays out a strategy for marketing lower-dose OxyContin to prescribers who had already prescribed higher doses to some patients. This document instructs sales representatives to "fram[e] the call" by saying "Doctor, I would like to talk to you about your persistent moderate to severe pain patient whose pain can no longer be controlled solely with NSAIDs, and whose pain is now progressing beyond propoxyphene or codeine." It also provides the following "Positioning Benefit Statements" to be used on sales calls with doctors:

> "Doctor, do you realize (or are you aware) that initiating 10 mg of OxyContin q12h is comparable to initiating 5 mg hydrocodone/oxycodone q6h, while also giving the patient all the benefits of less frequent dosing and the fact that OxyContin is a single-entity opioid, containing only oxycodone.
>
> You will be providing a more convenient q12h dosing regimen. Doctor, since these are established opioid patients with persistent ATC moderate to severe pain, doesn't this make sense?

This training document expressly positioned the 10-mg dose of OxyContin as superior to alternatives, even though nothing in this document acknowledges (or instructs sales representatives to explain) that Purdue's own studies show the 10-mg dose to be no more effective than a placebo.

202. In interviews conducted as part of the State's investigation into Purdue's deceptive marketing scheme, Vermont prescribers affirmed that they had not been aware that Purdue lacked evidence to support the efficacy of OxyContin at the 10- and 15-mg doses.

203. Purdue knew this marketing of low-dose OxyContin was deceptive. In 2000, FDA warned Purdue that an advertisement showing the 10-mg OxyContin pill under statements about the drug's efficacy misleadingly implied that the drug was effective at this dose:

> You present the headline, "IN A STUDY OF 133 PATIENTS WITH MODERATE TO SEVERE OSTEOARTHRITIS PAIN*," followed by bulleted claims about this study. This presentation is followed by the product logo for OxyContin along with various doses of OxyContin that are available. This presentation suggests that any dose of OxyContin can be used for the treatment of

> moderate to severe osteoarthritis pain. However, the study only demonstrated OxyContin 20mg given twice daily to be significantly more effective than placebo at day 7 and 14. In fact, Oxycontin 10mg given twice daily was no better than placebo in reducing pain intensity. Therefore, your suggestion that any dose of OxyContin can be used in the treatment of moderate to severe osteoarthritis pain is unsubstantiated, and consequently misleading.[126]

204. Despite this FDA warning, Purdue made similar misrepresentations during the Relevant Period as to the efficacy of the 10- and 15-mg doses for the treatment of pain. Purdue made these representations directly to prescribers, through a visual aid used by detailers during in-office visits that was specifically labeled as "retained" and "not for distribution." This visual aid was sent by Purdue to sales representatives in Vermont during the Relevant Period. These designations ("retained" and "not for distribution") were clearly intended to prevent documents from circulating. On information and belief, the State alleges that Purdue did not want these documents to come to the attention of regulators.

[126] Letter from Food and Drug Administration to Beth Connelly, R.N., Senior Associate Regulatory Affairs, Purdue Pharma (May 11, 2000), available at https://wayback.archive-it.org/7993/20161023000825/http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/EnforcementActivitiesbyFDA/WarningLettersandNoticeofViolationLetterstoPharmaceuticalCompanies/UCM166015.pdf.

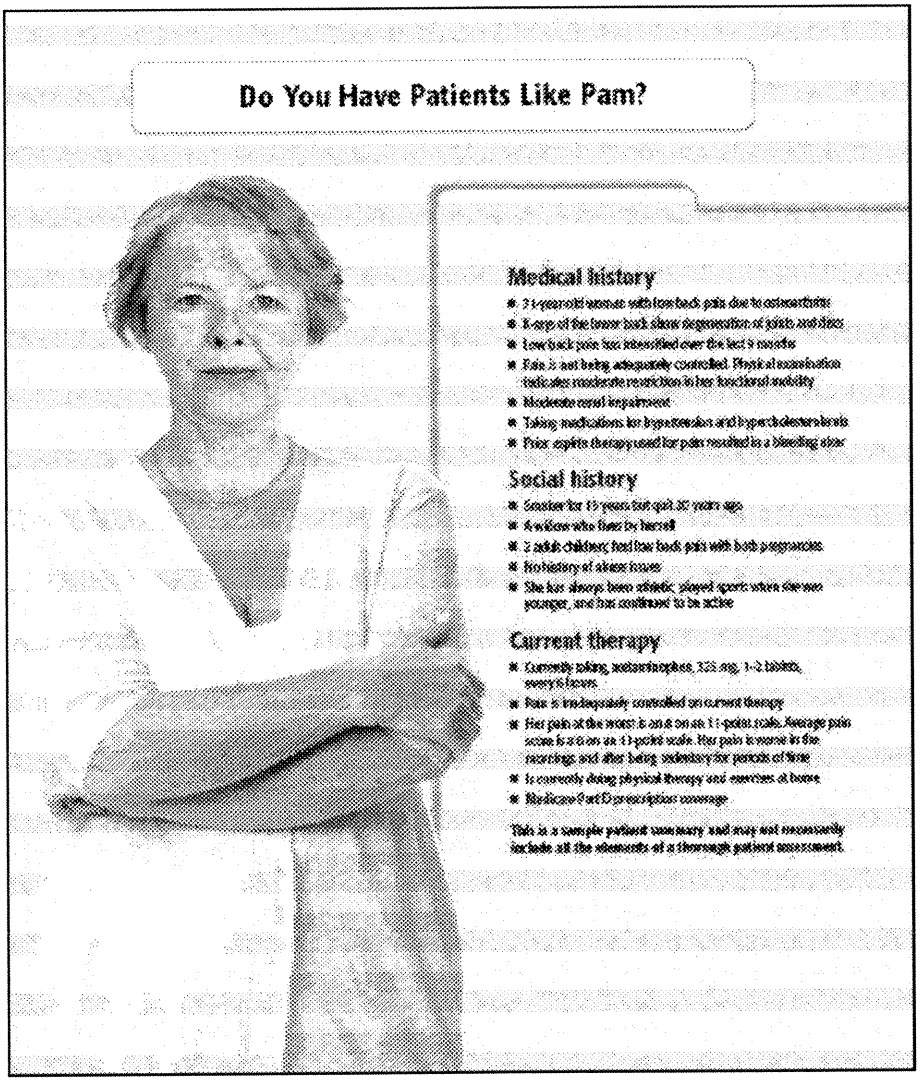

### c. *Targeting Elderly and Opioid-Naïve Patients*

205. Part of Purdue's strategy to continue expanding its market share, and hence its revenue, has been to target two overlapping markets in particular: the elderly, a demographic that has seen an explosion in opioid prescribing in recent years, and opioid-naïve patients—those who had not previously taken opioids.

206. Training materials, reviews of sales representatives, and Vermont detailer call notes include multiple references to Purdue's efforts to persuade doctors to start prescribing its ER/LA opioids to elderly patients.

207. Purdue also used its "patient vignettes" or "patient profiles" to subtly persuade doctors that OxyContin and Butrans were appropriate for their elderly patients, by featuring

fictional patients who were older and/or who suffered from conditions like osteoarthritis that are common in older patients.




208. Purdue's unbranded marketing efforts also targeted elderly patients. For example, *In the Face of Pain*'s publication "The Handbook for People with Pain: A Resource Guide (5th Edition"), available through *In the Face of Pain*'s website, included a section entitled "Special Considerations for Seniors." This section identified "pain in the absence of disease" as a major problem affecting seniors—"experienced daily by a majority of older adults in the United States." It goes on to list problems associated with pain, including "decreased mobility" and

"increased risk for falls and weight loss." It highlights the fact that "most pain can improve with treatment," instructing seniors to speak to their healthcare providers and develop a treatment plan. These unbranded marketing materials were intended to drive demand among elderly consumers for pharmacological pain treatment, including opioid therapy. However, they omit any reference to the risks and side effects of such treatments.

209. Purdue focused heavily on marketing its opioids in Vermont as medications that were covered by insurance plans, with a focus on educating physicians about Medicare Part D (prescription benefit) coverage for opioids, including OxyContin in particular. Sales representatives frequently wrote in call notes that they talked to prescribers about Medicare Part D coverage for OxyContin.

210. Purdue managers and sales representatives also focused detailing efforts on the nursing home market. For example, a call note from a visit to a Vermont pharmacy in May 2010 reflects the pharmacist's suggestion that the sales representative bring copies of the *Conversion and Titration Guide* to area nursing homes. In response text from the sales representative's supervisor, the supervisor stated "Good Call...you were given the names of two homes to focus on, lets [sic] talk about plans for these on our next work session." Other Vermont call notes from 2011 and 2012 discuss sales representatives' efforts to identify and gain access to providers at nursing homes and senior/assisted living facilities.

211. Purdue has targeted seniors for a reason: they have been an important growth sector for the opioid industry. In 2016, one-third of all enrollees in Medicare Part D—over 14.5 million beneficiaries, nationwide—received at least one opioid prescription.[127] And more than

[127] U.S. Department of Health & Human Services Office of the Inspector General, *Opioids in Medicare Part D: Concerns about Extreme Use and Questionable Prescribing*, HHS OIG Issue Brief (July 2017), https://oig.hhs.gov/oei/reports/oei-02-17-00250.pdf, at 1.

500,000 enrollees nationwide were on a high dose of at least 120 MME—well above the CDC's recommended maximum dosage of 90 MME.[128] These high doses underscore the eventuality that elderly patients will not simply remain on OxyContin 10-mg but will require escalating amounts—which come with escalating dangers and side effects that are particularly acute in the elderly.

212. Purdue's targeting of elderly patients overlapped with Purdue's broad marketing push to persuade doctors to prescribe OxyContin to opioid-naïve patients—even when faced with reluctant practitioners.

213. Sales representatives regularly suggested 10- and 15-mg OxyContin for elderly and opioid-naïve patients, without disclosing that Purdue had no evidence of efficacy at those doses. For example, during one sales call in April 2010, a sales representative wrote that she "[r]eviewed [OxyContin] newer strengths and IR to ER conversion guide, explained 10mg q12h is indicated for op[i]oid naive pts and well covered on part d. He will consider for his elderly." Another sales representative wrote in call notes in 2013 that he would ask providers about initiating opioid-naïve patients at the 10-mg dose: "Would it surprise you to know that an opioid naïve patient could be started on OxyContin 10 mg Q 12.?" None of these call notes indicate that sales representatives disclosed that OxyContin was no more effective than placebo at that dose.

214. Purdue's decisions to target the elderly and opioid-naïve patients reflect a business strategy that placed little value on the well-being and safety of consumers. For patients in these populations, opioid treatment generally—and especially OxyContin treatment—imposes significant risks and should be undertaken only if less-risky analgesics prove ineffective. .

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[128] *Id.*

215. Elderly patients taking opioids are at greater risk for fracture and hospitalization, and they have increased vulnerability to adverse drug effects such as respiratory depression, which Purdue acknowledges in its opioids' labels (but not in its marketing).[129] Elderly patients who use opioids also have a significantly higher rate of death, heart attacks, and strokes than users of NSAIDs.[130] The severity of these risks is increased with OxyContin treatment—which involves a higher opioid dose than as-needed opioids or opioid combination drugs—because the risks associated with opioids are dose-dependent. (*See* Section C(2)(d).)

216. Purdue's specific focus on opioid-naïve patients was likewise unwarranted, in light of the steady stream of information over the past decade emphasizing (as the CDC summarized in 2016), that "for the vast majority of patients, the known, serious, and too-often-fatal risks far outweigh the unproven and transient benefits [of opioids for chronic pain]."[131] Such risks are simply not warranted for most opioid-naïve patients. Other, less-risky analgesics are available on the market for opioid-naïve patients needing pain relief, including non-opioid pain relievers.

217. Nonetheless, through its marketing efforts, Purdue sought to capture elderly and opioid-naïve patients as a critical customer base that would grow Purdue's profits by continuing to require opioids as they became dependent on and/or addicted to these dangerous drugs.

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[129] OxyContin ER Full Prescribing Information (last revised 12/2016), https://www.accessdata.fda.gov/drugsatfda_docs/label/2016/022272s034lbl.pdf; OxyContin & Hysingla labels; Hysingla ER Full Prescribing Information (revised 12/2016), https://www.accessdata.fda.gov/drugsatfda_docs/label/2016/206627s004lbl.pdf; Kathleen W. Saunders, *et al.*, *Relationship of opioid use and dosage levels to fractures in older chronic pain patients*, J Gen Intern Med 2010; 25:310-5 (April 2010).

[130] *Relationship of opioid use and dosage levels to fractures in older chronic pain patients*, supra n.129.

[131] Thomas R. Frieden & Debra Howry, *Reducing the Risks of Relief—The CDC Opioid-Prescribing Guideline*, 374 New Eng. J. Med. 1501, 1503 (Apr. 21, 2016).

### d. *Marketing Directly to the General Public, to Drive Demand*

218. Through the *Partners Against Pain* website, Purdue spoke directly to patients and caregivers, encouraging patients to demand effective pain treatment and telling caregivers that they have a responsibility to advocate for "access to appropriate and effective pain care."

219. Purdue re-launched *Partners Against Pain* in 2010, with a re-designed website and celebrity spokesperson campaigns. These campaigns were effective in driving traffic to the website: the number of visitors doubled between October and November 2010, with the addition of content from country music star Naomi Judd and writer Lee Woodruff, the wife of an injured war correspondent. In 2011, after the "Hands On Approach to Pain Management" campaign with *Dirty Dancing* actress Jennifer Grey, site visits went up 542%. Through these campaigns, interviews with Judd, Woodruff, and Grey were widely reported in the news media, including the *Huffington Post*, *Woman's Day*, and *Parade*.


220. The re-designed Purdue's *Partners Against Pain* website provided numerous resources that Purdue positioned as helping consumers talk to their doctor about their pain and treatment options. Purdue suggested that consumers review and even complete the pain assessment tools that their doctor will use to evaluate their pain. Purdue also directed consumers to maintain a daily pain log to take to their doctor, providing numerous samples for patients to

download. In a brochure available on the *Partners Against Pain* website, Purdue provided a list of model questions for patients to ask their doctor, including questions about the proper storage and disposal of their medication, side effects of the medication, and drug interactions. But any discussion of the risks of opioids, in particular the risk of addiction, was conspicuously missing from the suggested list of questions patients should ask their doctors.

221. Elsewhere on the *Partners Against Pain* website, Purdue instructed patients to talk to their doctors if their current medication was not working and "adjust [their] pain management plan accordingly." Purdue omitted any mention of the serious risks associated with increasing the dosage level of opioids.

222. By designing the *Partners Against Pain* site for consumers, and communicating directly to consumers on the website, Purdue stoked consumer demand for its opioids—which it knew to be highly addictive—by creating an atmosphere of broad entitlement to pain medication. Purdue also used this website to coach consumers on how to ask for—and document the need for—pain medications like opioids. However, this website presented only part of the story to consumers, because it did not advise them of the serious risks of these drugs.

## D. Purdue Deliberately Continued its Misinformation Campaign, While Concealing its Deceptive Conduct from Regulators

*Despite agreeing in a 2007 settlement to stop deceptively marketing its opioids, Purdue continued its misconduct during the Relevant Period—fueling the opioid epidemic in Vermont—even though the Company knew it had no evidence about the benefits and effectiveness of opioids for indefinite use in the treatment of chronic pain and that they carried serious risks of abuse and addiction. In the face of growing scrutiny and regulatory efforts, Purdue concealed its ongoing misconduct from regulators.*

223. Purdue made, promoted, and profited from its misrepresentations about the risks and benefits of opioids for chronic pain during the Relevant Period, even though it knew that its marketing was false and misleading. Purdue also actively concealed its unfair and deceptive conduct from regulators and others who were working to curb the growing opioid epidemic.

224. The medical profession's historic understanding of the risks that opioids pose, as well as research and clinical experience over the last 20 years, established that opioids were highly addictive and responsible for a long list of serious adverse outcomes. FDA and other regulators warned Purdue of this, and Purdue entered into settlements in the hundreds of millions of dollars with the United States and numerous states (including Vermont) in 2007 to address similar misconduct. Purdue had access to scientific studies, detailed prescription data, and reports of adverse events, including reports of addiction, hospitalization, and deaths—all of which made clear the harms from long-term opioid use and that patients were suffering from addiction, overdose, and death in alarming numbers.

225. Notwithstanding this knowledge, at all times relevant to this Complaint, Purdue took steps to avoid detection of and to conceal its deceptive and unlawful conduct, and also to conceal or minimize questions or concerns raised by prescribers about addiction.

226. In Purdue's 2007 settlement with Vermont committed that it would not make written or oral claims about OxyContin that were deceptive, and that it would not market OxyContin in a way that was inconsistent with the "Indication and Usage" section of the Package Insert. Purdue also promised to provide "fair balance" statements in its marketing of OxyContin, including statements regarding OxyContin's potential for abuse, addiction, or physical dependence, and that it would not make misrepresentations about OxyContin's potential for abuse, addiction, or physical dependence.

227. However, unbeknownst to the State, Purdue continued its deceptive and misleading marketing. As alleged in greater detail above, Purdue sales representatives rarely discussed the risks of addiction during sales calls, and instead were trained to distinguish it from physical dependence (while omitting key information about the risks of physical dependence)

and "appropriate patient selection" (implying that the risks of dependence and addiction can be avoided through prescriber vigilance). These deflections misleadingly reassured doctors that they could safely prescribe Purdue's opioids long-term for chronic pain without fear of addiction.

228. In fact, only once Purdue was being investigated a second time by the State, did it make an attempt to educate prescribers about the risk of addiction posed by its drugs. There are zero references in the call note records to any addiction materials or handouts provided by Purdue sales representatives to Vermont prescribers prior to October 26, 2016. Yet, suddenly, in the fourteen-month period between October 26, 2016 and December 6, 2017 (the last date for which the State received call note records from Purdue), there are 62 references to a "Risk of Addiction" handout provided to prescribers (the handout was provided in approximately 47% of the 131 Vermont detailer visits that occurred between October 26, 2016 and December 6, 2017).

229. Purdue also disguised its own role in the deceptive marketing of chronic opioid therapy by funding and working through biased science, unbranded marketing, third-party advocates, and professional associations. Purdue purposefully hid behind the assumed credibility of these sources and relied on them to establish the accuracy and integrity of Purdue's false and misleading messages about the risks and benefits of long-term opioid use for chronic pain. Purdue masked or never disclosed its role in shaping, editing, and approving the content of this information. Purdue also distorted the meaning or import of studies it cited and offered them as evidence for propositions the studies did not support.

230. Purdue's public stance long has been that opioid misuse and diversion to illicit secondary channels are to blame for widespread addiction and abuse. But Purdue has consistently failed to address the problems caused by over-prescribing opioids. Instead, Purdue funded various drug abuse prevention programs nationwide and introduced abuse-deterrent

opioids reformulated to make non-oral ingestion more difficult. Purdue also generated papers for presentation at conferences of addiction prevention professionals that stressed the importance of patient selection and touted the efficacy of its "abuse deterrent" opioids. Depicting the opioid crisis as a problem of misuse and diversion, and promoting its pills as solutions, allowed Purdue to present itself as a responsible corporate citizen while continuing to profit from the commonplace prescribing of its drugs, even at high doses for long-term use.

231. At the heart of Purdue's public outreach has been its claim that the Company works hand-in-glove with law enforcement and government agencies to combat opioid abuse and diversion. Purdue has consistently trumpeted this partnership since at least 2008, and the message of close cooperation features in virtually all of Purdue's recent pronouncements in response to public scrutiny of opioid abuse: "[W]e are acutely aware of the public health risks these powerful medications create . . . . That's why we work with health experts, law enforcement, and government agencies on efforts to reduce the risks of opioid abuse and misuse . . . ."[132]

232. Purdue's statement on "Opioids Corporate Responsibility" likewise stated, until recently, that "[f]or many years, Purdue has committed substantial resources to combat opioid abuse by partnering with . . . communities, law enforcement, and government." But Purdue has failed to accurately and diligently report to authorities illicit or suspicious prescribing of its opioids, even as it publicly and repeatedly touted its "constructive role in the fight against opioid abuse" and "strong record of coordination with law enforcement." In responding to criticism of its failure to report suspicious prescribing to government regulatory and enforcement authorities,

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[132] Purdue Pharma L.P., *Opioids With Abuse-Deterrent Properties*, http://www.purduepharma.com/healthcare-professionals/responsible-use-of-opioids/opioids-with-abuse-deterrent-properties/ (last visited Aug. 6, 2018).

Purdue's website similarly proclaimed that Purdue "ha[s] a long record of close coordination with the DEA and other law enforcement stakeholders to detect and reduce drug diversion."

233. These public pronouncements created the misimpression that Purdue is proactively working with law enforcement and government authorities, nationwide and in Vermont, to root out drug diversion, including the illicit prescribing that can lead to diversion. They aimed to distance Purdue from its past, publicly-admonished conduct in deceptively marketing opioids, which gave rise to 2007 criminal pleas, and to make its current marketing seem more trustworthy and truthful. In fact, Purdue has consistently failed to report suspicious prescribing to authorities, despite having all the necessary tools—detailed prescribing data and the eyes and ears of its sales force—to observe such practices.

234. Since at least 2002, Purdue has maintained a database of health care providers suspected of inappropriately prescribing OxyContin or other opioids. According to Purdue, physicians could be added to this database based on observed indicators of illicit prescribing such as excessive numbers of patients, cash transactions, patient overdoses, and unusual prescribing volume. Purdue has said publicly that "[o]ur procedures help ensure that whenever we observe potential abuse or diversion activity, we discontinue our company's interaction with the prescriber or pharmacist and initiate an investigation." According to Purdue, it prohibits the detailing of health care providers added to the database, and sales representatives receive no compensation tied to these providers' prescriptions.

235. Yet, according to a 2016 investigation by the *Los Angeles Times*, Purdue failed to cut off these providers' opioid supply at the pharmacy level—meaning Purdue continued to generate sales revenue from their prescriptions—and failed to report these providers to state medical boards or law enforcement. In an interview with the *Los Angeles Times*, Purdue's

former senior compliance officer acknowledged that, in five years of investigating suspicious pharmacies, Purdue consistently failed to report suspicious dispensing or to stop supplies to the pharmacy, even where Purdue employees personally witnessed the diversion of its drugs. The same was true of prescribers. Despite its knowledge of illicit prescribing, Purdue did not report its suspicions, for example, until years after law enforcement shut down a Los Angeles clinic that Purdue's district manager described internally as "an organized drug ring" and that had prescribed more than 1.1 million OxyContin tablets.[133] The New York Attorney General's settlement with Purdue specifically cited the company for failing to adequately address suspicious prescribing.

236. Purdue thus successfully concealed from the medical community, patients, and the State facts sufficient to arouse suspicion of the claims that the State now asserts. The State was unaware of the existence or scope of Purdue's unlawful conduct and reasonable diligence would not have revealed this information at the time it was occurring. Only by conducting a second investigation of Purdue's marketing conduct, beginning in 2016, was the State able to gain access to information about Purdue's continued deceptive and misleading marketing conduct during the Relevant Period.

## CAUSES OF ACTION

*Purdue deliberately and, for over two decades, perpetuated a disinformation campaign and fraud on the medical community and the public—in the United States generally and in Vermont specifically. Purdue engaged in this deception for its own profit. And Purdue indeed profited—at a high cost to Vermont and its people. Accordingly, the State of Vermont seeks recourse from Purdue for its unlawful conduct.*

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[133] Harriet Ryan *et al.*, *More than 1 Million OxyContin Pills Ended Up in the Hands of Criminals and Addicts. What the Drugmaker Knew*, L.A. Times (July 10, 2016), http://www.latimes.com/projects/la-me-oxycontin-part2/

## COUNT ONE
## DECEPTIVE ACTS AND PRACTICES
## VIOLATIONS OF THE VERMONT CONSUMER PROTECTION ACT

237. The State realleges and incorporates by reference each of the allegations contained in all paragraphs of this Complaint as though fully set forth herein.

238. Defendants engaged in unfair and deceptive trade practices in commerce, in violation of the Vermont Consumer Protection Act, 9 V.S.A. § 2453(a), by making material misrepresentations and omissions regarding the risks and benefits of its opioid products, including by:

(a) making and disseminating false or misleading statements about the use of opioids to treat chronic pain [Purdue's affirmative misrepresentations];

(b) causing false or misleading statements about opioids to be made or disseminated [funding, influencing, and distributing misrepresentations made by third parties];

(c) making statements to promote the use of opioids to treat chronic pain that omitted or concealed material facts [Purdue's material omissions]; and

(d) failing to correct prior misrepresentations and omissions about the risks and benefits of opioids [continuing to market opioids without correcting past misrepresentations].

239. Purdue's statements about the use of opioids to treat chronic pain were not supported by or were contrary to substantial scientific evidence, as confirmed by recent pronouncements of the CDC and FDA based on that evidence. Further, Purdue's material omissions, which were false and misleading in their own right, rendered even seemingly truthful statements about opioids false and misleading because they were materially incomplete. At the time it made or disseminated its false and misleading statements or caused these statements to be made or disseminated, Purdue failed to include material facts about the risks and benefits of long-term opioid use and intended that the recipients of its marketing messages would rely upon those omissions.

240. At all times relevant to this Complaint, Purdue violated 9 V.S.A. § 2453(a) by engaging in deceptive acts or practices, including, but not limited to, the following:

(a) Misrepresenting the benefits and/or efficacy of long-term opioid use;

(b) Mischaracterizing OxyContin's onset of action and duration of efficacy to imply that the drug provides a full 12 hours of pain relief, when Purdue knew it does not.

(c) Mischaracterizing the risk of opioid addiction and abuse;

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

(e) Promoting the misleading concept of pseudoaddiction and drawing distinctions between "physical dependence" and "addiction," for the purpose of concealing the true risk of dependence and addiction and minimizing the risks of dependence;

(f) Claiming or implying that increasing the dose of opioids (titrating up) poses no significant additional risk;

(g) Misrepresenting the efficacy of 10- and 15-mg OxyContin doses;

(h) Targeting deceptive, unbranded marketing at the general public and medical community; and

(i) Exaggerating the efficacy of abuse-deterrent formulations of its drugs.

241. These misrepresentations and omissions were likely to mislead prescribers and consumers, affecting their decisions regarding the prescribing and use of opioids. The meaning Plaintiff ascribes to Defendants' misrepresentations herein is reasonable, given the nature thereof.

242. Purdue also engaged in unfair and deceptive trade practices in commerce, in violation of the Vermont Consumer Protection Act, 9 V.S.A. § 2453(a), because Purdue's affirmative statements were not substantiated by competent and reliable scientific evidence.

## COUNT TWO
## UNFAIR ACTS AND PRACTICES
## VIOLATIONS OF THE VERMONT CONSUMER PROTECTION ACT

243. The State realleges and incorporates by reference each of the allegations contained in all paragraphs of this Complaint as though fully alleged herein.

244. Defendants engaged in unfair acts or practices in commerce, in violation of the Vermont Consumer Protection Act, 9 V.S.A. § 2453(a), by:

(a) Engaging in deceptive, marketing that was unsupported by substantial scientific evidence to support its product claims in violation of 21 C.F.R. § 202.1(e);

(b) Engaging in a marketing campaign that failed, despite the known, serious risks of addiction and adverse effects posed by opioids, to present a fair balance of benefit and risk information in its promotion of opioids, in violation of FDA regulations, including 21 C.F.R. § 202.1(e);

(c) Promoting high doses for extended periods of time, in contravention of longstanding public policy to avoid and minimize the risk of addiction and abuse of controlled substances;

(d) Targeting a vulnerable population—the elderly—for promotion of opioids to treat chronic pain in the face of the known, heightened risks of opioid use to that population, including risks of addiction, adverse effects, hospitalization, and death;

(e) Targeting opioid naïve patients and patients using IR or weaker (Schedule III) opioids for conversion to Purdue's ER/LA opioid products;

(f) Promoting the initiation of opioid use and/or continuation of opioid use beyond 90 days by providing Savings Cards to reduce patients' out-of-pocket expense for these drugs; and

(g) Using unbranded marketing, front groups, and key opinion leaders to evade FDA oversight and rules prohibiting deceptive marketing and to deceive prescribers and consumers regarding the impartiality of the information conveyed.

245. These acts or practices may be deemed unfair in that they offend public policy reflected in (a) the CPA, which protects consumers and competitors from deceptive marketing and to ensure an honest marketplace, and (b) federal law, which requires the truthful and balanced marketing of prescription drugs, 21 C.F.R. § 202.1(e).

246. These acts or practices were unfair because they unethically deprived prescribers of the information they needed to appropriately prescribe—or not prescribe—these dangerous drugs. Patients who use opioids can quickly become dependent and addicted, such that neither the patient nor the prescriber can avoid injury by simply stopping or choosing an alternate treatment.

247. By reason of Purdue's conduct, Vermont consumers have suffered substantial injury by reason of the health risks associated with opioid use, including the pain, and suffering associated with opioid addiction, injury, disability, overdose, and death, as well as the associated financial costs.

**COUNT THREE**
**PUBLIC NUISANCE**

248. Purdue, through the actions described in the Complaint, has created—or was a substantial factor in creating— a public nuisance by unreasonably interfering with a right that is common to the general public and that harms the health, safety, peace, comfort, or convenience of the general community.

249. The State and its citizens have a public right to be free from the substantial injury to public health, safety, peace, comfort, and convenience that has resulted from Purdue's illegal and deceptive marketing of opioids for the treatment of chronic pain.

250. This injury to the public includes, but is not limited to (a) widespread dissemination of false and misleading information regarding the risks and benefits of opioids to treat chronic pain; (b) a distortion of the medical standard of care for treating chronic pain, resulting in pervasive overprescribing of opioids and the failure to provide more appropriate pain treatment; (c) high rates of opioid abuse, injury, overdose, and death, and their impact on Vermont families and communities; (d) increased health care costs for individuals, families,

employers, and the State; (e) lost employee productivity resulting from the cumulative effects of long-term opioid use, addiction, and death; (f) the creation and maintenance of a secondary, criminal market for opioids; and (g) greater demand for emergency services and law enforcement paid for by the State at the ultimate cost of taxpayers.

251. At all times relevant to the Complaint, Purdue's marketing substantially and unreasonably interfered in the enjoyment of this public right by the State and its citizens. Purdue engaged in a pattern of conduct that (a) overstated the benefits of chronic opioid therapy, including by misrepresenting OxyContin's duration of efficacy and by failing to disclose the lack of evidence supporting long-term use of opioids; and (b) obscured or omitted the serious risk of addiction arising from such use. This conduct effected and maintained a shift in health care providers' willingness to prescribe opioids for chronic pain, resulting in a dramatic increase in opioid prescribing and the injuries described above.

252. At all times relevant to the Complaint, Purdue exercised control over the instrumentalities constituting the nuisance—*i.e.*, its marketing as conveyed through sales representatives, other speakers, and publications, and its program to identify suspicious prescribing. As alleged herein, Purdue created, or was a substantial factor in creating, the nuisance through multiple vehicles, including (a) making in-person sales calls that contained false or misleading statements or material omissions; (b) disseminating deceptive advertisements and publications; (c) sponsoring and creating flawed and biased scientific research and prescribing guidelines; and (d) sponsoring and collaborating with third parties to disseminate false and misleading messages about opioids. To the extent Purdue worked through third parties, it adopted their statements as its own by disseminating their publications, and/or exercised control over them by financing, reviewing, editing, and approving their materials.

253. Purdue's actions were a substantial factor in creating the public nuisance by deceiving prescribers and patients about the risks and benefits of opioids and distorting the medical standard of care for treating chronic pain. Without Purdue's actions, opioid use would not have become so widespread, and the opioid epidemic that now exists in Vermont would have been averted or would be much less severe.

254. The public nuisance was foreseeable to Purdue. As alleged herein, Purdue engaged in widespread promotion of opioids in which it misrepresented the risks and benefits of opioids to treat chronic pain. Purdue knew that there was no evidence showing a long-term benefit of opioids on pain and function, and that opioids carried serious risks of addiction, injury overdose, and death. Purdue was positioned to foresee not only a vastly expanded market for chronic opioid therapy as the likely result of Purdue's conduct, but also the widespread problems of opioid addiction and abuse that have, in fact, materialized. Purdue was on notice and aware of signs that the broader use of opioids was causing just the kinds of injuries described in this Complaint.

255. This public nuisance can be abated—in part—through health care provider and consumer education on appropriate prescribing, honest marketing of the risks and benefits of long-term opioid use, addiction treatment, disposal of unused opioids, and other means.

## PRAYER FOR RELIEF

**WHEREFORE**, Plaintiff State of Vermont respectfully requests the Court enter judgment in its favor and the following relief:

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

(b) With respect to Counts 1 and 2, a permanent injunction prohibiting Purdue from engaging in the unfair and deceptive acts and practices described in the Complaint;

(c) With respect to Counts 1 and 2, a judgment requiring Purdue to disgorge all funds acquired and/or retained as a result of any acts or practices found to be unlawful;

(d) With respect to Counts 1 and 2, statutory civil penalties of $10,000 for each violation of the Vermont Consumer Protection Act;

(e) With respect to Count 3, an order providing for abatement of the nuisance that Purdue created or was a substantial factor in creating, enjoining Purdue from further conduct contributing to the nuisance, and damages as compensation for funds the State has already used to abate the nuisance;

(f) The award of investigative and litigation costs and fees to the State of Vermont; and

(g) Such other, further, and different relief as this Court may deem appropriate.

**JURY TRIAL DEMANDED**

The State demands a trial by jury.

Dated: October 26, 2018

Respectfully submitted,

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