SUPREME COURT OF THE STATE OF NEW YORK
COUNTY OF SUFFOLK

THE PEOPLE OF THE STATE OF NEW YORK, by BARBARA D. UNDERWOOD, Attorney General of the State of New York,	:	
Plaintiff	:	**SUMMONS**
v.	:	Index No.: 400016/2018
PURDUE PHARMA L.P., PURDUE PHARMA INC., PURDUE FREDERICK COMPANY, INC.,	:	
Defendants.	:	

TO PURDUE PHARMA L.P., PURDUE PHARMA INC., PURDUE FREDERICK COMPANY, INC.:

YOU ARE HEREBY SUMMONED to answer the attached complaint in this action and to serve a copy of your answer on the Plaintiff's attorney within twenty (20) days after service of this summons, exclusive of the day of service, or within thirty (30) days after service is complete if this summons is not personally delivered to you within the State of New York. In case of your failure to appear or answer, judgment will be taken against you by default for the relief demanded in the complaint. Plaintiff designates Suffolk County as the place of trial.

Dated: Suffolk County, New York
August 14, 2018

BARBARA D. UNDEREWOOD
Attorney General of the State of New York
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SUPREME COURT OF THE STATE OF NEW YORK
COUNTY OF SUFFOLK

THE PEOPLE OF THE STATE OF NEW YORK, by BARBARA D. UNDERWOOD, Attorney General of the State of New York,	
Plaintiff,	**COMPLAINT**
v.	Index No.: 400016/2018
PURDUE PHARMA L.P., PURDUE PHARMA INC., PURDUE FREDERICK COMPANY, INC.,	
Defendants.	

Plaintiff, the People of the State of New York, by its attorney, BARBARA D. UNDERWOOD, Attorney General of the State of New York, respectfully alleges, upon information and belief:

I. Introduction

1. This lawsuit seeks relief on behalf of the residents and government of the State of New York for the years-long deceptive and unlawful practices of Purdue Pharma L.P., Purdue Pharma Inc., and the Purdue Frederick Company (collectively, "Purdue") concerning powerful and highly-addictive opioids sold by the company. Purdue effectively created the market for use of powerful prescription opioids to treat chronic non-cancer pain, and it has dominated that market since the mid-1990s, generating over $30 billion from the sale of its drug OxyContin since it was introduced.[1] To create that market and achieve market dominance, Purdue promoted its opioids heavily, directly and through third parties, in a

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

manner that fraudulently oversold the drugs' efficacy and failed to adequately address the risks – and, as Purdue knew, the actual prevalence – of serious abuse and death presented by its drugs. Through its actions, Purdue and its owners obtained billions of dollars in profits, at the cost of lost lives and tens of billions of dollars in devastation inflicted on communities that are now awash in opioids and their ill effects. Purdue now must pay penalties and damages to the State of New York for its unlawful conduct, disgorge its ill-gotten gains, and abate the resulting harm inflicted throughout New York.

2. Ongoing investigation by New York and other governmental authorities, as well as recent investigative reporting, have revealed the nature, duration, and extent of Purdue's misconduct, despite Purdue's efforts to keep it hidden. Purdue misled regulators in an effort to get and maintain approval to market its long-acting and powerful opioid OxyContin. Purdue represented that OxyContin was potentially less subject to abuse than other opioids when it was aware that the opposite was likely true. It marketed OxyContin and other potent opioids as appropriate for the treatment of certain types of pain, including moderate long-term pain, when it was aware that there was a lack of sufficient scientific support for the safe and effective use of powerful opioids to treat those conditions. As part of its multifaceted and pervasive scheme to deliver misleading and false messages to New York prescribers and patients about opioids, Purdue:

- Misrepresented the extent to which opioids improve function;
- Concealed the link between long-term use of opioids and abuse and addiction;
- Misrepresented the extent to which addiction risk can be managed;
- Masked the signs of addiction by calling them "pseudoaddiction," and encouraged further harm to consumers (and further ill-gotten gains to Purdue) by calling for increased dosages of its opioids for those showing signs of "pseudoaddiction";

- Falsely claimed withdrawal is easily managed;
- Misrepresented or omitted the greater dangers from higher doses of opioids;
- Deceptively minimized the adverse effects of opioids and overstated the risks of alternative therapies for pain relief; and
- Deceptively asserted that that its drug OxyContin provides a full 12 hours of pain relief.

3. Purdue spent over $1 billion on a sales and marketing blitz, unprecedented in the history of controlled substances, which targeted doctors in multiple subspecialities, nurses, physicians' assistants, patients, advocacy groups, accreditation organizations, regulators, and others. It proceeded both directly and through third parties, including through medical professionals it paid to advance Purdue's messaging ("Key Opinion Leaders" or "KOLs"), and third-party organizations and websites that were in some cases secretly funded and/or created by Purdue ("Front Groups") to advance its messages. All of its messages were disseminated widely, through a multitude of conduits, with the intent that the audience would rely on them. For example, Purdue:

- Commissioned a massive sales force to visit or "detail" doctors to push its messaging;
- Disseminated branded promotional materials about its own products to prescribers and patients;
- Disseminated unbranded messaging, which referred to opioids more generally;
- Employed doctors who favored treating pain with opioids as "expert" KOLs to support and perpetuate Purdue's messaging;
- Funded and influenced the content of organizations such as the American Pain Foundation;
- Sponsored and influenced the content of medical education seminars; and

- Influenced the content of treatment guidelines that lacked evidentiary support and disseminated the guidelines to prescribers.

4. Purdue's goals in creating and carrying out the misleading sales and marketing campaign were twofold. First, the company sought to overcome the well-founded historical aversion to overuse of opioids because of their risks of addiction, abuse, and other ill effects on health by encouraging such use in a host of settings in which powerful opioids had not previously been used, including as an initial or routine therapy for the treatment of moderate to severe non-cancer pain.[2] Second, Purdue sought to promote maximum use of its drugs to treat this expanded set of conditions and patients by asserting its drugs' superiority to other treatments for pain, including other opioids. In pursuing both goals, Purdue misleadingly portrayed its opioids as presenting a low risk of addiction when used properly, and its powerful long-acting opioids, including OxyContin, as less subject to abuse, dependency, and addiction than other opioid therapies. Purdue persisted in these misleading claims and others even though the company became aware soon after it began marketing OxyContin that it was in fact creating mass dependency on opioids among its user population and that OxyContin quickly was becoming a favored drug of abuse and being diverted for inappropriate and dangerous uses.

5. Purdue's conduct attracted legal and regulatory enforcement action beginning in 2007, which resulted in various commitments by the company to improve its behavior and desist from its more egregious conduct. For Purdue, however, these run-ins with law

[2] *See, e.g.*, Barry Meier, *Pain Killer: An Empire of Deceit and the Origin of America's Opioid Epidemic* (2d Ed. 2018) (hereinafter, *Pain Killer*). The first edition of *Pain Killer* was published in 2003, well before the scale of the current epidemic, and the extent of Purdue's misconduct, was known. The second edition, published in 2018, reflected significant additional research and updating.

enforcement and regulatory authorities were mere speed bumps requiring it, at most, to moderate some of its behavior even as it persisted in aggressive direct and third party marketing that continued to underplay the risks and overstate the purported benefits of its drugs. The enforcement actions included:

- In 2007, the federal government entered into a global criminal, civil, and administrative settlement with Purdue and three top executives for $635 million, pursuant to which Purdue and the executives pleaded guilty to criminal conduct and committed to rectify the company's misleading marketing activities;

- In that same year, member states of the National Association of Medicaid Control Fraud Units entered into a $600 million settlement with Purdue for "misbranding," and a multistate group consisting of 26 states (not including New York) and Washington, D.C. entered into a $19.5 million settlement with Purdue for the company's failure to adequately disclose that OxyContin posed an unusually high risk of abuse; and

- In 2015, the New York Attorney General's Office entered into an Assurance of Discontinuance ("AOD") with Purdue. The subject matter of the AOD was narrow and focused on Purdue's failure to identify instances of possible abuse, diversion, or inappropriate prescribing occurring at the prescriber offices that were visited by its sales representatives. The AOD also addressed Purdue's support of an unbranded website, "In the Face of Pain," which promoted opioid use and featured testimonials of persons paid by Purdue (but not disclosed). As part of the AOD, Purdue pledged to strengthen its oversight of its sales representatives, bolster its identification and response to signs of abuse, diversion, or inappropriate prescribing by removing prescribers from its sales call lists, and disclose its financial arrangements with individuals on its unbranded websites.

6. Even after these agreements with federal and state authorities, however, and despite its pledges to improve its conduct, Purdue continued to aggressively promote its drugs directly through in-person marketing visits to healthcare providers and facilities (also known as "detailing"), making over 114,000 detailing visits in New York between August 2015 (the

date of the AOD) and December 2017 alone.[3] Although one of the goals of the agreements was to improve Purdue's recognition, reporting, and response to signs of abuse, diversion, or inappropriate prescribing, up until it stopped detailing in February 2018, Purdue typically flagged a prescriber as potentially problematic only when it learned that the prescriber had been arrested or was the subject of an active investigation or disciplinary proceeding. Purdue declined to use available data sources to more robustly target problematic prescribers. Purdue also continued to make sales calls to doctors who were previously disciplined for inappropriate prescribing.

7. In addition, despite New York and others' efforts to make Purdue's unbranded marketing more transparent, Purdue aggressively continued to fund such marketing. As revealed recently in a Congressional investigation, for example, even in 2017 Purdue covertly continued to prop up Front Groups that were, among other things, resisting common-sense efforts to establish national guidelines for the treatment of opioids that could reduce demand for its products.[4]

8. Purdue's deceptive conduct not only contributed to the over-prescription and overuse of Purdue's powerful opioid drugs; it also contributed to dramatic growth in over-prescription of branded and generic opioids more generally.

[3] In February 2018, in response to investigations and litigation by the OAG and other state and local governments, Purdue announced it would stop marketing opioids directly to prescribers. http://www.purduepharma.com/news-media/2018/02/purdue-pharma-l-p-issues-statement-on-opioid-promotion/.

[4] *See* U.S. Senate Homeland Security and Government Affairs Committee, Ranking Member's Office, *Fueling an Epidemic: Exposing the Financial Ties Between Opioid Manufacturers and Third Party Advocacy Groups* (Feb. 12, 2018) (hereinafter, *Fueling an Epidemic*), *available at* https://www.hsgac.senate.gov/imo/media/doc/REPORT-Fueling%20an%20Epidemic-Exposing%20the%20Financial%20Ties%20Between%20Opioid%20Manufacturers%20and%20Third%20Party%20Advocacy%20Groups.pdf.

9. Purdue's misleading efforts to create, dominate, and perpetuate the market for powerful opioids in the treatment of chronic non-cancer pain by overselling the benefits and underselling the risks of powerful opioids directly contributed to New York and other states' dramatic growth in opioid prescriptions, which grew ten-fold nationally over the past 20 years.

10. In 2016, close to 9 million opioid prescriptions were written in New York State alone. Prescription opioids are highly addictive and their users are susceptible to overdose and death. Based on the latest available statistics, in 2016, there were 3,086 deaths from overdoses involving all opioids in New York State. Of these opioid overdose deaths, 2,399 were from opioid analgesics, including the opioids sold by Purdue. Statewide, outpatient emergency department visits and hospitalizations for all opioid overdoses totaled 11,513 in 2016. By the middle of 2016, New York began logging more treatment facility admissions for opioids (105,822) than for alcohol abuse (103,469).

11. Nationally, more than 350,000 people have died from opioid-related overdoses in the United States since 1999; five times as many people died from opioid-related overdoses in 2016 as in 1999.[5] Indeed, in 2016, drug overdoses, over 60 percent of which were caused by opioids, caused more deaths in the United States than gun violence or car crashes, and took more lives than HIV/AIDS at the height of that epidemic. As the Cuomo administration has declared, the opioid epidemic has reached crisis proportions; in 2017, "life expectancy for Americans declined for the second year in a row . . .," the Governor noted, due to a "21 percent increase in drug overdoses. For Americans under 50 years old, drug overdoses, mostly opioid-related, are the leading cause of death."

[5] Opioid Overdose—Understanding the Epidemic, Div. Of Unintentional Injury, Ctrs. For Disease Control & Prevention (Aug. 17, 2017), https://www.cdc.gov/drugoverdose/epidemic/index.html.

12. Purdue's illegal and deceptive acts and practices contributed to a sea change in health care professionals' and the public's perception of opioids in general, and Purdue's drugs in particular, in a manner that eroded appropriate cautions and safeguards concerning powerful opioids and that led to its drugs' over-prescription and overuse. Purdue's acts and practices over the course of almost two decades of aggressive and misleading marketing violated New York law and contributed to the public health disaster with which New York and the nation are now coping.

13. New York and its residents have sustained and continue to suffer enormous harms as a result of the disaster that Purdue's actions helped cause. These harms include the loss of lives and the devastating emotional and financial effects on the loved ones and communities left behind, babies born addicted to opioids, adults unable to work, emergency treatment costs, law enforcement expenses, costs for overprescription and overuse of Purdue's drugs, costs of treatment for substance use disorders, medical examiner expenses, and foster care expenses, among many other costs. The State of New York bears and will continue to bear the primary burden of these costs through its state programs that fund drug treatment, health care, and public services. In fact, even as the volume of opioid prescriptions shows signs of slowing, the costs of treatment continue to escalate.

14. The State of New York brings this action to hold Purdue accountable for unconscionably contributing to this public health and financial crisis. Purdue's deceptive, fraudulent, and unconscionable acts or practices, and the effects thereof, are continuing, will continue, and are likely to recur unless permanently restrained and enjoined. In the pursuit of billions of dollars in profit, Purdue's conduct directly and substantially contributed to the creation of an opioid epidemic – which constitutes a public nuisance – that has caused enormous

public harm in New York and continues to jeopardize the health and safety of New York residents. Left unabated, the opioid epidemic will continue to threaten the health and safety of New York residents. The State of New York, acting on its own behalf and on behalf of its residents, therefore seeks monetary and injunctive relief to abate the public nuisance and halt the threat of future harm, as well as to compensate for and sanction past wrongdoing.

II. Jurisdiction and Parties

15. Plaintiff, the People of the State of New York, by Attorney General Barbara D. Underwood, brings this action pursuant to Executive Law § 63 and General Business Law ("GBL") Article 22-A. Barbara D. Underwood is the Attorney General of the State of New York and is authorized to: institute all actions and proceedings in which the State is interested, N.Y. Executive Law § 63(1), including the common law and statutory claims set forth herein; seek an order that enjoins repeated or persistent fraudulent or illegal business acts or practices and awards damages and restitution for such acts, N.Y. Executive Law § 63(12); and bring an action to enjoin deceptive acts or practices in the conduct of business and to obtain restitution and civil penalties, including additional civil penalties for fraud perpetrated against the elderly. GBL §§ 349, 349-c, 350, 350-d.

16. Purdue Pharma L.P. is a limited partnership organized under the laws of Delaware with its principal place of business in Stamford, Connecticut. Purdue Pharma Inc. is a New York corporation with its principal place of business in Stamford, Connecticut, and The Purdue Frederick Company, Inc. is a New York corporation with its principal place of business in Stamford, Connecticut. These defendants collectively are referred to herein as "Purdue."

17. Purdue manufactures the opioids OxyContin, MS Contin, Butrans, Hysingla ER, Dilaudid, and Dilaudid-HP. Purdue promotes, markets, advertises, and sells these opioids in

New York. Purdue regularly conducts business within the State of New York and derives substantial revenues from goods sold and/or consumed in New York.

18. The Attorney General provided Purdue with the pre-litigation notice required by GBL §§ 349(c) and 350-c on June 12, 2018.

III. Purdue Promoted its Opioids, Including OxyContin, in a Repeated and Persistent Illegal and Deceptive Manner

A. Opioids are Highly Addictive and Dangerous Narcotics

19. Opioids are powerful narcotic painkillers that include non-synthetic, partially synthetic, and fully-synthetic derivatives of the opium poppy.

20. Opioids have addictive properties and are subject to abuse. Due to concerns about their addictive properties, opioids have been regulated at the federal level as controlled substances by the U.S. Drug Enforcement Administration ("DEA") since 1970.

21. Medical research has shown that opioids, particularly powerful ones of the type marketed by Purdue, present unacceptable risks of harm to patients taking them except in limited settings. Among other things, independent scientific studies of opioid usage have found:

- Mixed to negative outcomes from long-term opioid therapy in pain management programs;
- A significant incidence of addiction among those taking opioids for all but short-term ailments;
- Greater pain complaints and reduced effectiveness as most patients developed tolerance to opioids;
- Opioid patients' diminished ability to perform basic tasks; and
- Patients' inability to make use of complementary treatments like physical therapy due to the side effects of opioids.

22. Moreover, physical dependency makes it extremely difficult for many patients to stop taking powerful opioids once they start. Research and experience reflect that

discontinuing opioids after more than just a few weeks of therapy will cause most patients to experience potentially severe and long-lasting withdrawal symptoms.

23. Research further demonstrates that the efficacy of opioids generally diminishes over time when used to treat chronic pain. When under the continuous influence of opioids over time, patients grow tolerant to their analgesic effects. As tolerance increases, a patient typically requires progressively higher doses to obtain the same levels of pain reduction to which he or she has become accustomed – up to and including doses that are frighteningly high. At higher doses, the effects of withdrawal are more substantial, thus leaving a patient at much higher risk of physical dependence and addiction. While public health and safety concerns counsel against increases in dosage, Purdue's business model envisioned increased profits each time a patient increased dosage levels.

24. Other risks of longer-term opioid usage include overdose, respiratory depression, hyperalgesia (increased sensitivity to pain), harmful interaction with other drugs, hormonal dysfunction, neonatal abstinence syndrome, decline in immune function, confusion, dizziness (and increased falls and fractures in the elderly), and potentially fatal interactions with alcohol or benzodiazepines. High-dose opioids of the type sold by Purdue, and long-term prescription of opioids for treatment of chronic pain, which have been a focus of Purdue's marketing efforts, present particular dangers of these adverse effects.

25. Usage of high-dose opioids generally, and the increasing dependency, tolerance, and usage patterns that frequently accompany it, may adversely affect patients' ability to work, focus, or perform tasks of daily living. Many users become so dependent on prescription opioids that they turn to drugs that have no lawful uses, including heroin, when prescribers limit their ability to obtain lawfully prescribed opioids sufficient to address their dependency or

addiction. Because powerful opioids are sought by those with opioid dependency or addiction, powerful prescription opioids, such as the ones sold by Purdue, are particularly at risk of being diverted from medical uses into the illegal drug market.

B. Prescribers and Patients are Reliant on Information Provided by Purdue, KOLs, and Third Party Organizations to Help Assess and Manage the Risks of Opioids

26. In view of the significant risks associated with consumption of prescription opioids summarized above, it is critical that regulators, prescribers, and patients have ready access to accurate information about the nature and extent of the risks, and the benefits actually derived from use of the drug, in order to make an informed decision about whether to prescribe or to take the drug. In particular, the practice of medicine requires prescribers and patients to weigh the potential risks and benefits of each treatment option, as well as the risks of non-treatment. Prescribers cannot do that without full and accurate information about the observed benefits and incidence of adverse effects of opioid use.

27. Prescribers and patients have particular need for full and accurate disclosure of benefits and risks of opioids for longer-term use, or for chronic conditions, *before* decisions are made to prescribe and take the drugs, because of the risk that patients will become physically and psychologically dependent on them as a result of longer-term use. Patients faced with opioid dependency and doctors who treat them will find it difficult to manage or terminate their use, even if the opioids are not providing the required benefit, or if adverse effects are outweighing any benefits provided.

28. Full and accurate disclosure of the risks of these powerful and dangerous controlled substances, however, would have run counter to Purdue's profit motives. Purdue therefore engaged in its wide-ranging scheme to ensure that full and accurate disclosure was

thwarted. As set forth in detail below, Purdue's misrepresentations and omissions operated outside of, and served to subvert the effectiveness of, the labels mandated by the Food and Drug Administration (FDA) for Purdue's opioids, and muddied the statements that were regulatorily required by the FDA. As a result, the disclosures that prescribers and patients rely upon could not be satisfied by the presence of the labels on Purdue's products. For these particularly pernicious drugs, the misleading marketing messages delivered by pharmaceutical sales representatives, educational materials, KOLs, and third-party organizations, including those established and/or funded by Purdue, were especially influential in the treatment decisions made by patients and their prescribing physicians.

C. Purdue Engaged in a Years-Long Scheme to Mislead the Public about the Benefits and Risks of Opioids and of its Drugs

29. Purdue took advantage of prescribers' and patients' reliance on its marketing messages, sales representatives, and KOLs, and on third-party organizations created, funded, and/or supported by Purdue, to mislead healthcare professionals, patients, and the general public. As set forth below, Purdue not only delivered misleading messages directly; it also funded and otherwise supported KOLs and third-party organizations, in many cases secretly, to ensure that its marketing messages were amplified, and that purportedly independent (but in fact paid-for and biased) third parties endorsed and echoed Purdue's misleading campaign and helped Purdue resist efforts to reduce overuse of opioids and limit its profits.

30. Over the course of its scheme to persuade health care professionals to overprescribe its powerful opioids, Purdue made numerous misrepresentations on a repeated and persistent basis. As noted above, among other things, Purdue:

- Misrepresented the extent to which opioids improve function;
- Concealed the link between long-term use of opioids and abuse and addiction;

- Misrepresented the extent to which addiction risk can be managed;
- Masked the signs of addiction by calling them "pseudoaddiction," and encouraged further harm to consumers (and further ill-gotten gains to Purdue) by calling for increased dosages of its opioids for those showing signs of "pseudoaddiction";
- Falsely claimed withdrawal is easily managed;
- Misrepresented or omitted the greater dangers from higher doses of opioids;
- Deceptively minimized the adverse effects of opioids and overstated the risks of alternative therapies for pain relief; and
- Deceptively asserted that that its drug OxyContin provides a full 12 hours of pain relief.

31. Purdue's misrepresentations, made directly and through third parties, were consumer-oriented, and were addressed to prescribers, patients, policymakers, and the general public. They were material to prescribing, consumption, public opinion, and public policy decisions, in part because of the particular importance of accuracy when describing the potential risks of consumption of powerful and dangerous narcotics. Each of the misrepresentations was made on a repeated and persistent basis, in some cases over the course of decades, both directly and through KOLs and Front Groups. Each contributed to Purdue's ability to pump up sales of its powerful opioids and resist efforts to regulate its conduct and avert or minimize the public-health crisis New York and the rest of the nation now face.

1. Purdue Developed and Carried Out a Continuing Fraudulent Scheme to Create a Market for Powerful Opioids for Treatment of Chronic Non-Cancer Pain, and to Dominate that Market

32. Purdue launched its blockbuster drug OxyContin as a timed-release formulation of oxycodone, an opioid that is up to twice as powerful as morphine, in December 1995. The launch occurred after Purdue persuaded the FDA examiner assigned to review the drug, over

internal objections from within the FDA, that Purdue could claim that the extended-release formulation of the opioid within OxyContin "is believed to reduce the abuse liability of a drug." Soon thereafter, the FDA examiner who approved this labeling claim was hired by Purdue.[6]

33. Purdue then transformed the FDA approval by equating "abuse liability," which was based only on the fact that OxyContin was not an immediate-release drug, into a misleading marketing message that OxyContin was less susceptible to abuse and addiction than other opioids. This misleading message, along with other deceptive and misleading messages and practices, completely transformed prescribing and consumption practices around the country.

34. Purdue explicitly focused its misleading marketing messages on potential prescribers who lacked experience with the risks and potential benefits of powerful opioids such as OxyContin. Marketing plans prepared by Purdue in connection with the launch of OxyContin demonstrate that the company deployed over $1 billion in sales and promotional spending during the first few years after launch of the drug to create a new market for powerful opioids as a front-line therapy for the treatment of chronic non-cancer pain, to dominate that market, and to expand that market regardless of the consequences for safety and public health. Purdue did so in large part by targeting less sophisticated audiences that were treating or experiencing non-cancer pain, and by delivering misleading messages directly to those audiences rather than relying on pain management and other specialists.[7]

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[6] *Pain Killer* at 76-77.

[7] *See, e.g.*, Kaiser Health News, "Purdue and the OxyContin Files," https://khn.org/news/purdue-and-the-oxycontin-files/ (containing redacted copies of Purdue's 1996-2002 marketing plans for OxyContin) (hereinafter, "Purdue and the OxyContin Files"). *See also* "OxyContin's 12-Hour Problem"; Art Van Zee, "The Promotion and Marketing of OxyContin: Commercial Triumph, Public Health Tragedy," 99(2) *Am J. Pub. Health* 221 (2009), *available at* https://www.ncbi.nlm.nih.gov/pmc/articles/PMC2622774/ (hereinafter, "Commercial Triumph, Public Health Tragedy").

35. For example, Purdue's initial marketing plans for OxyContin reflected, among other things, direct efforts to deliver its misleading marketing messages to nurses, physicians' assistants, pharmacists, and the general public, in an effort to overcome the well-founded concerns that the public and influential healthcare professionals had about Purdue's powerful opioids. Even among physicians, Purdue sought to expand the market for its powerful opioids to practice areas and specialties that Purdue knew or had reason to know at the time were not appropriate settings for its extremely powerful and highly-addictive medicines. Purdue's marketing plan for 2002, for example, which was created well after Purdue was on notice about the severe abuse potential of OxyContin, focused on "targeted efforts" to penetrate: "Primary Care," "OB/GYN," and "Sports/Physical Medicine/Rehabilitation."[8] Purdue also targeted medical residents and fellows for their aggressive marketing push, noting that their marketing effort "[p]rovides the ability to influence physicians still in training."[9]

36. As part of this all-out marketing push, Purdue sponsored thousands of all-expense-paid meetings and other continuing medical education ("CME") sessions that targeted not only cancer specialists and pain experts, who were already familiar with the risks and potential benefits of opioids, but also physicians, nurses, pharmacists, and other medical professionals who lacked training and experience with managing pain or recognizing patients prone to substance use disorder.[10]

37. During these sessions and through in-person sales calls and publications, Purdue sought to persuade medical professionals, many of them inexperienced in the use of opioids for

[8] "Purdue and the OxyContin Files" (2002 Marketing Plan) (hereinafter "Purdue 2002 Marketing Plan").
[9] *Id.*
[10] *Pain Killer* at 79; United States General Accounting Office, "OxyContin Abuse and Diversion and Efforts to Address the Problem" (Dec. 2003) at 23, *available at* https://www.gao.gov/new.items/d04110.pdf (hereinafter "GAO Report").

treatment of chronic pain, that they were undertreating chronic non-cancer pain, and that OxyContin presented a safe and effective means of treating that pain, with a lower risk of addiction, other side effects, and abuse, than other pain relievers. Sales representatives employed and/or funded by Purdue made aggressive sales pitches to OxyContin's expanded target audience of all health care professionals who were presented with patients complaining of non-cancer pain, saying, in essence, that OxyContin would enable "pain relief for these patients without addicting them to an opioid."[11] They encouraged primary care physicians and others unfamiliar with pain management that they could trust OxyContin as a front-line therapy for pain relief, as a pain reliever that doctors could "start with and stay with," and they asserted without foundation that OxyContin presented a risk of addiction to less than one percent of patients, when Purdue's own study demonstrated an addiction rate of thirteen percent.[12] Purdue's sales force was trained that this sales message would enable them to reach the "pot of gold" that awaited them "Over the Rainbow."[13] Dr. Raymond Sackler, one of the founders of Purdue, described OxyContin, armed as it was with these claims of safety, efficacy, and low risk of addiction and abuse, as the company's "ticket to the moon." [14]

38. Purdue also produced and disseminated to doctors, for use with the general public, videos and pamphlets amplifying this same misleading marketing message. The videos were disseminated without FDA review and approval, and contrary to federal regulations requiring submission to the FDA of promotional materials. When the FDA later reviewed videos with similar messaging, it concluded that the videos "appeared to make unsubstantiated

[11] *Pain Killer* at 82.
[12] *Id*. at 80; GAO report at 17.
[13] *Pain Killer* at 82.
[14] *Id.* at 41.

claims regarding OxyContin's effect on patients' quality of life and ability to perform daily activities and minimized the risks associated with the drug," a conclusion that Purdue did not dispute in its response to the report in which the FDA's conclusions were contained.[15]

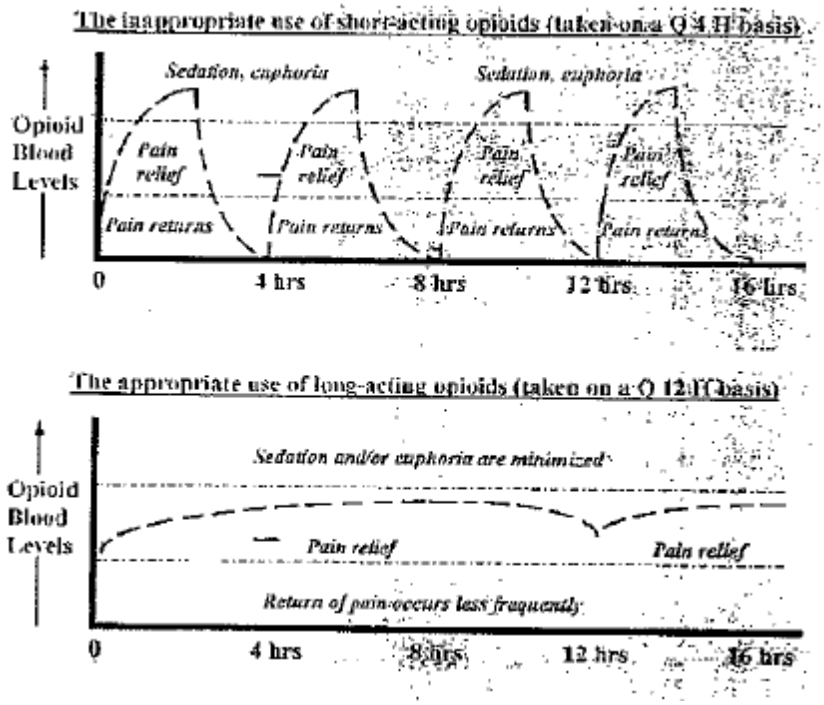
39. During the years after the introduction of OxyContin into the market, Purdue also engaged in other misleading efforts to market OxyContin as less addictive, less subject to abuse and diversion, and less likely to cause tolerance and withdrawal than other pain medications. Purdue specifically admitted, in pleading guilty to federal misbranding charges in 2007, that beginning in 1995 in its effort to launch and sell OxyContin, the company, "with the intent to defraud and mislead" had misrepresented[16]:

- That the oxycodone within OxyContin was more difficult to extract from the drug, when Purdue's own studies showed that it was easily extracted when crushed and dissolved in water;
- That patients could stop therapy abruptly without experiencing withdrawal symptoms and that patients who took OxyContin would not develop tolerance to the drug, when Purdue knew otherwise; and
- That OxyContin had fewer "peak and trough" blood level effects than short acting opioids.

40. Also described in its plea documents was an aspect of Purdue's manager training, where Purdue used "peak and trough" graphs that misleadingly represent that OxyContin, unlike immediate-release or short-acting opioids, did not swing up and down between euphoria and pain, and resulted in less abuse potential (hereinafter, the "Peak and Trough Graph"). Purdue admitted that this graphical representation, shown below, "falsely stated that OxyContin had significantly fewer "peak and trough" blood level effects than

[15] GAO report at 5, 27-28, 44.
[16] Agreed Statement of Facts, *United States v. The Purdue Frederick Company, Inc.*, 07 Cr. 29 (JPJ) (W.D. Va. filed May 9, 2007) (hereinafter, the "Agreed Statement of Facts")

immediate-release opioids resulting in less euphoria and less potential for abuse than short-acting opioids:" [17]



41. Health care providers, including those with limited prior experience prescribing and managing powerful opioids for chronic or longer-term conditions, responded to presentations like these by prescribing OxyContin as a front-line therapy for treatment of non-cancer pain. As use of OxyContin surged after its launch, Purdue quickly began reaping huge financial benefits from sales of the drug. But as revealed by recent reporting and investigation, Purdue also began to obtain clear evidence that its claims concerning the safety and lower susceptibility of OxyContin to abuse were not only unsubstantiated, they were plainly false.

42. While Purdue has consistently denied that it was aware of abuse and diversion issues associated with OxyContin until those issues were called to its attention by law enforcement in or after 2002, recent investigative reporting has revealed this continuing

[17] *Id.*

representation to be false. As revealed by the May 2018 publication of the second edition of the book *Pain Killer*, in fact Purdue's senior executives learned in 1997, less than two years after the introduction of OxyContin, that the drug was frequently appearing on websites and in chat rooms frequented by drug abusers, at a volume that was "enough to keep a person busy all day."[18] Also in 1996, Purdue's leadership began receiving anecdotal reports that the time-release mechanism used in both OxyContin and a predecessor drug MS Contin that contained a time-release version of morphine was being subverted easily by crushing and other straightforward methods. By 1998, the company's general counsel and owners were made aware of reports in a Canadian medical journal concerning the widespread abuse of MS Contin and a warning concerning the abuse potential of OxyContin. In addition, by 1999, the company and its sales staff were receiving widespread reports from the field that OxyContin was being widely diverted and abused.[19] Rather than withdraw the now-demonstrably false assertion that OxyContin presented an extremely low risk of addiction (at times citing the figure that less than 1 percent of patients become addicted), and was not prone to abuse, Purdue doubled down on it, reiterating misleading claims of Purdue's safety directly and indirectly to tens of thousands of prescribers and patients in an effort to influence their prescribing and usage decisions.

43. To address healthcare professionals' observations that individuals prescribed OxyContin were engaging in drug-seeking behavior consistent with addiction, Purdue falsely represented that many individuals who exhibited signs of addiction to opioids were actually experiencing a condition Purdue called "pseudoaddiction." The term "pseudoaddiction" was coined by Dr. David Haddox, who later became a senior executive with Purdue and who remains

[18] *Pain Killer* at 179.
[19] *Id.* at 177-80.

Purdue's Vice President of Health Policy to this day.[20] Pseudoaddiction describes the purported inaccurate interpretation of drug-seeking behaviors in patients with ineffectively treated pain.[21] According to Dr. Haddox and Purdue, drug-seeking behaviors consistent with addiction in many cases represented "legitimate" efforts to obtain more opioids for adequate treatment of pain – thus the term "pseudoaddiction."

44. This novel and empirically unsupported theory was advanced aggressively by Purdue repeatedly and persistently through the time period relevant to this Complaint, in a misleading effort to convert physicians' and patients' concerns about the drug-seeking behavior they were seeing among users of OxyContin into a sales opportunity. Purdue persisted in promoting its drugs to treat patients with these drug-seeking behaviors, arguing that most of them were experiencing pseudoaddiction related to undertreatment of pain – which could only be remedied by *more* of Purdue's opioids. Purdue effectively encouraged medical providers to ignore the hallmarks of actual addiction. Sales representatives understood when they were promoting this concept of pseudoaddiction that it lacked sufficient empirical support and was a sales tactic rather than a legitimate medical phenomenon.[22]

45. During the years after the launch of OxyContin, Purdue's sales representatives and advertising also misleadingly implied that OxyContin provided a full 12 hours of pain relief. An essential part of Purdue's marketing message was that OxyContin produced a "smoother" level of opioids in patients' bodies, with fewer "peaks" of euphoria and "troughs" of insufficient pain relief than competitor drugs, as reflected by the Peak and Trough Graph that Purdue

[20] https://www.linkedin.com/in/j-david-haddox-dds-md-9225931 (last visited July 17, 2018).
[21] *Pain Killer*. at 69-70.
[22] "Purdue Pharma used deceptive sales tactic for OxyContin after settlement, ex-sales rep says," *CBS News* (June 21, 2018), https://www.cbsnews.com/news/oxycontin-purdue-pharma-former-sales-representative-deceptive-sales-psuedoaddiction/.

acknowledged was misleading in connection with its guilty plea. This supported Purdue's efforts to persuade doctors and patients, including those without prior experience treating or receiving treatment for longer-term non-cancer pain with opioids, that OxyContin represented the best and safest front-line therapy for pain relief.[23]

46. Prior to formulating the 12-hour relief claim, as well as after it began disseminating it to the public, Purdue received numerous empirical reports that OxyContin was not in fact providing "smooth" 12-hour relief to many patients. Despite that, Purdue did not withdraw or qualify the misleading claim. Instead, it tried to "nip[ ] in the bud" any marketing messages that acknowledged the inadequacy of OxyContin to provide 12-hour pain relief to many patients. To address patients' claims that OxyContin was not providing the promised pain relief, Purdue misleadingly told physicians and patients that the appropriate remedy for insufficient pain relief was increasing the dosage of OxyContin, rather than increasing the frequency with which patients took the drug or changing to a different drug (either of which would have undermined Purdue's marketing messages and sales objectives). This had devastating effects on many patients. They became more vulnerable to adverse effects as a result of higher dosing, including poorer functioning, addiction, overdose, and death, but without gaining enhanced pain relief because the drug failed to provide adequate 12-hour pain relief even at higher dosage levels.[24]

47. Also in connection with the launch of OxyContin and its efforts to transform prescribing practices of healthcare providers throughout the country, Purdue funded efforts by

[23] "OxyContin's 12-Hour Problem."
[24] *Id.*

KOLs and Front Groups, including Front Groups Purdue helped create,[25] to amplify and echo its misleading marketing messaging through advocacy, publications, establishment of purported standards of care for treatment of pain, and other means. By acting through third parties, Purdue was able to both avoid FDA scrutiny and give the false appearance that the messages reflected the views of independent decisionmakers. On numerous occasions, including but not limited to those set forth below, Purdue misleadingly cited to these sources as "independent" corroboration of its own statements when in fact Purdue was in close contact with these third parties; had paid for and was aware of the misleading information they were disseminating about the use of opioids to treat chronic pain; and regularly helped them to tailor and distribute their misleading, pro-opioid messaging.

48. As discussed above, on May 10, 2007, Purdue and three of its top executives pleaded guilty to federal crimes in the United States District Court for the Western District of Virginia in connection with its misleading marketing campaign that accompanied the launch of the drug. In connection with the guilty plea, the company admitted to certain misconduct in the "Agreed Statement of Facts." Missing from the Statement of Facts, however, was any acknowledgement by Purdue about the misleading nature of many of the statements and conduct set forth herein, including statements concerning pseudoaddiction, the purported 12-hour relief properties of OxyContin, the use of KOLs and Front Groups to amplify misleading messages,

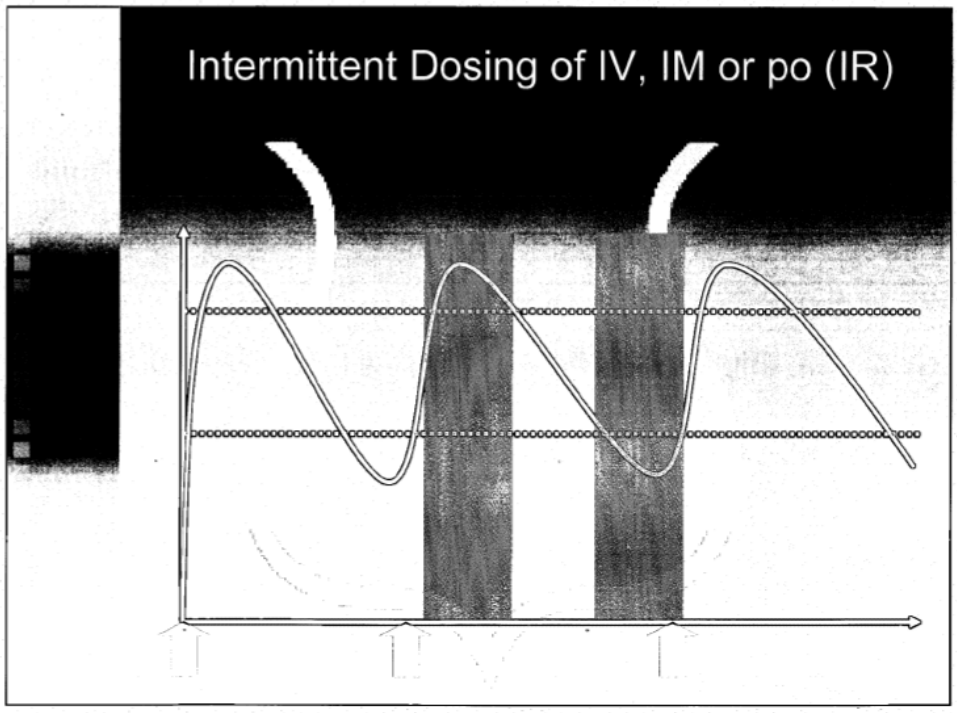
[25] *See, e.g.*, *Pain Killer* at 71-72 (describing Purdue's secret creation and support for the Appalachian Pain Foundation, which advocated for increased use of opioids and defended Purdue's practices in the face of evidence that the Appalachian region was awash in opioids); Charles Ornstein and Tracy Miller, "The Champion of Painkillers," *ProPublica* (Dec. 23, 2011), https://www.propublica.org/article/the-champion-of-painkillers (noting Purdue's role as an early funder and supporter of the American Pain Foundation, which supported Purdue's positions through publications, patient advocacy, and other means) (hereinafter, "The Champion of Painkillers"); Matthew Perrone and Ben Wieder, "Pro-painkiller echo chamber shaped policy amid drug epidemic," Center for Public Integrity (Sept. 19, 2016), https://www.publicintegrity.org/2016/09/19/20201/pro-painkiller-echo-chamber-shaped-policy-amid-drug-epidemic (describing Purdue's role in creating and helming the Pain Care Forum, which battled federal and state efforts to protect the public through regulation of opioid prescribing practices).

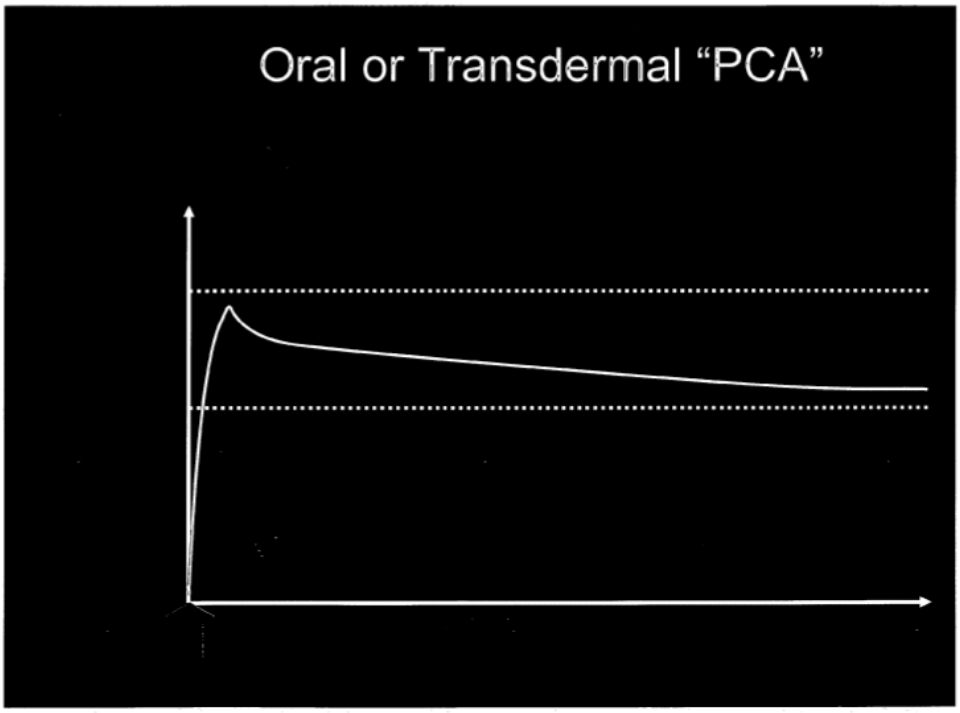
and other aspects of the company's marketing campaign that understated risks and overstated benefits of the drug.

2. Purdue's Scheme to Mislead Persisted Even After Its Guilty Plea

49. Perhaps most egregiously, even *after* pleading guilty to criminal conduct in connection with its misrepresentations about OxyContin, Purdue and its senior leadership continued the ongoing scheme to mislead prescribers, patients, policymakers, and the public about the risks and benefits of OxyContin, its other opioid products, and opioids more generally. Because their own written communications with prescribers and patients were more closely scrutinized as a result of the 2007 guilty plea, as set forth in greater detail below, Purdue relied more heavily upon misleading third-party communications from KOLs and Front Groups after 2007 to support and carry out its misleading communications. In short, notwithstanding the criminal guilty plea, Purdue's scheme to mislead the public, grow the market for its powerful opioids, and pump up the volume of its sales continued unabated.

50. For example, in September 2007, mere months after Purdue pleaded guilty to criminal misrepresentations concerning OxyContin, Dr. Haddox delivered a presentation to drug diversion investigators in which he effectively repeated many of those same misrepresentations and made others. Among other things, Dr. Haddox presented the Peak and Trough Graph that Purdue had acknowledged was misleading months earlier – though stripped of specific references to OxyContin and other named opioids – as an example of the adverse effects of immediate-release ("IR") opioids, and he compared it to another graph that displayed purported patient-controlled analgesia ("PCA") in which the peaks and troughs of euphoria and insufficient pain relief were eliminated, as set forth below:



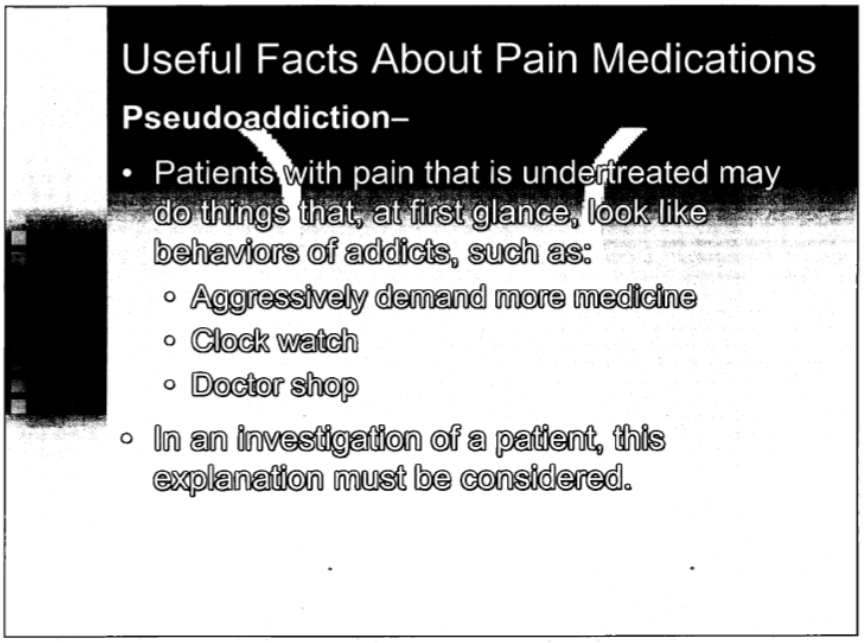


51. The next slide in the presentation asserted that the problems purportedly associated with immediate-release opioids, including a "roller-coaster ride with on-again-off-

again pain," could be avoided "[w]ith a controlled release tablet that lasts for 12 hours…, or a skin patch that lasts for a few days."

52. While the Peak and Trough Graph, the comparison graph, and the associated text did not specifically mention OxyContin (nor the then in-development Purdue opioid Butrans, which is a "skin patch that lasts for a few days"), the import of the marketing message, and its delivery by Purdue's most senior health policy executive, was obvious. It, like the earlier marketing messages Purdue admitted were fraudulent, continued to assert misleadingly that Purdue's opioids offered a safe and effective solution to problems of pain management that could not be provided through other means, including immediate-release opioids.

53. Dr. Haddox's September 2007 presentation, and other later marketing messages, also misleadingly claimed that physical dependence on opioids was a manageable issue, similar to the dependence that individuals taking asthma or blood pressure medicine experience after taking those drugs for some period of time. This representation was misleading because Purdue knew that physical dependence on opioids was qualitatively different from those drugs due to problems of tolerance, addiction, and adverse effects that developed alongside physical dependence and upon cessation of opioid consumption. The presentation also suggested that drug abuse and diversion investigators had to "consider" the medically-unsupported concept of pseudoaddiction, and undertreatment by opioids, as an alternative explanation for drug-seeking activity when investigating patient behavior, as set forth below:

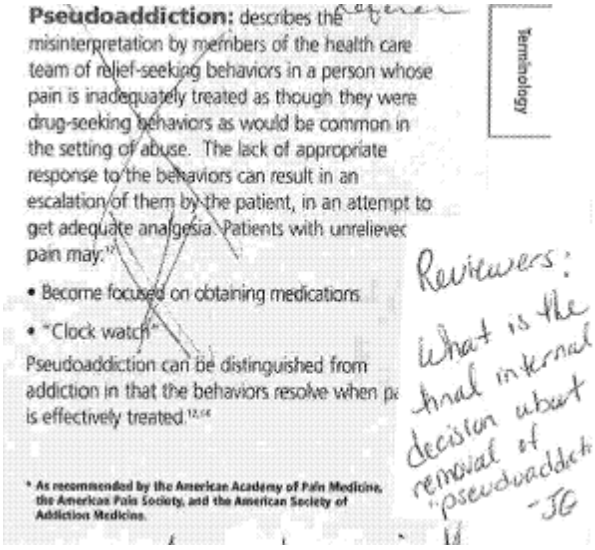


54. Finally, the presentation, which was consistent with later marketing messages, misleadingly attempted to draw a distinction between addiction and physical dependence by claiming, without adequate medical support, that addiction was wholly different from physical dependence: while addicts sought opioids to satisfy "the reward center" in the brain, according to the unsubstantiated presentation, legitimate opioid users experiencing physical dependence and engaging in drug-seeking behavior sought them to "reach opioid receptors in the spinal cord."

55. Purdue's ongoing misleading messaging campaign extended to printed publications issued by the company. For example, throughout the relevant time period, Purdue published a prescriber and law enforcement education pamphlet entitled *Providing Relief, Preventing Abuse* that contained numerous misrepresentations. Editions of the brochure published and disseminated throughout the country through at least 2013 related the same misleading assertions about pseudoaddiction that had been used in pre-2007 communications,

despite efforts by some within Purdue to remove references to pseudoaddiction from the pamphlet, as set forth below:

a. Attempt to delete reference to pseudoaddiction from a post-2007 version of brochure:



Pseudoaddiction: describes the misinterpretation by members of the health care team of relief-seeking behaviors in a person whose pain is inadequately treated as though they were drug-seeking behaviors as would be common in the setting of abuse. The lack of appropriate response to the behaviors can result in an escalation of them by the patient, in an attempt to get adequate analgesia. Patients with unrelieved pain may:[12]

- Become focused on obtaining medications
- "Clock watch"

Pseudoaddiction can be distinguished from addiction in that the behaviors resolve when pa is effectively treated.[12,14]

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

Terminology

Reviewers: What is the final internal decision about removal of "pseudoaddict -JG

b. Final version of updated brochure as circulated through at least 2013:

Other Considerations: Some patients may exhibit behaviors aimed at obtaining pain medication because their pain treatment is inadequate.[9] The term *pseudoaddiction* has emerged in the literature to describe the inaccurate interpretation of these behaviors in patients who have pain that has not been effectively treated.[9,10] Pseudoaddiction behaviors can be distinguished from addiction by the fact that, when adequate analgesia is achieved, the patient who is seeking pain relief demonstrates improved function, uses the medications as prescribed, and does not use drugs in a manner that persistently causes sedation or euphoria.[9] Such behaviors may occur occasionally even with successful opioid therapy for pain; a pattern of persistent occurrences should prompt concern and further assessment.[9]

56. Another misleading representation in all versions of the brochure, including those disseminated after 2013, was made under the heading, "Indications of Possible Drug Abuse." That section of the brochure showed pictures of individuals injecting or snorting opioids as indicia of abuse. In fact, as Purdue well knew, individuals who resort to these measures are uncommon; a far more typical reality is that patients become dependent and addicted, and that they begin to abuse opioids, through oral use. These misrepresentations therefore wrongly suggested to doctors and law enforcement that, as long as they did not observe signs of injections or snorting, they did not need not be concerned that their patients were abusing or addicted to opioids. In addition, all versions of the brochure misleadingly described addiction as a disease that is "not caused by drugs" and thus could be distinguished from physical dependence and other drug-seeking behaviors, when in fact its drugs were a necessary contributor to the dramatic increase in actual addiction that doctors were observing.

57. Purdue sales representatives also continued to spread misleading marketing messages concerning Purdue products to prescribers through direct sales calls throughout the relevant time period. Among other things, sales representatives were trained to continue misrepresenting the extent to which OxyContin could be relied upon for 12-hour relief and to recommend titration to greater doses, rather than alternative dosing schedules or medications, as a means of addressing potential effects of the drug's insufficient duration of pain relief. Sales representatives also touted the tamper-resistant properties of a reformulated version of OxyContin that began to be marketed in 2010, even though Purdue knew in 2010 that, as stated in an internal report based on surveillance of online forums used by drug abusers, "abusers are accepting the change [in formulation] and working to overcome the tamper-resistant properties

of the new formulation of OxyContin," and even though it was aware that oral ingestion – for which tamper resistance had no effect – was the most frequent method of abuse.

58. Moreover, Purdue paid for and promoted articles that stated or implied that its tamper-resistant drugs were safe, even while it was aware of the ease with which tamper-resistant drugs could be abused through oral ingestion and other means. In 2014, for example, Purdue placed three articles in *The Atlantic* magazine as sponsored content, including one entitled "Take My Pain Away....A Physician's Perspective of Prescription Opioids and Pain Management," by Dr. Gerald Aronoff. That article misleadingly called the tamper-resistant formulations (the most prominent of which was made by Purdue) "newer, safer alternatives" that were worth using despite their "higher price tag," and encouraged non-expert "physicians [to] embrace these additional choices, rather than decide to leave opioid prescribing[.]" Reports obtained from Purdue reflect that this promotional effort was closely monitored and measured, and that it generated over 88,000 page views on *The Atlantic*'s website.

59. Purdue's sales representatives also reiterated the misleading messaging of the Peak and Trough Graph, and compared it to Purdue's purportedly "smoother" concentration of opioids in the blood, for years after the company admitted that this messaging was misleading. Among other things, Purdue's sales representatives told prescribers that its drugs were "steady-state," the implication of which was that they did not produce a rush or euphoric effect, and therefore were less addictive and less likely to be abused.

60. In addition, continuing throughout the relevant time period, Purdue funded, supported, and exercised editorial input and control over several communications by Front Groups that (a) were less subject to governmental oversight and scrutiny than Purdue's written communications, and (b) enabled Purdue to claim that third parties had "validated" their

messaging when in fact, Purdue had exercised influence over and funded these third-party validators as well.

61. One of the primary Front Groups that Purdue used during the post-2007 period to disseminate misleading statements was the American Pain Foundation ("APF"). APF was a Front Group founded in 1997 that purportedly represented patients suffering from pain, but that in fact received up to 90 percent of its funding from opioid manufacturers including Purdue until it shut down in 2012 immediately after receiving a Congressional subpoena inquiring into its activities and funding sources.[26] As part of that support, APF reported to Purdue in 2010 that APF's pro-opioid promotional activities funded by Purdue reached more than 38.9 million people, as set forth below:

American Pain Foundation
2009 Local Market Media Outreach - Final Report
Submitted to Purdue Pharma L.P.
May 14, 2010 -- UPDATED

Executive Summary

More than **38.9 million** people have been reached with key messages about pain and overcoming barriers to treatment through print, television, radio and online placements as a part of Purdue's local market media outreach grant. The coverage has consistently conveyed APF key messages surrounding the scope of the pain problem, what it's like to live with pain and what's possible once pain is under control, barriers to pain management, including social stigma, and the right to effective and timely pain care. It is notable that throughout the past twelve months, APF has continuously secured a steady stream of news coverage in our priority markets.

62. In 2009, in response to a proposal from APF, Purdue agreed to sponsor and help distribute an APF publication targeted at veterans called *Exit Wounds.*[27] That book,

[26] The Champion of Painkillers;" Charles Ornstein and Tracy Weber, "American Pain Foundation Shuts Down as Senators Launch Investigation of Prescription Narcotics," *ProPublica* (May 8, 2012), https://www.propublica.org/article/senate-panel-investigates-drug-company-ties-to-pain-groups. Some of its publications, however, continue to remain available online, such as *Treatment Options:A Guide to People Living With Pain* (2007).
[27] Derek McGinnis, *Exit Wounds* (2009).

purportedly written by a disabled veteran who was employed by APF with the "assistance" of APF staff, deceptively portrays the risks, benefits, and superiority of opioids to treat chronic pain. The book misleadingly describes opioids as "underused" and the "gold standard of pain medications" while it fails to disclose the risk of addiction, overdose, or injury.[28] It falsely asserts that "[l]ong experience with opioids shows that people who are not predisposed to addiction are unlikely to become addicted to opioid pain medications," and it assures readers that "most side effects [of opioids] disappear after a few days."[29] *Exit Wounds* also minimizes the risks of chronic opioid therapy and does not disclose the risk that opioids may have fatal interactions with benzodiazepines, which are taken by a significant number of veterans. The publication also encouraged veterans that they "may need to push" doctors "hard" to get their preferred pain treatment.[30]

63. In 2011, Purdue sponsored APF's *A Policymaker's Guide to Understanding Pain & Its Management*, yet another publication containing numerous misleading statements. Among other things, the *Policymaker's Guide* characterized as a "Myth" the idea that "[c]hildren can easily become addicted to pain medications." According to the *Guide*, "[l]ess than 1 percent of children treated with opioids become addicted." This publication also asserted that pain is undertreated due to "misconceptions about opioid addiction."

64. Among the purposes of the Front Groups was the perpetuation of fraud and deceptive advertising and conduct against the elderly, in violation of Section 349-c of the General Business Law. From the outset of Purdue's deceptive campaign to create the market for use of its powerful and addictive opioids to treat non-cancer pain, Purdue focused on the

[28] *Id*. at 106.
[29] *Id*. at 107, 110.
[30] *Id*. at 128.

elderly as a target market, noting in its initial marketing plans for OxyContin that it viewed Long-Term Care (LTC) facilities, including nursing home MDs and RNs, as a primary audience for Purdue's marketing messages, and that it needed to reach "[i]nfluential decision-makers at LTC facilities and corporate level nursing home chains."[31] In 2012, Purdue contracted with a foundation associated with the American Geriatrics Society ("AGS") to develop new materials that supported and promoted the AGS's 2009 guidelines for the *Pharmacological Management of Persistent Pain in Older Persons*. These Purdue-supported and -promoted materials, which remain available, falsely claimed that "the risks [of addiction] are exceedingly low in older patients with no current or past history of substance abuse." The Purdue-sponsored materials, as well as other marketing messages delivered by Purdue, underrepresented the risks of addiction as well as other serious side effects for which the elderly are particularly at risk.

65. In 2007, Purdue influenced the content of a nationally disseminated publication issued by the Federation of State Medical Boards ("FSMB"), another group sponsored by Purdue, called *Responsible Opioid Prescribing*. This publication, which drew on earlier publications by FSMB also sponsored or created with input from Purdue, misleadingly recommended powerful opioids of the type offered by Purdue, underplayed the risk of addiction from those drugs, and reiterated the misleading concept of pseudoaddiction as an alternative explanation for drug-seeking behaviors or abuse. Dr. Haddox offered extensive input into the content of the publication; as he stated in an email to Purdue's Chief Legal Officer, who had pleaded guilty to federal criminal conduct, "I really want this to succeed, which is why I spent so much time on it." Even after 2012, FSMB continued to emphasize the misleading concept of pseudoaddiction.

[31] Purdue 2002 Marketing Plan.

66. Throughout the relevant time period, Purdue also engaged KOLs to make misrepresentations to physicians and the public regarding the length of time opioids would be effective against pain. While serving as faculty or speakers at meetings attended by prescribers, the KOLs used presentation slides created by Purdue to make these misrepresentations. Purdue also instructed its sales representatives to make these same misrepresentations to prescribers. The false statements and omissions by Purdue were made to doctors, other prescribers, and consumers and led them to prescribe and consume Purdue's opioid products.

67. Purdue's efforts to perpetuate the opioid crisis it had played a central role in creating continued even after it resolved an investigation of one aspect of its misconduct with the New York Attorney General's Office. In 2015, Purdue entered into an Assurance of Discontinuance ("AOD") with the State of New York in which it agreed to improve its abuse and diversion detection ("ADD") system, and in which it agreed to correct serious misrepresentations concerning one website Purdue controlled under the name "In the Face of Pain." But as revealed by a lengthy, ongoing Congressional investigation in 2018, as well as investigative reporting and investigation by New York and other states, even after the 2015 AOD, Purdue continued to engage in efforts to mislead the public, influence public policy and public opinion concerning opioids, and resist efforts to place reasonable restrictions on opioid prescription activity that might have reduced the scale of the crisis. In February 2018, the Senate publication *Fueling an Epidemic* revealed that Purdue had been the single largest funder of organizations that served as Front Groups or that otherwise advanced Purdue's interests, spending over $4.15 million between January 2012 and March 2017 on fourteen different organizations that were examined by the Senate committee. This sum constituted approximately half of all payments to third-party organizations examined by the committee

from large opioid prescribers over the same period of time.[32] Much of this funding went to organizations that, with Purdue's knowledge and in many cases Purdue's prior approval, minimized the risk of addiction and made other misleading statements set forth herein. Many of the payments from Purdue to these Front Groups were not adequately disclosed by Purdue or by the Front Groups themselves.[33]

68. Moreover, Purdue worked directly and through Front Groups it funded, in some cases secretly, to defeat measures that would restrict overprescription, to limit accountability for overprescribing physicians, and to resist and delay efforts by the United States Centers for Disease Control and Prevention ("CDC") to develop guidelines (the "CDC Guidelines") that had the potential to reduce use of the extremely powerful opioids sold by Purdue and mitigate the spiraling public health crisis that Purdue had helped create.[34]

69. Purdue and other makers of prescription opioids also spent heavily and deployed extensive resources to resist efforts by New York and other states to adopt measures that would have mitigated the public health crisis that Purdue had helped create. In particular, as revealed by a September 2016 investigative report by the Associated Press and the Center for Public Integrity, Purdue led an effort by opioid manufacturers to deploy an army of lobbyists that resisted common-sense restrictions on opioid prescribing and related practices. As part of that effort, Purdue and other manufacturers spent over $880 million on lobbying and campaign contributions targeting federal and state officials, including in New York, during the period 2006 to 2015 alone.[35] Among other things, as described in the investigative report and as

[32] *Fueling an Epidemic* at 4-5.
[33] *Id.* at 11-12.
[34] *Id.* at 12-17.
[35] Geoff Mulvihill, Liz Essley Whyte, and Ben Wieder, "Drugmakers fought state opioid limits amid crisis," *Associated Press* (Sept. 18, 2016), https://apnews.com/86e948d183d14091a80f5c3bfb429c68/drugmakers-

reflected in documents produced by Purdue pursuant to subpoena and reviewed by the OAG, Purdue and other manufacturers operated directly and through an entity called the Pain Care Forum, which was created and led by a Purdue lobbyist who used a Purdue corporate email account, to influence federal and state legislation and regulatory activities.[36]

70. Had Purdue conformed its behavior to the law when it began discovering the extent to which its representations about the safety and efficacy of OxyContin were false, far fewer prescribers would have received Purdue's misleading marketing messages, and far fewer people would have suffered the adverse effects of Purdue's conduct. Had Purdue not resisted the reasonable and common-sense efforts by the CDC, state and federal legislators and regulators, and others to mitigate the public health crisis it helped create, which constitutes a public nuisance in need of abatement, the scale and extent of the devastation it has wrought in New York State would have been lessened substantially. Finally, had Purdue not acted through Front Groups and KOLs, or continued to conceal its role in resisting common-sense efforts to mitigate the crisis, prescribers, policymakers, and the general public would have recognized that the resistance to these common-sense measures was being supported by a company that had been convicted of a federal felony for deceiving the public and that had a profound self-interest in continuing and extending the overprescription of its powerful and dangerous opioid products.

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fought-state-opioid-limits-amid-crisis. Members of the Purdue-created Pain Care Forum employed over 200 lobbyists in New York State in 2013 through 2015 – the most in any state – and made over $3.7 million in campaign contributions between 2006 and 2015 – the second-highest sum of any state—according to data obtained by the Associated Press. *See* http://data.ap.org/projects/2016/cpi_ap_opioids/indexcpiap.html.

[36] Matthew Perrone and Ben Wieder, "Pro-painkiller echo chamber shaped policy amid drug epidemic," Center for Public Integrity (Sept. 19, 2016), https://www.publicintegrity.org/2016/09/19/20201/pro-painkiller-echo-chamber-shaped-policy-amid-drug-epidemic.

71. Purdue's continuing deceptive, fraudulent, and illegal conduct, combined with its continued resistance to efforts to reduce the harms caused by that conduct, caused injury to the State of New York and its residents constituting a public nuisance through an unbroken chain of events commencing with the misleading marketing of OxyContin and other opioids and continuing into the present; the crisis of addiction and the opioid epidemic flows directly from Purdue's conduct described herein. Indeed, by getting patients addicted to its drugs, Purdue greatly increased the patients' risk of harm from many drugs that share the same addictive chemistry, such as heroin, fentanyl, and generic oxycodone.

72. Purdue fraudulently concealed many aspects of this scheme for years until they were discovered recently by governmental agencies and investigative reporting. Newly-discovered evidence published in *Pain Killer* reflects that Purdue and its most senior executives were in fact aware of critical aspects of the public health disaster that they were helping to create as it was unfolding, and that they nonetheless chose to persist in their misleading marketing campaign in order to obtain the billions of dollars of profits that ultimately accrued to the company, as well as the hundreds of millions of dollars that accrued to the company's senior executives and owners personally. Additional publications by Congress in February 2018, and by the Associated Press and the Center for Public Integrity in fall 2016, as well as document productions by Purdue since 2016, reveal the extent to which Purdue used Front Groups to advance and amplify its misleading messaging, and to resist efforts to forestall and combat the opioid crisis.

73. Had Purdue come clean about the full extent of its misconduct, its senior management's knowledge of the misleading nature of its representations, and its continuing use of third parties to advance its unlawful objectives, the resulting public health crisis that Purdue

helped create may have been averted or at least diminished. Purdue's misconduct could have been discovered and stopped or diminished far earlier. Purdue's ability to continue marketing or selling OxyContin could have been restricted or effectively ended through debarment or other proceedings, or further legal restrictions may have been placed on any representations it could make concerning the drug, both directly and through third parties. Additional Purdue executives who contributed and still contribute to the crisis may have been forced to resign or otherwise been held accountable for their actions, thereby deterring future misconduct. Moreover, the company's ability to influence public policy and prescribers' and patients' decisions through ongoing misrepresentations would have been far more difficult had recipients of Purdue's marketing messages known the extent to which OxyContin presented serious dangers to patients and to public health if used as recommended by Purdue, and the extent to which the company's management and leadership had deceived the public and remained untrustworthy.

FIRST CAUSE OF ACTION:
PUBLIC NUISANCE

74. Plaintiff realleges and incorporates by reference each and every allegation in the paragraphs above as if the same were fully set forth herein.

75. Purdue, individually and acting through its employees and agents, has engaged in conduct or omissions which offend, interfere with, or cause damage to the public in the exercise of rights common to all, in a manner such as to endanger or injure the property, health, safety, or comfort of a considerable number of persons in the State of New York by its production, promotion, and marketing of opioids for use by residents of the State of New York, and its conduct in connection with that activity. While Purdue's degree of care is not relevant

in a common law nuisance suit brought by the State of New York, Purdue has behaved negligently, recklessly, or intentionally as set forth above.

76. Purdue's conduct is not only unlawful, but has also resulted in substantial and unreasonable interference with the public health and safety, and the public's enjoyment of its right not to be defrauded or injured by wrongful conduct. Purdue's conduct created, maintained, and contributed to an interference with or injury to the public in the exercise of rights common to all.

77. Purdue's conduct is continuing in nature and has produced permanent and long lasting effects. Purdue's conduct is not insubstantial or fleeting. Indeed, its unlawful conduct commenced at least twenty years ago and has so affected prescribing practices, consumption of opioids, and public health on every geographic and demographic level that the public nuisance caused in substantial part by Purdue's conduct is commonly referred to as a "crisis" or an "epidemic." It has caused deaths, serious injuries, and a severe disruption of public peace, order, and safety; it is ongoing, and it is producing permanent and long-lasting damage. The public health crisis Purdue helped create was extended and worsened by Purdue's own conduct, and its use of Front Groups, KOLs, and other methods to continue to mislead the public and resist efforts to reduce overprescription of opioids.

78. Purdue's conduct constitutes a public nuisance. The State of New York therefore is entitled to an injunction requiring Purdue to abate the public nuisance by, among other things, funding treatment, addressing the other adverse effects of the opioid epidemic, supporting counter-detailing to educate prescribers and patients on the proper use of opioids, and other measures required to remedy the harms it caused.

SECOND CAUSE OF ACTION:
DECEPTIVE ACTS AND PRACTICES

79. Plaintiff realleges and incorporates by reference each and every allegation in the paragraphs above as if the same were fully set forth herein.

80. GBL § 349 provides that "[d]eceptive acts or practices in the conduct of any business, trade or commerce or in the furnishing of any service in [New York] are ... unlawful."

81. By engaging in the acts and practices described above, Purdue has engaged in and continues to engage in deceptive business practices in violation of GBL § 349.

THIRD CAUSE OF ACTION:
DECEPTIVE ADVERTISING

82. Plaintiff realleges and incorporates by reference each and every allegation in the paragraphs above as if the same were fully set forth herein

83. GBL § 350 prohibits “false advertising in the conduct of any business.”

84. By engaging in the acts and practices described above, Purdue has engaged in and continues to engage in false advertising in violation of GBL § 350.

FOURTH CAUSE OF ACTION:
REPEATED AND PERSISTENT FRAUD

85. Plaintiff realleges and incorporates by reference each and every allegation in the paragraphs above as if the same were fully set forth herein.

86. Executive Law § 63(12) makes “repeated fraudulent or illegal acts or…persistent fraud or illegality in the carrying on, conducting or transaction of business” actionable by the Attorney General.

87. By engaging in the acts and practices described above, Purdue has engaged in and continues to engage in repeated fraudulent acts or persistent fraud in violation of Executive Law § 63(12).

FIFTH CAUSE OF ACTION:
REPEATED AND PERSISTENT ILLEGALITY
DECEPTIVE PRACTICES AND ADVERTISING

88. Plaintiff realleges and incorporates by reference each and every allegation in the paragraphs above as if the same were fully set forth herein.

89. Executive Law § 63(12) makes "repeated fraudulent or illegal acts or…persistent fraud or illegality in the carrying on, conducting or transaction of business" actionable by the Attorney General.

90. By engaging in the acts and practices described above, which include violations of GBL §§ 349 and 350, Purdue has engaged in and continues to engage in repeated illegal acts or persistent illegality in violation of Executive Law § 63(12).

SIXTH CAUSE OF ACTION:
REPEATED AND PERSISTENT ILLEGALITY
CRIMINAL NUISANCE

91. Plaintiff realleges and incorporates by reference each and every allegation in the paragraphs above as if the same were fully set forth herein.

92. New York Penal Law § 240.45 provides that a person is guilty of a criminal nuisance in the second degree when, "By conduct either unlawful in itself or unreasonable under all the circumstances, he knowingly or recklessly creates or maintains a condition which endangers the safety or health of a considerable number of persons."

93. By engaging in the acts and practices described above, which include violations of Penal Law § 240.45, Purdue has engaged in and continues to engage in repeated illegal acts or persistent illegality in violation of Executive Law § 63(12).

SEVENTH CAUSE OF ACTION:
VIOLATION OF SOCIAL SERVICES LAW

94. Plaintiff realleges and incorporates by reference each and every allegation in the paragraphs above as if the same were fully set forth herein.

95. Purdue violated Social Services Law § 145-b by knowingly, by means of a false statement or representation, or by deliberate concealment of any material fact, or other fraudulent scheme or device, on behalf of itself or others, attempting to obtain or obtaining payment from public funds for services or supplies furnished or purportedly furnished pursuant to Chapter 55 of the Social Services Law.

96. As set forth herein, Purdue has knowingly set forth false statements or representations, deliberately concealed material facts, and/or perpetuated a fraudulent scheme, in attempts to obtain payment for opioids from public funds for services or supplies furnished by Plaintiff pursuant to Chapter 55.

97. By reason of Purdue's violation of § 145-b, the State of New York have been damaged.

98. Plaintiff is entitled to recover its damages caused by Purdue's violation of § 145-b in an amount to be determined at trial and subject to the treble damages and apportionment provisions of § 145-b.

EIGHTH CAUSE OF ACTION:
COMMON LAW FRAUD

99. Plaintiff realleges and incorporates by reference each and every allegation in the paragraphs above as if the same were fully set forth herein.

100. Purdue, individually and acting through its employees and agents, knowingly made material misrepresentations and omissions of facts to Plaintiff, its agents and employees, and third parties to purchase, administer, and consume opioids as set forth in detail above.

101. Purdue knew at the time that it made these misrepresentations and omissions that they were false. In the alternative, Purdue recklessly disregarded the falsity of its representations regarding opioids.

102. Purdue intended that Plaintiff, physicians, patients, and/or others would rely on their misrepresentations and omissions.

103. Plaintiff, physicians, patients, and/or others reasonably relied upon Defendants' misrepresentations and omissions.

104. By reason of their reliance on Purdue's misrepresentations and omissions of material fact, Plaintiff suffered actual pecuniary damage.

105. Purdue's conduct was willful, wanton, and malicious and was directed at the public generally.

106. Plaintiff is entitled to recover its damages caused by Defendants' fraud in an amount to be determined at trial.

NINTH CAUSE OF ACTION:
UNJUST ENRICHMENT

107. Plaintiff realleges and incorporates by reference each and every allegation in the paragraphs above as if the same were fully set forth herein.

108. As an expected and intended result of Purdue's conscious and continuing wrongdoing, Purdue, individually and acting through its employees and agents, unjustly enriched itself at Plaintiff's expense.

109. It is against equity and good conscience to permit Purdue to retain the funds it received as a result of its wrongful and continuing acts, practices, and omissions.

110. By reason of the foregoing, Purdue must disgorge its unjustly acquired profits and other monetary benefits resulting from its unlawful conduct.

PRAYER FOR RELIEF

WHEREFORE, Plaintiff, the People of the State of New York, respectfully requests that a judgment and order be entered that:

A. Permanently enjoins Purdue from engaging in the deceptive, fraudulent, and unlawful conduct alleged herein;

B. Directs Purdue to abate the public nuisance and pay all costs of abatement;

C. Directs Purdue to disgorge all amounts obtained in connection with or as a result of the violations of law alleged herein;

D. Directs Purdue to pay a civil penalty of $5,000 to the State of New York pursuant to GBL § 350-d for each instance of a deceptive or unlawful act or practice that violates GBL Article 22-A;

E. Directs Purdue to pay an additional civil penalty of $10,000 to the State of New York pursuant to GBL § 349-c for deceptive and unlawful practices and fraud committed against the elderly;

F. Directs Purdue to pay restitution and damages to the State of New York based on Purdue's fraudulent, deceptive, and illegal practices;

G. Awards the State of New York's costs; and

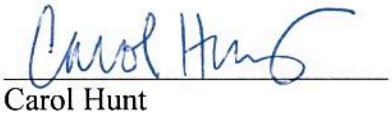
H. Grants all other relief that is just and proper.

Suffolk County, New York
August 14, 2018

Respectfully submitted,

BARBARA D. UNDERWOOD
Attorney General of the State of New York
Attorney for Plaintiff

By:



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