IN THE COMMONWEALTH COURT OF PENNSYLVANIA

COMMONWEALTH OF PENNSYLVANIA by ATTORNEY GENERAL JOSH SHAPIRO	:	**Case No.:**
PLAINTIFF,	:	**CIVIL ACTION**
v.	:	
PURDUE PHARMA L.P., PURDUE PHARMA INC., and THE PURDUE FREDERICK COMPANY	:	257 MD 19
DEFENDANTS.	:	

NOTICE TO DEFEND

You have been sued in court. If you wish to defend against the claims set forth in the following pages, you must take action **within twenty (20) days** after this complaint and notice are served, by entering a written appearance personally or by attorney and filing in writing with the court your defenses or objections to the claims set forth against you. You are warned that if you fail to do so the case may proceed without you, and a judgment may be entered against you without further notice for any money claimed in the complaint or for any other claim or relief requested by the

plaintiff. You may lose money or property or other rights important to you.

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COMPLAINT

AND NOW, comes the Commonwealth of Pennsylvania, by Attorney General Josh Shapiro (hereinafter "Commonwealth" or "Plaintiff"), and brings this action to permanently enjoin, as well as recover damages and penalties for violations of the Pennsylvania Unfair Trade Practices and Consumer Protection Law, 73 P.S. § 201-1, *et seq.* (hereinafter "Consumer Protection Law"). The Consumer Protection Law authorizes the Attorney General to bring an action in the name of the Commonwealth of Pennsylvania for permanent or temporary injunctive relief, civil penalties, and restoration damages for unfair methods of competition or unfair or deceptive acts or practices in the conduct of any trade or commerce declared unlawful by Section 201-3 of the Consumer Protection Law. In support of this action the Commonwealth respectfully represents the following:

JURISDICTION

1. This Court has jurisdiction over this action pursuant to 42 Pa. C.S.A. § 761.

PARTIES

2. Plaintiff is the Commonwealth of Pennsylvania, by Attorney General Josh Shapiro, through the Bureau of Consumer Protection, 15th Floor, Strawberry Square, Harrisburg, Dauphin County, Pennsylvania 17120.

3. Defendant Purdue Pharma, L.P. is a limited partnership organized under the laws of Delaware with its principal place of business in Stamford, Connecticut. It includes the commercial group responsible for promoting and selling opioids in Pennsylvania. It is controlled by Purdue Pharma, Inc.

4. Defendant Purdue Pharma, Inc. is a New York corporation with its principal place of business in Stamford, Connecticut. Since the 1990s, its official purpose has been manufacturing, sales, distribution, and research and development with respect to pharmaceutical, toiletry, chemical and cosmetic products, directly or as the general partner of a partnership engaged in those activities. It is the general partner of Purdue Pharma L.P.

5. Defendant Purdue Frederick Company is a New York corporation with its principal place of business in Stamford, Connecticut. All of the

Purdue entities enumerated herein are collectively referred to as "Purdue" or the "Company".

BACKGROUND

PURDUE CREATED THE OPIOID EPIDEMIC THAT IS KILLING PENNSYLVANIANS

6. Opioids are dangerous and potentially deadly narcotics that can cause patients to stop breathing and suffocate. Opioids' dangers have been known for more than 100 years.

7. Opioids are highly addictive. Patients using opioids for more than a few days can experience severe withdrawal symptoms if they stop taking the drugs, including: anxiety, insomnia, pain, blurry vision, rapid heartbeat, chills, panic attacks, nausea, vomiting, and tremors. Withdrawal can last so long and be so painful that it is difficult to stop taking opioids.

8. Patients who take opioids at higher doses and for longer periods face increasingly higher risk of addiction and death.

9. Opioids are killing people all around the Commonwealth and around the United States. From 1999 to 2017, more than 200,000 people died from overdoses related to prescription opioids in the United States.[1]

[1] CDC/National Center for Injury Prevention and Control, https://www.cdc.gov/drugoverdose/data/prescribing.html

10. Pennsylvania is among the top four states with the highest opioid use and overdose rates[2]—nearly *thirteen people die every day* from a drug overdose in the Commonwealth.[3] Drug-related fatalities in Pennsylvania now outnumber everyone killed in car accidents and murders combined.[4]

11. The rate of drug-related overdose deaths in Pennsylvania far exceeds the national average.[5] According to recent studies, opioids killed an estimated 26,300 Pennsylvanians from 1999 to 2017.[6] The people of Pennsylvania also survived more than 6,400 opioid overdoses from just April 2015 through 2017 alone that were not fatal, but still devastating.[7]

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[2] CDC/National Center for Injury Prevention and Control, https://www.cdc.gov/drugoverdose/data/statedeaths.html and https://www.drugabuse.gov/drugs-abuse/opioids/opioid-summaries-by-state

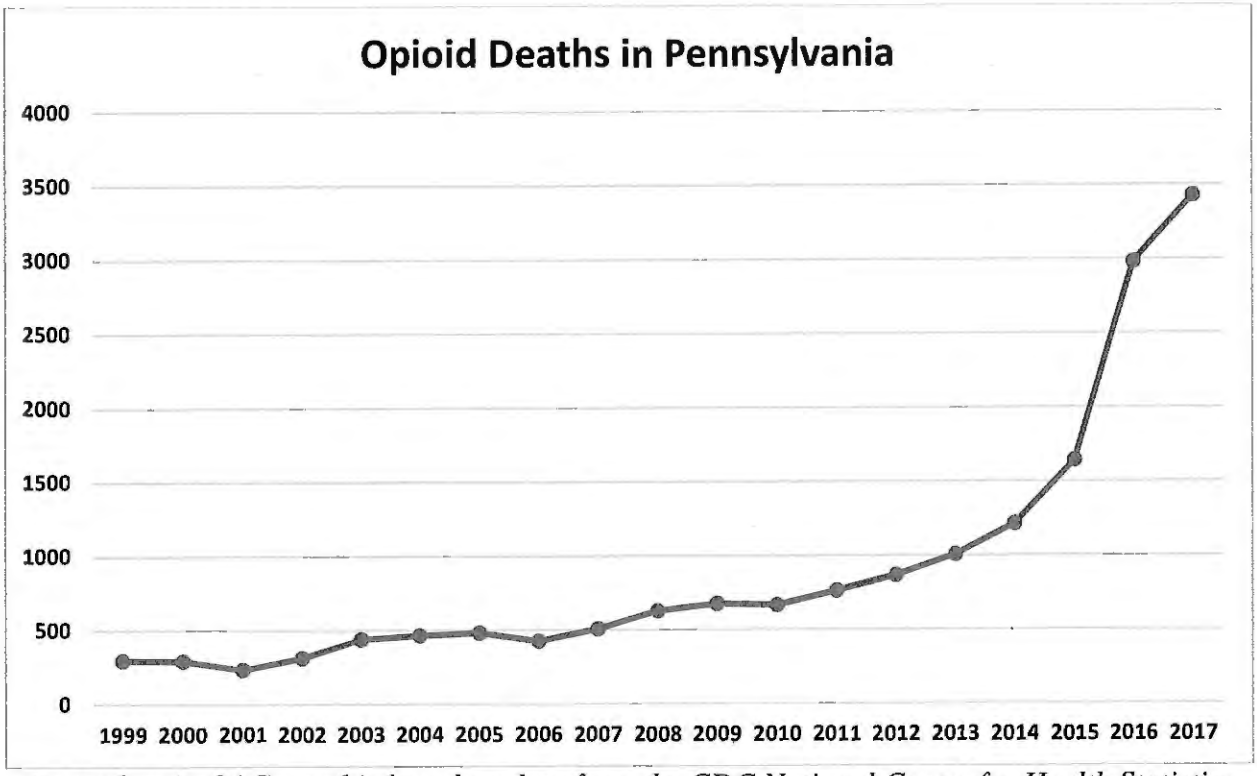
[3] Pennsylvania Department of Drug and Alcohol Programs, https://data.pa.gov/stories/s/Rescue/dji6-fb2x

[4] CDC/National Center for Health Statistics, https://www.cdc.gov/nchs/pressroom/sosmap/homicide_mortality/homicide.htm and Pennsylvania Department of Transportation, https://www.penndot.gov/TravelInPA/Safety/Pages/Crash-Facts-and-Statistics.aspx

[5] Pennsylvania DEA Opioid Threat Report 2018, https://www.overdosefreepa.pitt.edu/wp-content/uploads/2018/10/PA-Opioid-Report-Final.pdf

[6] *Id. See also* Jeanine Buchanich et al., *The effect of incomplete death certificates on estimates of unintentional opioid-related overdose deaths in the United States, 1999-2015*, Public Health Rep. (2018), https://doi.org/10.1177/0033354918774330; *see also* Kaiser Family Foundation analysis of CDC/National Center for Health Statistics (Multiple Cause of Death Files 1999-2017), https://www.kff.org/state-category/health-status/opioids/

[7] Pennsylvania Department of Drug and Alcohol Programs, https://data.pa.gov/stories/s/Rescue/dji6-fb2x



Pennsylvania OAG graphic based on data from the CDC National Center for Health Statistics (Multiple Cause of Death Files, 1999-2017)[8]

12. The human toll of the opioid epidemic continues to ravage communities across the Commonwealth. For example, between 2015 and 2017, Pennsylvania coroners and medical examiners reported 13,408 drug-related overdose deaths—a 65% increase from previous years.[9] Over half of those deaths involved opioids of which nearly a quarter were prescribed.[10] Oxycodone is the most frequently reported prescription opioid in toxicology tests of drug-related overdose

[8] Kaiser Family Foundation analysis of CDC/National Center for Health Statistics (Multiple Cause of Death Files 1999-2017), https://www.kff.org/state-category/health-status/opioids/
[9] OverdoseFreePA, https://www.overdosefreepa.pitt.edu/know-the-facts/death-data-overview/; Pennsylvania DEA Opioid Threat Report 2018
[10] *Id.*

decedents.[11]

13. Despite these fatalities, opioid use in Pennsylvania remains one of the highest in the country. The CDC estimates that Pennsylvania practitioners wrote an average of 69.5 opioid prescriptions per 100 persons in 2016—among the highest rates in the country—and at least 60% of Pennsylvania counties still have prescribing rates above the national average.[12]

14. As the number of opioid-related overdoses continues to rise in Pennsylvania and nationwide, the economic cost of the epidemic has skyrocketed in recent years. From health care spending to addiction treatment and from lost productivity to criminal justice expenses, the financial impact and extent of these costs demonstrate the sheer breadth of the problem. Between 2012 and 2016, opioid-related fatalities in Pennsylvania cost the Commonwealth more than $142 billion dollars.[13] It more than doubled from 2015 to 2016.[14] This staggering amount represents only four years of this approximately two decades-old cataclysm.

15. Unlike prior epidemics that have ravaged mankind throughout history, this epidemic is not natural or normal. Drug companies *created* this costly

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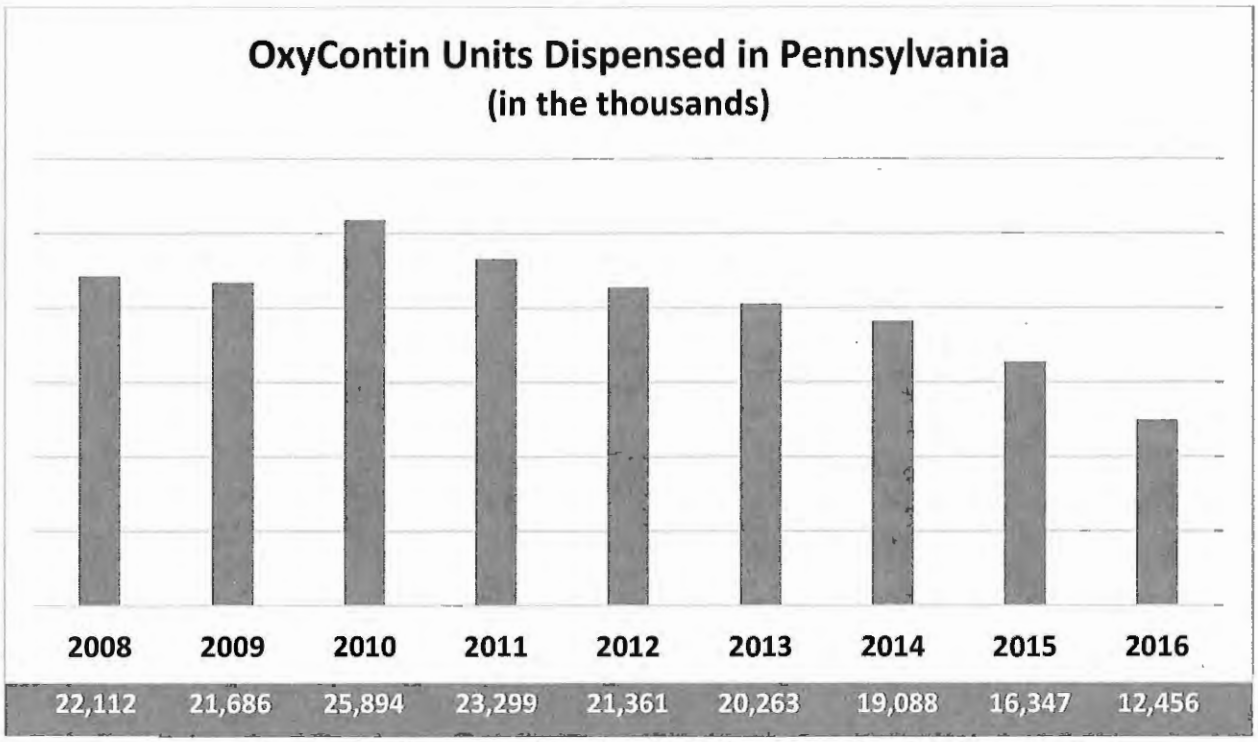
[11] Pennsylvania DEA Opioid Threat Report 2018
[12] *Id.*
[13] Report from the U.S. Senate Committee on Health, Education, Labor, and Pensions: *The Economic Cost of the Opioid Epidemic in Pennsylvania*, https://www.overdosefreepa.pitt.edu/wp-content/uploads/2018/10/The-Economic-Cost-of-the-Opioid-Epidemic-in-Pennsylvania.pdf
[14] *Id.*

tragedy by deceiving doctors and patients about their dangerous drugs, and their deception continues to extract a heavy toll on Pennsylvania lives.

16. Simply stated, Purdue took advantage of addiction to make money. For decades, physicians reserved the use of opioids for treating short-term severe pain, or for patients near the end of life. But the traditional, appropriate practice of limiting opioids to short-term treatment ended after Purdue introduced OxyContin in 1996. OxyContin's sole active ingredient is Oxycodone, a molecule nearly identical to heroin. In 2010, Purdue introduced Butrans, another dangerous drug that releases opioids into the body from a skin patch.[15] Purdue subsequently introduced Hysingla ER in 2014,[16] which contains yet another opioid. Purdue is (and at all relevant times was) simply an opioid manufacturing company. Only a tiny percentage of its revenues are non-opioid related.

17. Since May 8, 2007, when this Court last ruled on Purdue's marketing and sale of OxyContin, Purdue has sold more than 2.9 million prescriptions amounting to over 200 million doses of opioids in Pennsylvania.

[15] https://www.accessdata.fda.gov/drugsatfda_docs/nda/2010/021306_butrans_toc.cfm
[16] https://www.accessdata.fda.gov/drugsatfda_docs/nda/2014/206627Orig1s000TOC.cfm



Pennsylvania OAG graphic based on IMS data from Purdue documents

18. Purdue accomplished these massive sales in part by directing its highly trained and highly incentivized in-state opioid sales force to make more than *half a million* sales calls on Pennsylvania prescribers since 2007. In fact, excluding California, Purdue made more sales visits in Pennsylvania than any other state. Purdue trained its sales force to deliver a misleading and deceptive message to prescribers about the effectiveness and addictive nature of Purdue's opioids more than 500,000 times.

19. For Purdue, opioids have been a gold mine—the Company has made more than $35 billion in revenue since OxyContin's release in 1996.[17]

[17] Patrick Raddon Keefe, *The Family That Built an Empire of Pain*, The New Yorker (2017), https://www.newyorker.com/magazine/2017/10/30/the-family-that-built-an-empire-of-pain

20. For patients, opioids have been a nightmare. Thousands of patients who took Purdue's opioids in Pennsylvania became addicted and died. Drug overdoses skyrocketed 81% in 2016 alone.[18] In 2017, Pennsylvania suffered 5,388 drug overdose deaths—more than any other state[19]—and a majority of those deaths were caused by opioids.[20]

21. The Pennsylvanians we lost came from all walks of life, were rich and poor, young and old. They lived and died in every part of the Commonwealth.

22. As set forth herein, Purdue's misconduct also imposed terrible injuries on the living. People who are addicted to opioids are often unable to work. The addiction of parents can force their children into foster care. Patients who survive addiction need lengthy, difficult, and expensive treatment. Because of Purdue's dishonesty, too many children have lost their parents. Too many parents have buried their children. Too many grandparents are raising their grandchildren.

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[18] Jessica Glenza, *Opioid crisis: overdoses increased by a third across US in 14 months, says CDC*, The Guardian (2018), https://www.theguardian.com/us-news/2018/mar/06/opioid-crisis-overdoses-increased-by-a-third-across-us-in-14-months-says-cdc.

[19] Erin Durkin, *US drug overdose deaths rose to record 72,000 last year, data reveals*, The Guardian (2018), https://www.theguardian.com/us-news/2018/aug/16/us-drug-overdose-deaths-opioids-fentanyl-cdc; Lenny Bernstein, *Bloomberg Philanthropies will donate $50 million to battle opioid epidemic*, The Washington Post (2018), https://www.washingtonpost.com/national/health-science/bloomberg-philanthropies-will-donate-50-million-to-battle-opioid-epidemic/2018/11/29/14fccc5c-f3fb-11e8-80d0-f7e1948d55f4_story.html?utm_term=.363ebb1843b3

[20] Pennsylvania DEA Opioid Threat Report 2018

23. No demographic has been left untouched by this epidemic of addiction and death, including Pennsylvania's most vulnerable population—the babies born to mothers battling opioid addiction. Infants are often born addicted to opioids because they are exposed to these drugs in the womb. Newborns in opioid withdrawal then endure severe discomfort as they are weaned from the drugs taken by their addict mothers. In Pennsylvania, the number of drug-exposed infants—most often opioids—increased *more than 1,000%* from 788 in 2000 to nearly 3,300 in 2017.[21] About 60% suffer from withdrawal, also called neonatal abstinence syndrome or NAS, and signs and symptoms can last as long as six months.[22]

24. Purdue's misconduct described herein has also imposed heavy costs on the people of Pennsylvania and on the Commonwealth. For example, in the past two years, the rate of maternal hospital stays involving substance use in Pennsylvania reached 1 in 25—opioid drugs were present in almost half of those hospitalizations.[23] In fiscal year 2017 alone, intensive care for newborns in opioid

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[21] Pennsylvania Health Care Cost Containment Council, http://www.phc4.org/reports/researchbriefs/neonatal/17/docs/researchbrief_neonatal2017.pdf; *see also* Marie McCullough & Dylan Purcell, *Babies addicted to opioids: A crisis crying for a count*, The Philadelphia Inquirer (2018), http://www2.philly.com/philly/health/addiction/opioid-addiction-crisis-babies-mothers-data-20180223.html; Marie McCullough, *Newborns in opioid withdrawal may do better on methadone than morphine, major study finds,* The Philadelphia Inquirer (2018), http://www2.philly.com/philly/health/newborns-in-opioid-withdrawal-may-do-better-on-methadone-than-morphine-major-study-finds-20180618.html.

[22] March of Dimes, https://www.marchofdimes.org/complications/neonatal-abstinence-syndrome-(nas).aspx

[23] Pennsylvania Health Care Cost Council, http://www.phc4.org/reports/researchbriefs/opioids/121118/docs/researchbrief_opioids121118.p

withdrawal added an estimated $14.1 million in costs even before the baby came home from the hospital. The Pennsylvania Medicaid program was the anticipated payer for 86.9% of NAS-related hospitalizations and nearly 82% maternal stays involving opioid use, costing taxpayers across the state millions of dollars.[24] The injuries from addiction and overdose are staggering. Recently, the White House Council of Economic Advisers (CEA) determined that a middle estimate of the cost of each death from opioid overdose is $9.6 million.[25] Using the methodology adapted from the CEA report, a U.S. Senate Committee analysis shows the economic impact on Pennsylvania exceeded $142 billion from 2012 to 2016. The opioid crisis cost Pennsylvania over $53 billion in 2016 alone (most recent data available)—and this does not account for the many prior years of this scourge.[26]

25. In order to illegitimately expand the market for its dangerous drugs, Purdue engaged in a multi-faceted and illegal campaign of deception targeting both Pennsylvania doctors and patients. First, Purdue deceived patients and doctors about the dangers and risks of long-term opioid use to get more and more people on its drugs. Second, Purdue conducted a deceptive marketing scheme to mislead them into prescribing and taking higher, more potent doses. Third, Purdue encouraged

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[24] *See* note 21 and 23, *supra*.

[25] White House Council of Economic Advisers (CEA) Report, https://www.whitehouse.gov/sites/whitehouse.gov/files/images/The%20Underestimated%20Cost%20of%20the%20Opioid%20Crisis.pdf

[26] *See* note 13, *supra*.

them to stay on its opioids for longer and more harmful periods of time despite the known risks.

26. All the while, Purdue peddled falsehoods to keep patients away from safer alternatives. Even when Purdue knew people were addicted and dying, Purdue treated patients and their doctors as "targets" to sell more drugs. Tragically, each part of Purdue's campaign of deception earned the company more money, and caused more addiction and death.

27. Ultimately, Purdue's false statements played a major role in moving Pennsylvania out of a world in which opioid use was sharply limited, due to well-documented concerns about addiction and patient safety, and into a world where opioid prescriptions, addictions, and overdoses—and all of the pain and loss that flows directly from them—have become omnipresent.

28. Pennsylvania's Consumer Protection Law is intended to protect members of the public from being harmed by unethical and unscrupulous business practices, including deceptive statements and conduct, carried out in Pennsylvania commerce. Since the Consumer Protection Law was enacted, few commercial situations have been created within Pennsylvania that have caused as much harm to as many Pennsylvanians as the opioid epidemic. Through this legal action, the Attorney General of Pennsylvania seeks to hold Purdue accountable for its wrongful and illegal actions, and to put a stop to them.

FACTUAL ALLEGATIONS

I. PURDUE CREATED THE MARKET FOR CHRONIC USE OF OPIOIDS IN PENNSYLVANIA THROUGH A RELENTLESS CAMPAIGN OF DECEPTION

29. For decades (if not centuries) before 2007—when Purdue executives entered criminal guilty pleas and Purdue agreed to pay $650 million to resolve state and federal fraud charges for corporate behavior strikingly similar to the allegations herein—opioids were widely recognized by the medical community as highly addictive. Consequently, they were prescribed only in very limited, carefully controlled, *short term* circumstances: for severe cancer and post-surgical pain, and for palliative (end of life) care. Even then, providers generally prescribed opioids for short-term use, except for when a patient was dying.

30. But the market for responsible treatment of acute and end of life pain was small, with cancer-related pain constituting only 14% of the total pain market in 1999.[27] Thus, when Purdue launched OxyContin in 1996, the company sought to dramatically and illegitimately expand that small market by broadening the drug's use to chronic pain—back pain, arthritis, and headaches among other examples. These more "everyday" ailments are not only more widespread in Pennsylvania, but allegedly (according to Purdue) require taking opioids for months

[27] Art Van Zee, *The Promotion and Marketing of OxyContin: Commercial Triumph, Public Health Tragedy*, 99(2) Am J Public Health (2009).

and even years. To pursue that goal, Purdue embarked on an ambitious, multi-faceted campaign of deception with the aim of fundamentally changing attitudes, practices, and culture around pain management. However, Purdue's deceptive and misleading money-making scheme met early resistance because there was *no scientific support* for the use of opioids in this unprecedented manner. As Purdue found out, doctors were appropriately too worried about the risk of addicting their patients to prescribe opioids for regular aches and pains.

31. To overcome this barrier to widespread prescribing, Purdue embarked on its campaign of deception throughout Pennsylvania to convince doctors of a basic (and ultimately lethal) falsehood: that patients with legitimate chronic pain under a doctor's care would not become addicted to opioids. Shockingly, this statement had *no basis in science* when Purdue peddled it brazenly in 2007 (and before), nor does it have any such basis now. In order to "make the sale" Purdue also made other deceptive claims to Pennsylvania prescribers and patients, including, for example: (1) pain is undertreated; (2) long term use of OxyContin was appropriate to treat moderate to severe chronic pain; (3) OxyContin has no maximum dose and prescribers could increase the potency of a prescription without posing an added risk of addiction; (4) OxyContin's dose is effective for twelve hours; and (5) OxyContin is superior to other opioid and non-opioid pain medications.. Unfortunately, despite the lack of any scientific basis for any of these claims, Purdue's relentless campaign

of deception was hugely successful.

32. The effects of Purdue's multi-faceted campaign of deception have been devastating. As discussed more fully below, in addition to being ineffective as a pain treatment, the long-term use of opioids for chronic pain is particularly dangerous because patients develop a tolerance to the drugs over time, which then requires higher doses to achieve their therapeutic effect. High doses of opioids depress the respiratory system and eventually cause the user to stop breathing, which is what makes opioid overdoses fatal. Unfortunately, patients who avoid this lethal fate also quickly become dependent on opioids and will often experience severe withdrawal symptoms if they stop using the drugs. Consequently, patients struggle to discontinue opioid use even after periods of use as short as five days.[28] The risk of addiction increases with the duration of use and causes patients to use opioids at even higher doses, even when such higher use can cause harms like overdose and death. It is this mix of tolerance, dependence, and addiction that has made the use of opioids for chronic pain so deadly.

33. Unlike other terrifying epidemics throughout history, this epidemic did not need to happen—it was *entirely avoidable*. Contrary to Purdue's massively deceptive marketing claims, pain patients who use opioids *precisely as*

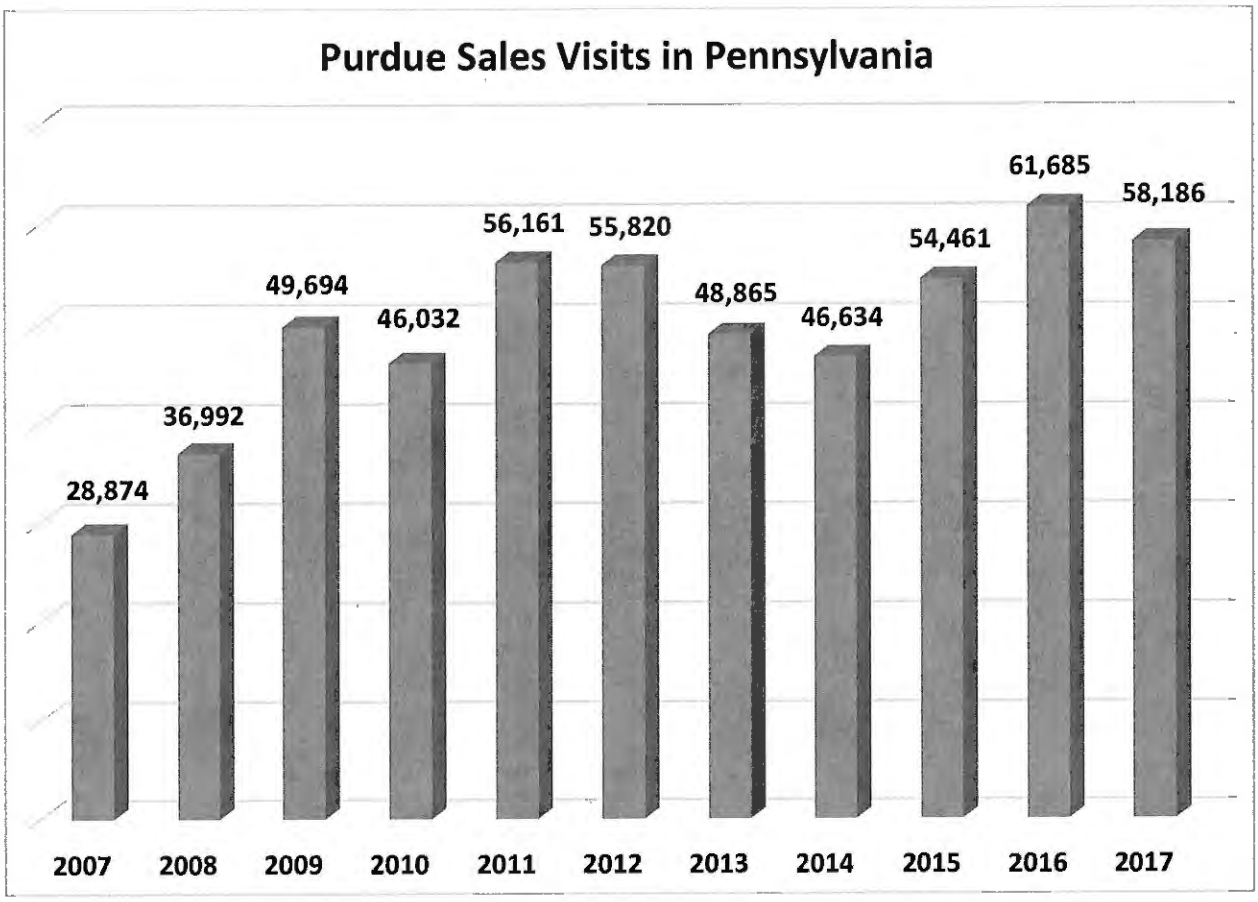
[28] Anuj Shah et al., *Characteristics of Initial Prescription Episodes and Likelihood of Long-Term Opioid Use — United States, 2006–2015*, 66(10) MMWR Morb Mortal Wkly Rep 265 (2017), http://dx.doi.org/10.15585/mmwr.mm6610a1.

prescribed by a legitimate doctor can—and do—become addicted, with crippling and often fatal consequences. Despite Purdue's best efforts to convince Pennsylvanians otherwise, addiction is the result of *using* opioids, not just misusing or abusing them.

A. Purdue's Campaign of Deception—How It Worked

(1) Purdue Made More Than Half a Million In-Person Sales Calls

34. Purdue's campaign of deception took several forms. First, Purdue deployed its highly trained sales staff to blanket the Commonwealth, making more than a half million sales calls on Pennsylvania prescribers since 2007. The process of in-person pharmaceutical sales calls is known as "detailing".



Pennsylvania OAG graphic based on Purdue documents

35. Pennsylvania prescribers stated that Purdue sales representatives visited once a week (or more) even absent any new developments in their drugs requiring explanation. At all relevant times, Purdue sales representatives have been required to create "call notes" (*i.e.*, recorded summaries of their sales calls with health care providers). As Purdue's call notes document, its sales representatives, acting at Purdue's direction, repeatedly made deceptive statements and distributed deceptive materials in their hundreds of thousands of interactions with Pennsylvania providers.

36. Each of these in-person sales visits cost Purdue money, but the

company made that money back many times over by pushing doctors to prescribe more and more of its addictive drugs. When Purdue identified a doctor as a profitable "target," Purdue sent its sales staff to him or her frequently—often weekly, sometimes almost every day. Purdue salespersons asked doctors to list specific patients they were scheduled to see, and pushed them to "commit" to putting the patients on Purdue opioids. By the time a patient walked into a clinic, the doctor had already "guaranteed" that he would prescribe Purdue's drugs. Purdue rewarded high-prescribing Pennsylvania doctors with attention, meals, gifts and money, spending more than $1.5 million dollars from 2007 to 2017 alone during the course of its sales detailing to nearly 15,000 individual Pennsylvania providers.

37. Purdue studied the "return on investment" of its sales visits, marketing techniques, and payments to doctors. The Company judged its employees based on how many prescriptions they got doctors to write. Sales representatives who generated the most prescriptions won bonuses and prizes from Purdue. Salespeople who failed to get enough patients on opioids were placed on probation, put on performance improvement plans, and fired.

(2) Purdue Engaged in Branded and Unbranded Promotion

38. To complement this massive in-person sales effort, the Company engaged in aggressive branded promotion—giveaways of stuffed animals, CDs, clocks, and luxury getaways for top OxyContin sellers and prescribers.

39. As described more fully below, Purdue also deceptively used general, unbranded materials produced by Purdue or (seemingly) "independent" third parties to build the newly fabricated market for long-term opioid use to treat chronic pain. (Unbranded promotion does not name a specific drug and is often more persuasive because it does not seem to directly advertise the pharmaceutical company's product). For example, Purdue secured rights to distribute "Pain as a Fifth Vital Sign," an initiative of the Joint Commission for Accreditation of Hospital Organizations ("JCAHO").[29] Virtually every health care facility and provider in the country was exposed to Purdue's novel and self-serving recommendation that pain was as vital a measure of health as other constantly tested vitals, such as pulse, breathing, temperature, and blood pressure. Once doctors asked about pain, they were obligated to treat it, and Purdue labored tirelessly to make sure that doctors knew its opioids were an allegedly appropriate option.

40. Purdue also sponsored and maintained a promotional website called *In the Face of Pain* at www.inthefaceofpain.com. The Company used this

[29] *See e.g.*, U.S. Gen. Accounting Office, GAO-04-110, *Prescription Drugs: OxyContin Abuse and Diversion and Efforts to Address the Problem* (2003), https://www.govinfo.gov/content/pkg/GAOREPORTS-GAO-04-110/pdf/GAOREPORTS-GAO-04-110.pdf; Brian F. Mandell, *The Fifth Vital Sign: A Complex Story of Politics and Patient Care*, 83(6) Clev. Clin. J. Med. 400 (2016), https://www.mdedge.com/ccjm/article/109138/drug-therapy/fifth-vital-sign-complex-story-politics-and-patient-care; Carl E. Noe et al., *Outcomes of a Pain Management Educational Initiative at Baylor University Medical Center*, 15(1) Proc (Bayl Univ Med Cent) 3 (2002), https://www.ncbi.nlm.nih.gov/pmc/articles/PMC1276325/.

website extensively to disseminate deceptive information about its opioid products. The website contained little or no Purdue branding, and was designed to appear (except on very close examination) as if it were operated by a neutral third party. One way Purdue used the website was by having its sales representatives refer healthcare providers to it as a source of information about opioids.

41. Purdue launched the *In the Face of Pain* website in 2001, and continued in operation until the Company deactivated it effective October 1, 2015. Purdue only deactivated this deceptive website following an investigation by the New York Attorney General into the Company's marketing practices.[30] Purdue's *In the Face of Pain* website was viewed in Pennsylvania more than 18,200 times.

(3) Purdue Employed "Key Opinion Leaders"

42. Purdue also deployed "key opinion leaders" ("KOLs")—medical experts in the field who were especially influential in the prescribing community because of their reputations and seeming objectivity—to deliver paid talks and continuing medical education programs ("CMEs") about opioids. These programs repeatedly provided deceptive and misleading information about treating chronic pain and the risks, benefits, and use of opioids. Purdue paid the "independent" KOLs handsomely, a fact that was intentionally shrouded in secrecy like so much of

[30] Attorney General of the State of New York, In the Matter of Purdue Pharma L.P., Assurance No.: 15-151 (August 19, 2015), http://www.ag.ny.gov/pdfs/Purdue-AOD-Executed.pdf

Purdue's devastating campaign. The Company pioneered this strategy, which allowed Purdue to control the messenger, the message, and the distribution of the speaker programs. Only doctors supportive of the use and safety of opioids for chronic pain received these funding and speaking opportunities, which were not only lucrative, but also helped doctors build their reputations and bodies of work. Purdue designed its KOL strategy to unduly influence physicians' opioid prescribing behavior, and tragically, the Company's efforts were wildly successful.

43. One leading KOL, Dr. Russell Portenoy, subsequently acknowledged in a September 2012 interview with *The Wall Street Journal* that he gave lectures on opioids (sponsored by Purdue and other opioid manufacturers) that reflected "misinformation" and "were clearly the wrong thing to do."[31]

(4) Purdue Sponsored "Front Groups" to Spread its Deceptive Message

44. In addition to pharmaceutical speaker programs and CMEs, these KOLs permeated the medical community by serving on the boards of patient advocacy groups and influential professional associations, such as the high profile American Pain Foundation ("APF") and the American Pain Society ("APS"). These groups were able to exert tremendous influence due in no small part to their

[31] Thomas Catan & Evan Perez, *A Pain-Drug Champion Has Second Thoughts*, The Wall Street Journal (2012), https://www.wsj.com/articles/SB10001424127887324478304578173342657044604

seeming—but illusory—independence. As with the undisclosed speaker deals with KOLs, Purdue and other pharmaceutical companies controlled these groups covertly as well. These "front groups" for the opioid industry (which included but were not limited to APF and APS) put out scientifically unsupported and self-serving patient education materials and treatment guidelines that deceptively promoted the use of opioids for chronic pain. All the while, these publications overstated the benefits of opioids and understated their risks. As discussed more fully below (*see* ¶¶ 55 – 120), Purdue distributed thousands of these publications to prescribers throughout Pennsylvania and posted them on its website, which were available to and viewed by Pennsylvanians.

45. In 2012, as the United States Senate Finance Committee launched an investigation into the makers of opioids and the organizations that pushed them, the American Pain Foundation shut its doors.

(5) Purdue Targeted Vulnerable Populations

46. Purdue's campaign of deception did not target Pennsylvania prescribers alone—through those health care professionals Purdue also targeted very specific (and potentially lucrative) patient groups, including the elderly and veterans. Both patient populations were uniquely vulnerable to Purdue's deception, and the Company moved aggressively to exploit these markets as part of its deceptive campaign.

a. Elderly Patients

47. Elderly patients are particularly vulnerable to the dangers posed by opioids. The elderly are highly vulnerable to adverse interactions between different drugs. Opioids' greatest threat—respiratory depression (where patients stop breathing and die)—poses a heightened risk in Pennsylvania's older patient population. Purdue also knew that prescribing opioids to elderly patients increases their risk of death.

48. The Center for Disease Control (CDC) has recognized older adults as a population at greater risk of harm because they have an increased risk for falls and fractures while taking opioids; toxic levels of opioids can accumulate in their systems because they have decreased clearance of drugs; cognitive impairment can increase the risk for medication errors; and they are more likely to have additional medical conditions that require medications that could interact with opioids. The CDC Guideline indicates that providers "should use additional caution and increased monitoring…to minimize risks of opioids prescribed for patients aged [greater than or equal to] 65."[32] OxyContin's label even recognizes that respiratory depression as a side effect of OxyContin "is a particular problem in elderly or debilitated patients."[33]

[32] CDC Guideline at 27.
[33] OxyContin [package insert]. Purdue Pharma L.P. (2007), Stamford, CT.

49. Unfortunately, despite these profound risks, Pennsylvania's elderly population presented Purdue with a potentially huge market for its opioids. The elderly market also offered another advantage to Purdue in its quest for profits—the public would pay through Medicare. Purdue's internal documents, while discussing an advertisement in a publication called the *Annals of Long Term Care*, noted that the advertisement was "targeted to HCPs (health care providers) that practice in the long term care setting, this journal ad reinforces the brand's excellent Medicare Part D coverage and leverages images of older patients." Other Purdue documents reveal that the Company targeted "patients over the age of 65 as more Medicare Part D coverage is achieved." Records of sales meetings in Pennsylvania indicate that Purdue discussed Medicare Part D and other insurance coverage more than 6,500 times.

50. Purdue disregarded and obscured the risks to the health of elderly patients in its deceptive sales campaign. Purdue sales supervisors aggressively coached their sales staff to emphasize the prescribing of OxyContin and other Purdue opioids to elderly patients during their constant sales visits to prescribers throughout the Commonwealth. For example, Purdue supervisors repeatedly urged detailers to "focus on the geriatric population" within various prescribers' practices. Upon learning that a prescriber's practice was "50% geriatric" a Purdue sales manager demanded that the Purdue salesperson "focus more on geriatric patients and pain

management" and follow-up "within this patient population to identify appropriate new patients for OxyContin." Purdue also urged its sales representatives to exploit the elderly population in Pennsylvania for profits by urging them to "follow up on identifying specific patients especially within UHC/AARP."

51. This focused targeting of elderly patients generated a substantial increase in sales: from 1996 to 2010, the number of opioid prescriptions provided to older patients increased nine-fold. More alarming, 35% of patients aged 50 or older who experienced chronic pain reported misuse of their opioid prescriptions within thirty days of the survey into their behaviors. The hospitalization rate for geriatric misuse of opioids has quintupled in the past 20 years alone.[34]

b. Veterans

52. Similarly, Purdue demanded that its sales staff blanketing the Commonwealth day in and day out emphasize veterans to prescribers as ideal patients for its opioid products. Like the elderly, many veterans' prescriptions are paid for by the public, providing yet another source of revenue for Purdue—if it could persuade health care professionals to prescribe OxyContin and its other opioid products.

53. To target veterans, Purdue funded a book titled *Exit Wounds: A*

[34] Uma Suryadevara et al., *Opioid Use in the Elderly*, 35(1) Psychiatric Times (2018), https://www.psychiatrictimes.com/special-reports/opioid-use-elderly

Survival Guide to Pain Management for Returning Veterans and Their Families." The book also had a companion website (www.exitwoundsforveterans.org) accessible at all relevant times to Pennsylvania veterans. The book was developed by APF, a Purdue front group, and included a preface written by Scott Fishman, MD, then-president of APF and a Purdue KOL. *Exit Wounds* deceptively assured veterans that Purdue's opioids are not addictive:

> *"The pain relieving properties of opioids are unsurpassed; they are today considered the "gold standard" of pain medications, and so are often the main medications used in the treatment of chronic pain. Yet, despite their great benefits, opioids are often underused. For a number of reasons, healthcare providers may be afraid to prescribe them, and patients may be afraid to take them. At the core of this wariness is the fear of addiction, so I want to tackle this issue head-on...Long experience with opioids shows that people who are not predisposed to addiction are unlikely to become addicted to opioid pain medications."*

54. While it advances Purdue's campaign of deception to boost opioid sales to a vulnerable population, nowhere does *Exit Wounds* mention the risk of death or respiratory depression posed by the use of opioids, nor does it mention risks to reproductive health or to the well-being of the elderly. Although the book provided spoke of some common side effects of opioids—*e.g.* constipation, sleeping, and difficulty urinating—it failed to disclose the risk of addiction, overdose, or injury associated with opioid use. The book also failed to disclose that interactions between opioids and anti-anxiety medications (taken by many veterans for PTSD) can be fatal.

B. Purdue's Campaign of Deception—The Message

55. For years, Purdue has used the tools and methods described above to spread self-serving and deceptive untruths about opioid medications among Pennsylvania prescribers and patients. To accomplish their endgame, the Company purposefully misled and/or omitted material information in their branded and unbranded marketing about the risks of opioids, while overstating their efficacy and benefits in treating chronic pain long-term.

56. Purdue employees and KOLs identified, funded, published, and disseminated research that was designed to advance Purdue's bogus marketing efforts by skewing or misreporting the scientific evidence.

57. Neither these third-party unbranded materials nor the marketing messages or scripts relied on by Purdue's sales representatives were reviewed or approved by the U.S. Food & Drug Administration ("FDA"). Purdue disseminated all of the unvetted messages described below to Pennsylvania prescribers and patients through sales visits, company-sponsored medical education programs, marketing materials, websites, and other promotional sources.

58. Purdue's marketing budget has exploded since the launch of OxyContin, with the largest promotional spending taking place *after* 2007. In Pennsylvania alone, Purdue spent ***at least*** $2.5 million from 2007-2017 on opioid marketing through its sales detailing, speaker programs, educational grants and a

variety of CME programs.

59. Specifically, Purdue has affirmatively misrepresented that: (a) "legitimate" pain patients do not become addicted to opioids and/or the addiction risk is extremely low; (b) its long-acting opioids are "steady state" and therefore less addictive; (c) doctors can identify and manage the risk of addiction; (d) patients who seem addicted are merely "pseudoaddicted" and should be treated with more opioids; (e) opioid addiction is not the product of pharmaceutical opioids themselves, but problem patients and doctors; and (f) opioid abuse and addiction primarily manifests in snorting and injecting the drugs when, in fact, oral abuse is far more common. In addition to these affirmative misrepresentations, Purdue did not disclose the high abuse potential of its drugs or the massive risks of addiction to—and withdrawal from—opioids in general. The Company further spread misinformation that opioids improve patient functioning and quality of life, exaggerated the risks of non-opioid pain medication and downplayed the adverse effects of opioids, and misleadingly promoted OxyContin as providing 12 hours of continuous pain relief. These misrepresentations were targeted to Pennsylvania prescribers and patients both directly and through third parties.

60. The facts alleged below are examples of Purdue's false, deceptive, and unfair conduct identified to date. It is not an exhaustive list, and discovery may identify additional practices that were part of the same overreaching

scheme by Purdue to build and maintain a market for its opioids in Pennsylvania, which will be part of the Commonwealth's evidence and claims for relief in this matter.

(1) Purdue Misrepresented and Minimized the Risk of Addiction from Long-Term Opioid Use

61. During their sales conversations with Pennsylvania prescribers, Purdue representatives repeatedly downplayed and/or misrepresented the risk of addiction from the long-term use of opioids. Their deceptive omissions have inflicted catastrophic injury to the health, safety, and welfare of Pennsylvanians throughout the Commonwealth.

62. Moreover, Purdue continued to affirmatively misrepresent that pain patients would not become addicted to its opioids. According to one Pennsylvania doctor, when asked about the risks associated with long-term opioid use, Purdue representatives "glossed over" the potential for addiction by redirecting him to focus on pain reduction for patients. During detailing visits to Pennsylvania prescribers, sales staff also frequently promoted the "safety and efficacy" of Purdue opioids (especially in lower dosage strengths) in treating all types of chronic pain conditions, including osteoarthritis and diabetic neuropathic pain. As just one example of many, Purdue promised in one of its promotional videos that "less than

one percent" of patients would become addicted to opioids.[35]

63. To back its unsupported claim that opioids were rarely addictive (and because it had no other evidence), Purdue included in promotional and educational materials a citation to the prestigious *New England Journal of Medicine*, but failed to disclose its (now notorious) source was merely an anecdotal, non-scientific, and non-peer reviewed one-paragraph letter to the editor that contended, based on nothing more than casual observation of a few hospital patients, that opioids are non-addictive (the "Porter/Jick letter").[36] Remarkably, Purdue hawked this flimsy letter as an authoritative, well-founded source to convince prescribers and patients in Pennsylvania and elsewhere that its new opioids were not addictive. Of course, that conclusion was "not in any shape or form what we suggested in our letter," according to one of its authors, Dr. Hershel Jick.[37] Unfortunately, Dr. Jick's admonition was too little too late. A June 2017 analysis in the *Journal* found that citation of the Porter/Jick letter in medical literature significantly increased after Purdue introduced OxyContin and "contributed to the North American opioid crisis

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[35] *See, e.g.*, Purdue Pharma, L.P., *I Got My Life Back*, YouTube (1998), https://www.youtube.com/watch?v=Er78Dj5hyeI (published Sept 22, 2016).
[36] J. Porter & H. Jick, *Addiction Rare in Patients Treated with Narcotics*, 302(2) New Eng. J. Med. 123 (1980)
[37] Taylor Haney & Andrea Hsu, *Doctor Who Wrote 1980 Letter On Painkillers Regrets That It Fed The Opioid Crisis*, NPR (2017), https://www.npr.org/sections/health-shots/2017/06/16/533060031/doctor-who-wrote-1980-letter-on-painkillers-regrets-that-it-fed-the-opioid-crisis

by helping to shape a narrative that allayed prescribers' concerns about the risk of addiction associated with long term opioid therapy."[38] Unfortunately the anecdotal letter continues to be widely cited in medical literature and materials.

64. As noted above, *more than half a million sales calls* blanketing the Commonwealth were only one tool in Purdue's campaign of deception concerning opioid addiction. Not satisfied with this marketing blitzkrieg, Purdue also disseminated misleading information about opioids and addiction through APF. For example, *A Policymaker's Guide to Understanding Pain & Its Management,* a 2011 APF publication that Purdue sponsored, claimed (without scientific support) that pain had been "undertreated due to "[m]isconceptions about opioid addiction." This guide also deceptively claimed that "less than 1% of children treated with opioids become addicted" and perpetuated the entirely made-up concept of pseudoaddiction, the Purdue-created notion that addictive behaviors should be seen not as warnings, but as indications of undertreated pain (*see ¶¶* 73 – 83). Upon 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.* It is still available to Pennsylvania prescribers online.[39]

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[38] Pamela T.M. Leung et al., *A 1980 Letter on the Risk of Opioid Addiction*, New Eng. J. Med. (2017), https://www.nejm.org/doi/full/10.1056/NEJMc1700150

[39] http://s3.documentcloud.org/documents/277603/apf-policymakers-guide.pdf

65. Another Purdue publication, the *Resource Guide for People With Pain* (2010), falsely assured patients and doctors that opioid medications are not addictive, stating:

> *Many people living with pain and even some healthcare providers believe that opioid medications are addictive. The truth is that when properly prescribed by a healthcare professional and taken as directed these medications give relief - not a "high."*

66. Purdue funded and distributed many more publications in Pennsylvania that were similarly misleading. *Opioid Prescribing: Clinical Tools and Risk Management Strategies* (2009) told doctors that "addiction is rare in patients who become psychologically dependent on opioids while using them for pain control," and that "behaviors that suggest abuse may only reflect a patient's attempt to feel normal."

67. Similarly, Purdue's *Responsible Opioid Prescribing* (2007) told doctors that only "a small minority of people seeking treatment may not be reliable or trustworthy" and not suitable for addictive opioid drugs.

68. Purdue also deceptively told Pennsylvania prescribers that its long acting opioids released the drug steadily over 12 hours, with no peaks and troughs. This promise of steady release implies (and is understood by prescribers to mean) that Purdue's opioids are less addictive than other opioids because they do not trigger the euphoric rush and crash that fuel drug cravings. According to one

Pennsylvania doctor, Purdue representatives never told him that the original formulation released an initial 10% "surge" of oxycodone, which was one the reasons many patients preferred the drug.

69. Besides deceiving and misleading Pennsylvania prescribers about the often fatal risks of opioid addiction, Purdue sales representatives also did not disclose to Pennsylvania prescribers the difficulty of *withdrawing* from opioids. Discontinuing or delaying opioids can cause intense physical and psychological effects, including anxiety, nausea, headaches, and delirium (among others). Withdrawal symptoms can leave many patients unwilling or unable to give up opioids and heightens the risk of addiction.

(2) Purdue Deceptively Claimed Risk of Addiction Could Be Managed With Simple Tools

70. Purdue claimed that by using a simple questionnaire, doctors could identify and segregate "high risk" patients and safely prescribe to all other patients without risk of addiction. As with virtually every other element of Purdue's campaign of deception, *there is no scientific basis for this claim.*[40] Purdue failed to disclose that there is no scientific evidence that screening and other risk management strategies promoted by the Company, such as patient contracts, actually mitigate

[40] Deborah Dowell et al., *CDC Guideline for Prescribing Opioids for Chronic Pain – United States, 2016*, 65(1) MMWR Recomm. Rep. (2016), https://www.cdc.gov/mmwr/volumes/65/rr/pdfs/rr6501e1.pdf.

addiction risk.

71. For instance, Purdue distributed more than 5,300 units of its *Partners Against Pain* "Pain Management Kits" into Pennsylvania. These kits contained several "drug abuse screening tools," and CDs with catalogues of Purdue materials, which also included these tools. Purdue sponsored CMEs that propped up the same deceptive message promoted in the Pain Management Kits. For example, a 2011 CME program taught by Dr. Lynn Webster (another "independent" KOL covertly funded by the Company) and viewed by Pennsylvania prescribers was titled *Managing Patients Opioid Use: Balancing the Need and Risk.* This presentation deceptively instructed that screening tools, patient agreements, and urine tests prevented overuse of prescriptions and overdose deaths. Another Purdue-funded 2012 CME, *Chronic Pain Management and Opioid Use: Easing Fears, Managing Risks, and Improving Outcomes*, deceptively instructed doctors that through this use of screening tools, more frequent refills, and other techniques, high-risk patients showing signs of addictive behavior could be treated with opioids.

72. Purdue used its investment in another third-party group, the Philadelphia-based College on the Problems of Drug Dependence ("CPDD"), to promote the bogus idea that addiction risk can be managed. CPDD provides training and support to addiction treatment professionals nationwide, and from approximately September 2014 through June 2018, a Purdue employee served on

the Board of Directors. During this time period, the Purdue employee and CPDD director made numerous presentations at CPDD's Annual Scientific Meetings in support of pharmaceutical opioids. Purdue was also allowed more opportunities to present its research than other drug companies at each CPDD conference, and provided very different messages from non-Purdue presentations. One of Purdue's consistent themes is that "bad apple" patients, not opioids, are the source of the addiction crisis, and that once those patients are identified doctors can safely prescribe opioids without addicting patients. For example, at the 2015 CPDD Meeting, Purdue presented a paper challenging the correlation between opioid dosage and overdose. Hundreds of addiction treatment specialists from across the country attended these conferences.

(3) Purdue Promoted the Fabricated Concept of Pseudoaddiction to Discount Signs of Addiction

73. Purdue also advised doctors to ignore actual signs of addiction when prescribing its opioids, arguing that these signs were instead merely the product of a completely fabricated (and now debunked) condition that Purdue labeled as "pseudoaddiction." The Company's contrived, "nothing to see here" pseudoaddiction theory was (once again) utterly devoid of scientific support. Purdue used the concept of pseudoaddiction to justify continuing to prescribe opioids even after a patient begins to show signs of addiction, including "clock watching,"

inappropriate drug-seeking behavior, "illicit drug use," and "deception." Instead of acknowledging that a patient adopting these behaviors is likely addicted to opioids, Purdue claimed that these are signs of pseudoaddiction, caused not by the opioid, but by undertreated pain. According to Purdue, patients showing signs of these troubling behaviors were actually not being given enough opioids. The bogus "theory" of pseudoaddiction was coined by one biased doctor, David Haddox (a covertly paid KOL later hired by Purdue) and hung on a very scientifically thin, non-peer reviewed reed—the observation of a single patient. Undaunted by its wholly illegitimate origin, Purdue deceptively described pseudoaddiction as an accepted scientific concept.

74. In *Providing Relief Preventing Abuse*, a key marketing pamphlet published by Purdue in 2011 for prescribers and law enforcement, Purdue described pseudoaddiction as a term that "has emerged in the literature to describe the inaccurate interpretation of [drug-seeking] behaviors in patients who have pain that has not been effectively treated." Purdue distributed more than 3,300 copies of this pamphlet in Pennsylvania. The pamphlet failed to disclose that: (1) Purdue itself was the source of the term; (2) none of the "literature" it cited included scientific or medical evidence supporting pseudoaddiction as a diagnosis separate from addiction; and (3) all of the cited "literature" was linked to organizations and doctors paid by Purdue. Soon, leading proponents of pseudoaddiction were forced to face

the devastating and deadly consequences of peddling this dangerous concept, and several prominent KOLs paid by Purdue later reversed themselves.[41]

75. Purdue's promotion of the made-up notion of pseudoaddiction dates back to at least 2007. A Purdue presentation for doctors entitled *Medication Therapy Management* (November 2007) recited what had been the consensus view for decades: "many medical students are taught that if opioids are prescribed in high doses or for a prolonged time, the patient will become an addict." Purdue then assured doctors that this traditional concern about addiction was wrong, claiming instead that patients instead suffer from "pseudoaddiction" because "opioids are frequently prescribed in doses that are inadequate."

76. A Purdue pamphlet entitled *Clinical Issues in Opioid Prescribing* (2008) deceptively urged doctors to embark on a mission to detect pseudoaddiction:

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

Purdue again urged doctors to prescribe higher doses, stating that opioids "are

[41] John Fauber, *Painkiller Boom Fueled by Networking*, Milwaukee Wisc. J. Sentinel (2012), http://www.seattle.gov/documents/departments/cityAttorney/opioidLitigation/FN17-PainkillerBoomFueled.%202-18-2012.pdf

frequently underdosed—or even withheld due to a widespread lack of information…about their use among healthcare professionals." In other words, when confronted with a drowning man Purdue recommended making the water deeper. Purdue distributed nearly 1,500 copies (at least) of this pamphlet to Pennsylvania prescribers.

77. Purdue also disseminated a CD-ROM entitled "Complexities of Caring For People in Pain." In it, Purdue characterized untreated and undertreated pain as an epidemic and falsely attributed this undertreatment of pain as "pseudoaddiction."

78. Purdue also distributed copies of a CD-ROM entitled "Consensus Paper: Definitions Related to the Use of Opioids for the Treatment of Pain," which stated that pseudoaddiction is a term which has been used to describe patient behaviors that may occur when pain is undertreated." Purdue stated that psuedoaddictive behaviors "resolve when pain is effectively treated."

79. In an earlier 2008 version of Purdue's *Providing Relief, Preventing Abuse: A Reference Guide to Controlled Substance Prescribing Practices,* the Company admonished doctors that "[u]ndertreatment of pain is a serious problem" and "pain should be treated aggressively." Purdue further stated that "[m]isunderstanding of addiction and mislabeling of patients as addicts result in unnecessary withholding of opioid medications."

80. Purdue urged doctors to prescribe higher opioid doses in a Purdue-sponsored book available in Pennsylvania, *Responsible Opioid Prescribing: A Clinician's Guide* (2007) written by Scott Fishman. This book claimed that certain problem behaviors—such as taking another person's opioids, requesting drugs by name, asking for medications before they are due, seeing more than one provider to obtain opioids, using more opioids than recommended, and other—were signs not of real addiction, but of pseudoaddiction. These deceptive message were again repeated in the 2011 version of the publication.

81. Purdue promoted pseudoaddiction on its website *Partners Against Pain* through at least 2013.[42] This website was available to Pennsylvanians at all relevant times and viewed in Pennsylvania nearly 22,000 times. Additionally, Purdue distributed more than 5,700 printouts from the *Partners Against Pain* website to Pennsylvania doctors and patients.

82. Upon information and belief, Purdue knew that the concept of pseudoaddiction was misleading and deceptive. A number of physicians with close ties to Purdue—and who had helped spread earlier marketing messages to other

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

physicians—have since acknowledged that pseudoaddiction is not a valid concept. Dr. Lynn Webster, a Utah pain specialist and former president of the AAPM, conceded that pseudoaddiction "obviously became too much of an excuse to give patients more medication. It led us down a path that caused harm. It is already something we are debunking as a concept." Likewise, Dr. Russell Portenoy, a Purdue KOL, admitted "the term has taken on a bit of a life of its own. That's a mistake."[43] Unfortunately, the epiphanies of these KOLs were too late for many Pennsylvanians.

83. Purdue knew its relentless and catastrophic campaign of deception to push higher doses of opioids was wrong. Doctors on Purdue's payroll admitted in writing that pseudoaddiction was used to describe "behaviors that are clearly characterized as drug abuse" and put Purdue at risk of "ignoring" addiction and "sanctioning abuse." Nevertheless, Purdue urged doctors to respond to clear signs of addiction with more aggressive opioid treatment by prescribing higher doses of Purdue's drugs. Purdue representatives continued to promote the clinical construct of pseudoaddiction during sales visits to Pennsylvania prescribers as late as 2014.

(4) Purdue Falsely Portrayed Addiction as a Drug Abuse and Diversion Problem and not a Problem with Opioid Use

84. In addition to deceptively chalking up real signs of opioid

[43] *See* note 41, *supra*.

addiction to so-called "pseudoaddiction," Purdue falsely portrayed "true" addiction in its narrowest form. For instance, as a tool to "educate" Pennsylvania prescribers, *Providing Relief, Preventing Abuse* shows pictures of the signs of injecting or snorting opioids—track marks and perforated nasal septa—under the heading "Potential Signs Consistent With Drug Abuse." However, just like the rest of Purdue's campaign of deception, this "education" was in fact disinformation. As discussed more fully in Section III, Purdue knew that opioid addicts who resort to the extremes of injecting and snorting are uncommon; users far more typically become dependent and addicted by swallowing intact pills (*see, e.g.*, ¶¶ 138-140).

85. These skewed depictions misleadingly reassured doctors in Pennsylvania that, in the absence of these extreme signs, they need not worry that their patients were abusing or addicted to opioids.

(5) Purdue's Statements and Omissions Regarding the Risk of Addiction Contradict and are Unsupported by Scientific Evidence

86. As with every other facet of its profit driven campaign of deception, Purdue's deceptive efforts to trivialize the risk of opioid addiction were, and remain, directly at odds with the scientific evidence. In fact, prescription opioids like OxyContin are, for the most part, "no less addictive than heroin."[44] Studies have

[44] Thomas R. Frieden & Debra Houry, *Reducing the Risks of Relief—The CDC Opioid-Prescribing Guideline*, 374(16) N Eng. J. Med. (2016),

shown that at least 8-12% of opioid users experience problems with addiction, and as many as 26% of patients receiving long-term opioid therapy suffer addiction.[45] In March 2016, after a "systematic review of the best available evidence," the CDC published the *CDC Guideline for Prescribing Opioids for Chronic Pain* ("CDC Guideline").[46] The CDC Guideline noted that "[o]pioid pain medication use presents serious risks, including overdose and opioid use disorder" (a diagnostic term for addiction).[47] The CDC Guideline also emphasized that "continuing opioid therapy for three months substantially increases risk for opioid use disorder."[48]

87. Purdue's claims that its long-acting opioids are any less addictive than other opioids are equally specious. In fact, long-acting opioids, including Purdue's Hysingla ER and OxyContin, are categorized by the FDA as Schedule II narcotics for their "high potential for abuse" which "may lead to severe psychological or physical dependence."[49] Controlled Substances Act of 1970, 21

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https://www.nejm.org/doi/10.1056/NEJMp1515917?url_ver=Z39.88-2003&rfr_id=ori:rid:crossref.org&rfr_dat=cr_pub%3dwww.ncbi.nlm.nih.gov.

[45] *See, e.g.,* Kevin E. Vowles et al., *Rates of opioid misuse, abuse, and addiction in chronic pain: a systematic review and data synthesis*, 156(4) Pain (2015), https://www.ncbi.nlm.nih.gov/pubmed/25785523.

[46] Deborah Dowell et al., *CDC Guideline for Prescribing Opioids for Chronic Pain – United States, 2016*, 65(1) MMWR Recomm. Rep. (2016), https://www.cdc.gov/mmwr/volumes/65/rr/pdfs/rr6501e1.pdf.

[47] CDC Guideline at 2.

[48] CDC Guideline at 25.

[49] Under the Controlled Substances Act (CSA), drugs classified as controlled substances are divided into five schedules based on their currently accepted medical use in treatment, abuse potential, and likelihood of causing dependence when abused. Schedule I drugs have no medicinal value and have not been approved by the FDA for treatment in the United States.

U.S.C § 812(b)(2). Purdue's representation that its long acting opioids had fewer peaks and valleys, or were less addictive, was one of the many deceptive statements cited in the Company's 2007 settlements and its executives' criminal guilty pleas. These claims are still not true.

88. Further, a study indicates that patients who "doctor-shop" (*i.e.*, visit multiple prescribers to obtain opioid prescriptions) are only responsible for roughly 2% of opioid prescriptions.[50] The epidemic of opioid overprescribing is not, contrary to Purdue's assertions, the result of problem patients or doctors.

89. Purdue's deception about the utility of patient screening and management strategies in managing addiction risk was also exposed by the CDC. The Guideline notes that there are *no studies* assessing the effectiveness of risk mitigation strategies—such as screening tools or patient contracts—"for improving outcomes related to overdose, addiction, abuse or misuse."[51] The CDC Guideline further recognizes that available 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

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While medically accepted, Schedule II drugs have the highest potential for abuse of any approved controlled substances and may lead to severe psychological or physical dependence. An updated and complete list of the schedules is published annually in Title 21 Code of Federal Regulations (C.F.R.) §§ 1308.11 through 1308.15.

[50] Douglas C. McDonald and Kenneth E Carlson, *Estimating the prevalence of opioid diversion by "doctor shoppers" in the United States,* 8(7) PloS one (2013).

[51] CDC Guideline at 11.

risks from long-term opioid therapy."[52]

90. As noted above, Purdue peddled its bogus pseudoaddiction theory despite the fact that no competent scientific source has validated the concept. Moreover, nowhere does the CDC Guideline recommend attempting to provide more opioids to patients exhibiting symptoms of addiction. Ultimately, a "scientific" theory devoid of any science must come crashing down. As discussed above (*see* ¶¶ 73 – 83), this was the fate of pseudoaddiction—a contrivance good for profits but lethal for patients.

(6) Purdue Overstated the Effects of Opioids on Patient Functioning and Quality of Life

91. Unfortunately, Purdue's campaign of deception went beyond misrepresenting the addictive nature and efficacy of opioids. Purdue also claimed—once again without evidence—that long-term opioid use would improve patients' daily function and quality of life, and used both branded and unbranded materials to reinforce this unfounded and deceptive message. Purdue-controlled front groups then disseminated these erroneous claims in publications that were distributed and/or available throughout Pennsylvania.

92. For example, in 2007, Purdue mailed out thousands of deceptive marketing materials to healthcare providers—including more than 4,000

[52] CDC Guideline at 28.

publications in Pennsylvania alone—many of which misrepresented that opioid use improved patient function long-term. The single most distributed material was volume #1 of Purdue's *Focused and Customized Education Topic Selections in Pain Management* (FACETS). In FACETS, Purdue falsely instructed doctors and patients that physical dependence on opioids is not dangerous and instead improves patients' "quality of life." In the same material, Purdue also falsely told doctors and patients that signs of addiction are actually "pseudoaddiction," and that doctors should respond by prescribing more opioids. Since 2007, nearly 200 copies of FACETS have been distributed to Pennsylvania providers.

93. Purdue also distributed the 2011 APF publication A *Policymaker's Guide,* which 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." *Exit Wounds*, another APF book published in 2009, asserted unequivocally that "[w]hen used correctly, opioid pain medications increase a person's level of functioning" and that opioids "can go a long way toward improving your functioning in daily life." Moreover, a series of medical journal advertisements for OxyContin in 2012 presented "Pain Vignettes"—case studies featuring patients with chronic pain conditions—that also implied functional improvement. One advertisement described a "writer with osteoarthritis of the hands" and misleadingly implied that OxyContin would help

him work more effectively.

94. In what has by now become a familiar pattern, there is no clinical support for Purdue's claims that long-term use of opioids improves patient function and quality of life. As discussed more fully in ¶¶ 121 through 129, there are no controlled studies of the use of opioids beyond sixteen weeks, and there is no evidence that opioids improve patients' pain and function long-term. In fact, the available evidence indicates opioids are not effective to treat chronic pain, and may actually worsen patients' health and pain. Contrary to Purdue's deceptive messaging, increasing the duration of opioid use is strongly associated with an increasing prevalence of mental health conditions (depression, anxiety, post-traumatic stress disorder, and substance abuse), increased psychological distress, and greater health care utilization.

95. As one pain specialist observed, "opioids may work acceptably well for a while, but over the long term, function generally declines, as does general health, mental health, and social functioning. Over time, even high doses of potent opioids often fail to control pain, and these patients are unable to function normally."[53] Studies of patients with lower back pain and migraine headaches, for example, have consistently shown that patients experience deteriorating function

[53] Andrea Rubinstein, *Are We Making Pain Patients Worse?* Sonoma Med. (Fall 2009).

over time, as measured by ability to return to work, physical activity, pain relief, rates of depression, and subjective quality-of-life measures.[54] Analyses of workers' compensation claims have found that workers who take opioids are almost four times more likely to reach costs over $100,000, stemming from greater side effects and slower returns to work.[55] According to these studies, receiving an opioid for more than seven days also increased the patients' risk of being on work disability one year later.[56]

96. Moreover, in its exhaustive review of existing data, the CDC Guideline concluded there was "[n]o evidence show[ing] a long-term benefit of opioids in pain and function versus no opioids for chronic pain with outcomes

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[54] Laxmaiah Manchikanti & Angelie Singh, *Therapeutic Opioids: A Ten Year Perspective on the Complexities and Complications of the Escalating Use, Abuse, and Nonmedical Use of Opioids*, 11 Pain Physician S63 (2008); E. Kalso et al., *Opioids in chronic non-cancer pain; systematic review of efficacy and safety*, 21 Pain, 372 (2004); Katherine Sullivan Dillie et al., *Quality of life associated with daily opioid therapy in a primary care chronic pain sample,* 21 J. of the American Board of Family Medicine 108 (2008); Jorgen Eriksen, et al., *Critical issues on opioids in chronic non-cancer pain,* 125 Pain 172 (2006); Harry W. Daniell, *Hypogonadism in men consuming sustained-action oral opioids*, 3 J. of Pain, 377 (2002); Harry W. Daniell, *Opioid endocrinopathy in women consuming prescribed sustained-action opioids for control of nonmalignant pain,* 9 J. of Pain 28 (2008); Nathaniel Katz & Norman Mazer, *Impact of opioids on the endocrine system*, 25 Clinical J. of Pain 170 (2009); J.D. Fortin et al., *Does opioid use for pain warrant routine bone density screening in men?* 11 Pain Physician 539 (2008); Mohammed Mogri et al., *Hypoxemia in patients on chronic opiate therapy with and without sleep apnea*, 13 Sleep Breath 49 (2008); Larry F. Chu et al., *Opioid-induced hyperalgesia in humans*, 24 Clinical J. of Pain 479 (2008).

[55] Jeffrey A. White et al., *The Effect of Opioid Use on Workers' Compensation Claims Cost in the State of Michigan,* 54(8) J. of Occupational & Environ. Med. 948-953 (2012).

[56] Gary M. Franklin et al., *Early Opioid Prescription and Subsequent Disability Among Workers with Back Injuries: The Disability Risk Identification Study Cohort*, 33(2) Spine 199-204 (2008).

examined at least one year later"[57] and advised that "there is no good evidence that opioids improve pain of function with long-term use."[58] The FDA and other federal agencies have made this clear for years.[59] The CDC also noted that the risks of addiction and death "can cause distress and inability to fulfill major role obligations."[60] Recently, one study found that opioids may be responsible for roughly 20% of the decline in workforce participation among prime-age men and a 25% decrease for women.[61]

97. The CDC Guideline concluded that "[w]hile benefits for pain relief, function, and quality of life with long-term opioid use for chronic pain are uncertain, *risks associated with long-term opioid use are clearer and significant*"

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[57] CDC Guideline at 15.

[58] CDC Guideline at 20.

[59] The FDA has warned other drug makers that claims of improved function and quality of life were misleading. *See* Warning Letter from Thomas Abrams, Dir., FDA Div. of Mktg., Adver., & Commc'ns, to Doug Boothe, CEO, Actavis Elizabeth LLC (Feb. 18, 2010) (rejecting claims that the Actavis opioid Kadian had an "overall positive impact on a patient's work, physical and mental functioning, daily activities, or enjoyment of life"); *See also* 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), *available at* https://wayback.archiveit.org/7993/20170405203713/https://www.fda.gov/downloads/AdvisoryCommittees/CommitteesMeetingMaterials/Drugs/AnestheticAndAnalgesicDrugProductsAdvisoryCommittee/UCM233236.pdf (finding the claim that "patients who are treated with [Avinza (morphine sulfate ER)] experience an improvement in their overall function, social function, and ability to perform daily activities…has not been demonstrated by substantial evidence or substantial clinical experience.") Purdue had access to the FDA's warning letters on the FDA website.

[60] CDC Guideline at 20.

[61] Alan B. Krueger, *Where Have All the Workers Gone? An Inquiry into the Decline of the U.S. Labor Force Participation Rate,* Brookings Papers on Economic Activity Conference Draft (Aug 26 2017).

(emphasis added).[62] According to the CDC, "for the vast majority of patients, the known, serious, and too-often-fatal risks far outweigh the unproven and transient benefits [of opioids for chronic pain]."[63] Once again, Purdue did not let actual science get in the way of profiting from its deception.

(7) Purdue Omitted or Mischaracterized the Adverse Effects of Opioids While Exaggerating the Risks of Non-Opioid Pain Medications

98. Purdue, an opioid-only company, competes in the pain treatment marketplace with a variety of non-opioid pain medications. As described above, in materials it produced—sponsored or controlled—Purdue downplayed and/or omitted known risks of chronic opioid therapy as part of its campaign of deception. At the same time, it also emphasized or exaggerated the risks of non-opioid analgesics so that prescribers and patients would be more likely to choose opioids over other therapies, such as over-the-counter acetaminophen or nonsteroidal anti-inflammatory drugs (NSAIDs), antidepressants, and other drugs which do not create a risk of addiction. Purdue not only deceived Pennsylvanians about its own products—it misled them about competitors' products as well. Once again, none of these claims were corroborated by scientific evidence.

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[62] CDC Guideline at 18.

[63] Thomas R. Frieden & Debra Houry, *Reducing the Risks of Relief—The CDC Opioid-Prescribing Guideline*, 374(16) N Eng. J. Med. (2016), https://www.nejm.org/doi/10.1056/NEJMp1515917?url_ver=Z39.88-2003&rfr_id=ori:rid:crossref.org&rfr_dat=cr_pub%3dwww.ncbi.nlm.nih.gov.

99. In addition to not disclosing the deadly risks of addiction, abuse, overdose, and respiratory depression in promotional materials disseminated in Pennsylvania, Purdue routinely omitted the risks of: hyperalgesia, a "known serious risk associated with chronic opioid analgesic therapy in which the patient becomes more sensitive to certain painful stimuli over time."[64] Other risks include hormonal or endocrine dysfunction; decline in immune function; mental clouding, confusion, and dizziness; increased falls and fractures in the elderly; neonatal abstinence syndrome (when an infant exposed to opioids in the womb painfully withdraws from the drugs after birth); and potentially fatal interactions with alcohol or benzodiazepines, which are used to treat post-traumatic stress disorder and anxiety—comorbid conditions often present in chronic pain patients.

100. Meanwhile, Purdue sponsored publications distributed throughout Pennsylvania, such as APF's *Treatment Options: A Guide for People Living With Pain* (2007), that misleadingly emphasized the risks from NSAIDs. *Treatment Options* deceptively counseled patients that opioids differ from NSAIDs in that they have "no ceiling dose" and are therefore the most appropriate treatment for severe pain. The publication inaccurately attributes 10,000 to 20,000 deaths

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[64] *See* Letter from Janet Woodcock, M.D., Dir., Ctr. for Drug Eval. & Res., to Andrew Kolodny, M.D., Pres. Physicians for Responsible Opioid Prescribing, Re Docket No. FDA-2012-P-0818 (Sept. 10, 2013) at 10 n.41, *available at* http://paindr.com/wp-content/uploads/2013/09/FDA_CDER_Response_to_Physicians_for_Responsible_Opioid_Prescribing_Partial_Petition_Approval_and_Denial.pdf.

annually to NSAIDs (the actual figure is approximately 3,200[65]—far fewer than the staggering losses from opioids). This publication also warned Pennsylvanians that risks of NSAIDs increase if "taken for more than a period of months," with no corresponding warning about opioids. *Treatment Options* was available throughout Pennsylvania on the APF website from the date of its publication until APF closed its doors in May 2012. It can still be viewed on-line today.[66]

101. Similarly, Purdue covertly sponsored APF's *Exit Wounds* (2009), a book distributed throughout Pennsylvania and aimed at veterans. This book omits warnings of the potentially fatal risk of interactions between opioids and benzodiazepines, a class of drugs commonly prescribed to veterans with post-traumatic stress disorder. *Exit Wounds* is still available throughout Pennsylvania from Amazon.com and other retailers.

102. Purdue used its CMEs to control and disseminate similarly deceptive messages about using NSAIDs compared with opioid treatment. For example, a Purdue-sponsored CME program, *Overview of Management Options*, published by the American Medical Association in 2005, 2007, 2010, and 2013,

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[65] Courtney Krueger, *Ask the Expert: Do NSAIDs Cause More Deaths Than Opioids?*, Prac. Pain Management (2013), https://www.practicalpainmanagement.com/treatments/pharmacological/opioids/ask-expert-do-nsaids-cause-more-deaths-opioids; *see also* Tarone RE et al., *Nonselective nonaspirin nonsteroidal anti-inflammatory drugs and gastrointestinal bleeding: relative and absolute risk estimates from recent epidemiologic studies*, 11(1) Am J Ther. (2004).

[66] https://assets.documentcloud.org/documents/277605/apf-treatmentoptions.pdf

presented the same highly misleading view of opioids. Purdue sales representatives in Pennsylvania were given 100 promotional flyers touting *Overview of Management Options* each to distribute to their targeted prescriber customers. The CME was edited by prominent Purdue KOLs, including Dr. Russell Portenoy, and taught that NSAIDs and other drugs—but not opioids—are unsafe at high doses. As always, Purdue's financial relationship with Dr. Portnoy was kept carefully obscured from Pennsylvanians.

103. These endorsements for treating chronic pain with opioids omitted the adverse side-effects of long-term opioid use and resulted in catastrophic outcomes for patients and prescribers. A Cochrane Collaboration review of evidence relating to the use of opioids for chronic pain found that 22% of patients in opioid trials dropped out before the study began because of the "adverse effects" of opioids.[67] Moreover, a 2015 study comparing patient outcomes at 1 week and 3 months following Emergency Department visits for acute lower back pain concluded that the addition of opioids to naproxen, a frequently prescribed NSAID, failed to improve functional outcomes or pain at day seven and was therefore unsupported by clinical evidence.[68] The CDC also found *no evidence* that opioids were more

[67] Meredith Noble M, et al., *Long-term Opioid Management for Chronic Noncancer Pain (Review),* Cochrane Database of Systematic Reviews, Issue 1, 11 (2010).
[68] Benjamin W. Friedman et al., *Naproxen With Cyclobenzaprine, Oxycodone/Acetaminophen, or Placebo for Treating Acute Low Back Pain*, 314(15) JAMA (2015), available at https://jamanetwork.com/journals/jama/fullarticle/2463257.

effective for pain reduction than NSAIDs for back pain or antidepressants for neuropathic pain (typically, nerve pain), but instead determined that non-opioids were better tolerated and more effective at improving physical function, with little or no risk of addiction and lower risks of overdose and death.[69]

104. Purdue went to great lengths to pursue its campaign of deception in Pennsylvania (and elsewhere) because it worked. By deceiving the medical community and the public, Purdue increased its own sales and drove down those of alternative, less risky and less costly treatments. A study of 7.8 million doctor visits nationwide between 2000 and 2010 found that opioid prescriptions nearly doubled from 11.3% to 19.6% of visits while NSAID and acetaminophen prescriptions fell from 38% to 29%.[70]

105. In an apparent effort to stem the use of NSAIDs and other opioid alternatives, Purdue falsely claimed to Pennsylvania prescribers that opioids could be taken in ever-increasing strengths to obtain pain relief, without disclosing that higher doses increased the risk of addiction and overdose. This was a particularly dangerous omission because patients on opioids for more than a brief period develop

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[69] Thomas R. Frieden & Debra Houry, *Reducing the Risks of Relief—The CDC Opioid-Prescribing Guideline*, 374(16) N Eng. J. Med. (2016), available at https://www.nejm.org/doi/10.1056/NEJMp1515917?url_ver=Z39.88-2003&rfr_id=ori:rid:crossref.org&rfr_dat=cr_pub%3dwww.ncbi.nlm.nih.gov.

[70] Matthew Daubresse, et al., *Ambulatory Diagnosis and Treatment of Nonmalignant Pain in the United States, 2000–2010*, 51(10) Med. Care (2013), https://journals.lww.com/lww-medicalcare/pages/articleviewer.aspx?year=2013&issue=10000&article=00003&type=abstract.

tolerance, requiring increasingly higher doses to achieve pain relief. As part of its deceptive and dangerous end-run around real science, Purdue needed to generate this comfort level with opioids among doctors to ensure that prescribers maintained patients on its drugs.

106. Through at least June 2015, Purdue's *In the Face of Pain* website went so far as to promote the notion throughout Pennsylvania that if a patient's doctor did not prescribe a sufficient dose of opioids, the patient should find a doctor who would. As noted above, the website was viewed in Pennsylvania more than 18,200 times (*see* ¶ 41).

107. Purdue publications and CMEs were similarly deceptive. For example, *A Policymaker's Guide*, the 2011 publication that Purdue collaborated on with APF, taught that dose escalations are "sometimes necessary," but did not disclose the risks from high dose opioids. This publication is still available online to Pennsylvanians.[71]

108. Likewise, Purdue's 2012 Conversion and Titration Guide advises Pennsylvania prescribers to increase the OxyContin dose by increasing the total daily dose, not by changing the 12-hour dosing interval. Once again, this advice was not accompanied by warnings regarding the known increased risk of addiction associated with increased doses.

[71] http://s3.documentcloud.org/documents/277603/apf-policymakers-guide.pdf

109. The Purdue-sponsored CME, *Overview of Management Options*, discussed above and available in Pennsylvania, instructed physicians that NSAIDs are unsafe at high doses (because of risk to patients' kidneys), but did not disclose the severe and potentially deadly risks associated with opioid use at high doses.

110. Purdue's deceptive assertions and omissions concerning the use of high doses of opioids fly directly in the face of scientific evidence. Patients receiving high doses of opioids (*e.g.*, doses greater than 100 mg morphine equivalent dose, or MED, per day) as part of long-term opioid therapy are three to nine times more likely to suffer from opioid-related overdoses than those on low doses.[72]

111. The CDC Guideline concludes that the "[b]enefits of high-dose opioids for chronic pain are not established"[73] while "[o]verdose risk increases in a dose-response manner."[74] That is why the CDC advises doctors in Pennsylvania to "avoid increasing doses" above 90 mg MME per day. Once again, Purdue buried legitimate science because its sales depended upon high-dose use.

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[72] Kate M. Dunn, et al., *Opioid Prescriptions for Chronic Pain and Overdose: A Cohort Study*, 152(2) Ann Intern Med (2010), https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3000551/.

[73] CDC Guideline at 22. The 2016 CDC Guideline reinforces earlier findings announced by the FDA. In 2013, the FDA acknowledged "that the available data do suggest a relationship between increasing opioid dose and risk of certain adverse events." *See* Sept. 10, 2013 FDA Letter from Janet Woodcock at 12. For example, the 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." *Id.* at 14.

[74] Thomas R. Frieden & Debra Houry, *Reducing the Risks of Relief—The CDC Opioid-Prescribing Guideline*, 374(16) N Eng. J. Med. (2016), available at https://www.nejm.org/doi/10.1056/NEJMp1515917?url_ver=Z39.88-2003&rfr_id=ori:rid:crossref.org&rfr_dat=cr_pub%3dwww.ncbi.nlm.nih.gov.

(8) Purdue Misleadingly Promoted OxyContin in Pennsylvania as Supplying 12 Hours of Pain Relief When Purdue Knew That It Did Not for Many Patients

112. Purdue's profit-driven deception concerning its opioids contradicted, or simply ignored, legitimate science time and time again. However, beyond legitimate science, Purdue faced another obstacle to maximizing profits: how to distinguish this drug in a very crowded opioid market. By turning to the scientifically unsupported notion that OxyContin provided 12 hours of pain relief per dose, Purdue once again turned to deception to accomplish the task.

113. In an effort to distinguish its opioid products from competitors that manufactured opioids effective for a lesser duration, Purdue misrepresented that OxyContin provided continuous pain relief for 12 hours with each dose—a claim they knew was not true years before they introduced the drug to the market. Since it was launched in 1996, OxyContin has been FDA-approved for twice-daily "Q12" dosing frequency. Purdue's decision to distinguish OxyContin from other less long-acting opioids *required* that it submit OxyContin for FDA approval with 12-hour dosing. Under FDA guidelines for establishing dosing, Purdue merely had to show that OxyContin lasted for 12 hours for at least half of patients, and Purdue submitted only a single study to clear that bar. It is telling that while OxyContin's label indicates "[t]here are no well-controlled clinical studies evaluating the safety and

efficacy with dosing more frequently than every 12 hours,"[75] Purdue itself has not conducted any such studies, nor has it been able to present support for its 12-hour duration claim based on other evidence.

114. From the outset, Purdue leveraged 12-hour dosing to promote OxyContin as providing continuous, around-the-clock pain relief with the convenience of not having to wake-up to take a third or fourth pill. The 1996 press release for OxyContin touted a difference-making, product-separating claim: 12 hour dosing provided "smooth and sustained pain control all day and all night."[76] But the FDA has never approved such a marketing claim. To the contrary, in response to a 2004 Citizen Petition by the Connecticut Attorney General, the FDA found that a "substantial portion" of chronic pain patients taking OxyContin will experience "end of dose failure" (*i.e.*, little or no pain relief at the end of the 12-hour dosing period).

115. Moreover, the Company's deception was exacerbated by the fact that dating back to its development of OxyContin, Purdue has known the drug wears off well before 12 hours in many patients. In one early clinical trial, a third of patients dropped out because treatment was ineffective. Researchers then changed the rules

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[75] OxyContin [package insert]. Purdue Pharma L.P. (April 2013), Stamford, CT, https://www.accessdata.fda.gov/drugsatfda_docs/label/2018/022272s039lbl.pdf.

[76] *See* 1996 OxyContin Press Release, available at http://documents.latimes.com/oxycontin-press-release-1996/

to allow patients to take supplemental short-acting painkillers ("rescue medication") in between OxyContin doses.[77] In another study, 95% of patients resorted to rescue medication at least once.[78] Even the single study submitted with Purdue's FDA drug application showed that OxyContin wore off in under 8 hours in 25% of patients and nearly 47% resorted to a rescue drug in less than 12 hours.

116. Not surprisingly, Pennsylvania prescribers discovered for themselves that OxyContin's indicated dosage regimen was ineffective when patients repeatedly complained about inadequate pain relief. Additionally, hundreds of patients and healthcare providers in Pennsylvania reported directly to Purdue that OxyContin "did not last" for 12 hours. A review of product complaints from Purdue's Adverse Event Reporting Database (ARGUS) further revealed that Pennsylvania doctors were significantly increasing dosage strength and/or frequency because patients "were not getting 12 hours of pain relief." In one ARGUS report, a Pennsylvania doctor disclosed that he had resorted to prescribing 100mg of OxyContin *three times daily* to a patient for *nearly 3 years*. Purdue knew all along about OxyContin's 12-hour dosing problem, but still claimed (and continues to

[77] Harriet Ryan et al., *You Want a Description of Hell? OxyContin's 12-Hour Problem.* LA Times (May 5, 2016), https://www.latimes.com/projects/oxycontin-part1/; Richard Kaplan et al., *Comparison of controlled-release and immediate-release oxycodone tablets in patients with cancer pain*, 16(10) J Clin Oncol. (1998), https://www.ncbi.nlm.nih.gov/pubmed/9779696)

[78] *See* Citron ML, et al., *Long-term administration of controlled-release oxycodone tablets for the treatment of cancer pain*, 16(8) Cancer Investigation (1998), https://www.ncbi.nlm.nih.gov/pubmed/9844616.

claim) otherwise in order to maintain its competitive advantage over other opioids[79]—even when patients and doctors submitted complaint after complaint. Although OxyContin's FDA-approved label directs 12-hour dosing, Purdue has gone well beyond the label's instructions by affirmatively claiming that OxyContin *lasts* for 12 hours while knowing directly and failing to disclose that it does not provide "around-the-clock" pain relief to many patients.

117. Beyond promoting its product illegitimately, Purdue's deception had profound consequences for Pennsylvanians. End-of-dose failure renders OxyContin ever more dangerous. As the dose fails, patients begin to experience distressing psychological and physical withdrawal symptoms, followed by a euphoric rush with their next dose—a cycle that fuels a craving for the drug. 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."[80] Many patients will exacerbate this perfect storm by taking their next dose ahead of schedule or resorting to a rescue dose of another opioid, increasing the overall amount of opioids they are taking.

118. 12-hour dosing is key to OxyContin's market dominance and comparatively high price. In a 2004 letter to the FDA, Purdue acknowledged that it

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[79] 1996 OxyContin Press Release.

[80] Harriet Ryan, "*You Want a Description of Hell? OxyContin's 12 Hour Problem,*" Los Angeles Times, May 5, 2016, http://www.latimes.com/projects/oxycontin-part1/.

had not pursued approval to allow more frequent dosing in the label (*e.g.* every 8 hours) because 12-hour dosing was "a significant competitive advantage." Without this advantage, the drug had little to offer over less expensive, short-acting opioids. The Company's internal marketing plans indicate that 12-hour dosing was the key to differentiating OxyContin from short-acting, typically combination opioids (combinations of an opioid and another pain reliever such as acetaminophen) on the market when Purdue launched the drug.

119. Without appropriate caveats, promoting 12-hour dosing is misleading because it implies that each dose actually provides continuous pain relief for that period of time—a claim that Purdue knew to be untrue for many, if not most, patients. FDA approval of 12-hour *dosing* of OxyContin does not give Purdue license to misrepresent the duration of pain relief the drug actually provides to patients; moreover, Purdue had a responsibility to correct its misleading label to reflect appropriate dosing and to disclose to prescribers what it knew about OxyContin's actual efficacy duration, regardless of any marketing advantage.[81]

120. As discussed above, Purdue was also aware that some physicians commonly prescribed OxyContin more frequently than 12 hours (*see e.g.*, ¶ 116).

[81] *See* 21 C.F.R. § 201.56 (2018), Requirements on content and format of labeling for human prescription drug and biological products. Subsection (a)(2) states that "labeling must be informative and accurate and neither promotional in tone nor false or misleading in any particular. In accordance with §§314.70 and 601.12 of this chapter, the labeling must be updated when new information becomes available that causes the labeling to become inaccurate, false, or misleading."

Purdue's promoted solution to this problem was to increase the dose rather than the frequency of prescriptions, even though higher dosing carried its own risks—such as addiction, overdose and death—and patients would experience higher highs and lower lows, increasing their craving for the next pill. While Purdue sales representatives continued touting the benefits of OxyContin's twice-daily convenience and efficacy, Pennsylvania doctors knew pain relief lasted only 6 to 8 hours in many patients. One prescriber in Pennsylvania reported that he often prescribed short-acting painkillers to prevent "end of dose failure" between 12-hour doses, and that his patients "were always looking at their watches [to] avoid pain coming back before the next dose."

II. PURDUE PROMOTED THE USE OF DANGEROUS OPIOIDS FOR THE TREATMENT OF CHRONIC PAIN TO PENNSYLVANIA PRESCRIBERS AND PATIENTS DESPITE NO SCIENTIFIC EVIDENCE SUPPORTING LONG-TERM OPIOID USE

121. As noted above, the treatment of "chronic" pain (*i.e.*, pain lasting more than ninety days) presented a rich source of opioid profits for Purdue (*see* ¶¶ 29 – 54), but only if the Company could find a way into the market. To convince Pennsylvania prescribers and patients that opioids should be used to treat long-term chronic pain, Purdue also had to persuade them of a significant upside to long-term opioid use. This facet of Purdue's deceptive campaign was once again confronted by (what should have been) the insurmountable hurdle of actual, stubborn science.

Unfortunately, Purdue was undeterred.

122. The CDC Guideline makes clear that there is "*insufficient evidence* to determine the long-term benefits of opioid therapy for chronic pain."[82] In fact, the CDC further stated 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 one year later"[83] and that other treatments were more or equally beneficial and less harmful than long-term opioid use. The few longer-term studies of opioid use had "consistently poor results," and "several studies have showed that opioids for chronic pain may actually worsen pain and functioning…"[84] The FDA, too, has recognized the lack of evidence to support long-term opioid use. In 2013, the FDA stated that it was "not aware of adequate and well-controlled studies of opioid use longer than 12 weeks."[85] As a result, the CDC recommends that opioids be used not in the first instance for the treatment of chronic pain and only after prescribers have exhausted alternative treatments. The journal *Neurology* concurred, noting in 2014 that "there is no substantial evidence for maintenance of pain relief

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[82] CDC Guideline at 9.
[83] *Id.* at 15.
[84] Thomas R. Frieden & Debra Houry, *Reducing the Risks of Relief—The CDC Opioid-Prescribing Guideline*, 374(16) N Eng. J. Med. (2016), available at https://www.nejm.org/doi/10.1056/NEJMp1515917?url_ver=Z39.88-2003&rfr_id=ori:rid:crossref.org&rfr_dat=cr_pub%3dwww.ncbi.nlm.nih.gov.
[85] Letter from Janet Woodcock, M.D., Dir., Center for Drug Eval and Research, to Andrew Kolodny, M.D. (Sept. 10, 2013), https://www.regulations.gov/document?D=FDA-2012-P-0818-0793.

or improved function over long periods of time without incurring serious risk of overdose, dependence, or addiction."[86]

123. Nevertheless, Purdue brazenly touted the made-up benefits of long-term opioid use, while deceptively suggesting that these benefits were supported by scientific evidence. According to Pennsylvania prescribers, Purdue sales representatives promoted the Company's drugs for chronic pain but did not disclose in their sales conversations the lack of evidence supporting long-term opioid use.

124. In 1997, Purdue front groups APS and AAPM issued a "consensus statement" entitled *The Use of Opioids for the Treatment of Chronic Pain*, which endorsed opioids to treat chronic pain and claimed the risk that patients would become addicted to opioids was low. Unfortunately, the co-author of the statement, Dr. David Haddox (also responsible, as noted above, for coining the term pseudoaddiction), was a Purdue KOL at that time and later became a senior executive for the Company. The sole consultant on the project was Dr. Russell Portenoy, a pain management specialist who received multiple Purdue research grants and was also a prominent Purdue KOL (*see also* ¶ 82). Thus, the "consensus" on the efficacy of opioids to treat chronic pain was more accurately a non-scientific

[86] Gary M. Franklin, *Opioids for chronic noncancer pain: A position paper of the American Academy of Neurology*, 83 Neurology, 1277-1284 (2014)

hypothesis advanced by two doctors on Purdue's payroll. The Consensus statement remained on AAPM's website available throughout Pennsylvania until 2011.

125. AAPM and APS issued treatment guidelines in 2009 ("AAPM/APS Guidelines") which continued to recommend the use of opioids to treat chronic pain. Treatment guidelines were particularly important in securing acceptance for chronic opioid therapy. They are relied upon by doctors, especially general practitioners and family doctors who have no specific training in treating chronic pain. Six of the twenty-one opioid panel members who drafted the AAPM/APS Guidelines, including Dr. Portenoy, were paid by Purdue, and another eight received support from other opioid manufacturers.

126. The AAPM/APS Guidelines were valuable tools in Purdue's campaign of deception to promote opioids as "safe and effective" for treating chronic pain. Not surprisingly, the panel made "strong recommendations" despite "low-quality evidence" and concluded that the risk of addiction was manageable for patients—even with a prior history of drug abuse. These bogus, self-serving "conclusions" were immediately (and deservedly) controversial. One panel member, Dr. Joel Saper, Clinical Professor of Neurology at Michigan State University and founder of the Michigan Headache and Neurological Institute, resigned from the panel because of his concerns that the AAPM/APS Guidelines were influenced by contributions from drug companies—including Purdue—to the

sponsoring organizations and committee members.

127. The AAPM/APS Guidelines (still available online to Pennsylvania prescribers and patients)[87] were reprinted in the *Journal of Pain,*[88] disseminated in Pennsylvania, and have not only influenced treating physicians, but have also poisoned the body of scientific evidence on opioids. According to Google Scholar, they now have been cited nearly 2,000 times in academic literature. Purdue's army of opioid salespeople misled on a meticulous, doctor-by-doctor basis by citing to these guidelines more than 500 times with Pennsylvania doctors.

128. APS and AAPM are just two of the professional and patient advocacy organizations that Purdue controlled. From 1997 to 2012, the Company paid APS more than $3 million, and gave AAPM another $2 million. Upon information and belief, other professional and patient advocacy groups, including the American Pain Foundation (APF), were effectively controlled by Purdue and also failed to disclose the absence of evidence supporting the use of opioids for chronic pain. Again, Purdue paid these third-party organizations millions of dollars to peddle its bogus claims. Even Dr. Richard Sackler (former company president and current board member) referred to Purdue as "founding funders" of APF, with the Company contributing more than $3.6 million to the front group until its closure in

[87] *See* http://americanpainsociety.org/education/guidelines/overview
[88] *See* https://www.jpain.org/article/S1526-5900(08)00831-6/fulltext

2012.

129. Purdue also published misleading studies to enhance the perception that opioids were effective for the long-term treatment of chronic pain conditions. One Purdue-sponsored study asserted that OxyContin was safe and effective for treating osteoarthritis, but only provided opioids to participants for thirty days. The authors acknowledged that the "results...should be confirmed in trials of longer duration to confirm the role of opioids in a chronic condition such as OA [osteoarthritis]."[89] Nonetheless, the authors concluded that "[t]his clinical experience shows that opioids were well tolerated with only rare incidence of addiction and that tolerance to the analgesic effects was not a clinically significant problem when managing patients with opioids long-term."[90] Purdue advanced this statement despite the fact that it was not supported by clinical data—a substantial number of patients dropped out because of adverse effects, there was no reported data regarding addiction, and the study was not long-term.

III. PURDUE DECEPTIVELY MARKETED ITS ABUSE DETERRENCE FORMULATION IN PENNSYLVANIA

130. By the mid-2000s, widespread addiction to and abuse of

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[89] Jacques R. Caldwell, et al., *Treatment of Osteoarthritis Pain with Controlled Release Oxycodone of Fixed Combination Oxycodone Plus Acetaminophen Added to Nonsteroidal Antiinflammatory Drugs: A Double Blind, Randomized, Multicenter, Placebo Controlled Trial*, 266.4 Journal of Rheumatology 862-869 (1999).
[90] *Id.*

OxyContin had emerged in the public eye. Rather than acknowledging these problems were the inevitable result of the Company's deceptive campaign to promote the widespread prescribing of opioids for chronic pain, Purdue claimed that abuse and addiction resulted from diversion of opioids by abusers injecting or snorting the drugs. Purdue also brought to market an "abuse deterrent" formulation ("ADF") of OxyContin and subsequently marketed it deceptively to doctors as a solution to the opioid epidemic.

131. The FDA approved reformulated OxyContin in April 2010. However, the FDA did not permit reference to its abuse-deterrent properties in Purdue's label until 2013. When Purdue launched Hysingla ER in 2014, the drug also included similar abuse deterrent properties.

132. While permitting ADF labeling of reformulated OxyContin, the FDA warned in its medical review of Purdue's application that "tamper-resistant properties will have no effect on abuse by the oral route (the most common mode of abuse)."[91] The FDA also found that "[w]hile the reformulation is harder to crush or chew, possibly mitigating some accidental misuse, oxycodone HCl is still relatively easily extracted."[92] Purdue's labels also acknowledge that (1) reformulated

[91] New Drug Application 22-272, OxyContin, Division Director Summary Review for Regulatory Action, at 7 (Dec. 30, 2009), available at https://www.accessdata.fda.gov/drugsatfda_docs/nda/2010/022272s000MedR.pdf

[92] *Id.*

OxyContin still maintained high likeability among drug abusers when snorted; (2) the abuse-deterrent properties can be defeated; and (3) the opioids can be abused orally notwithstanding their abuse-deterrent properties.[93] What the labels do *not* indicate is that ADF opioids prevent or reduce addiction, abuse, misuse, or diversion. Rather, it warns that all patients using OxyContin "require careful monitoring for signs of abuse and addiction, since use of opioid analgesic products carries the risk of addiction *even under appropriate medical use*."[94]

133. Despite their limitations, Purdue sales representatives in Pennsylvania used the alleged abuse deterrent properties of Purdue's opioids as a primary selling point to differentiate its products from competitors. Specifically, Purdue detailers falsely claimed or misrepresented that Purdue's ADF opioids: (a) *prevent* tampering and could not be crushed or snorted; (b) *reduce* opioid addiction, abuse and diversion;[95] and (c) are "safer" than other opioids. They failed to disclose, however, that Purdue's ADF opioids still do not prevent oral abuse or misuse (the most common route of opioid abuse).[96]

134. Purdue sales representatives were not the only Company employees making these misrepresentations. Senior executives did as well. Dr.

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[93] OxyContin [package insert]. Purdue Pharma L.P. (April 2013), Stamford, CT, available at https://www.accessdata.fda.gov/drugsatfda_docs/label/2013/022272Orig1s014lbl.pdf.
[94] *Id.*
[95] See ¶ 139
[96] See ¶ 140

David Haddox, the former KOL who became Vice President of Health Policy for Purdue, falsely claimed in 2016 that the evidence does not show that Purdue's ADF opioids are being abused in large numbers. "If you like snorting oxycodone," Haddox told Business Insider, "it's a lot easier to use something like a generic oxycodone tablet rather than spending the time and the effort to work around a product designed to deter snorting."[97]

135. Despite the lack of any supporting evidence, Purdue's marketing of both Hysingla ER and OxyContin as reducing abuse and addiction was a critical element of Purdue's deceptive sales and marketing campaign, both nationally and in Pennsylvania. For example, Purdue's 2015 OxyContin National Marketing Plan directed an increase in sales force education regarding the importance of promoting Purdue's abuse deterrent clinical information; a national sales training presentation instructed Purdue representatives to stress the positive attributes of OxyContin ADF; another sales training memo in 2015 reminded Purdue's entire sales force to use "abuse-deterrent" terminology when promoting Purdue long-acting opioids; and the Company's 2015 Commercial Strategy Plan for OxyContin discussed the proper Purdue counter-positions and responses to customer concerns about opioid abuse and addiction risk.

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[97] Harrison Jacobs, *There is a big problem with the government's plan to stop the drug-overdose epidemic*, Business Insider (2016), https://www.businessinsider.com/robert-califf-abuse-deterrent-drugs-have-a-big-flaw-2016-3.

136. Purdue's marketing of its ADF is and was false, misleading and catastrophic for Pennsylvanians. It has no scientific support and is inconsistent with the FDA-approved labels for Purdue's ADF opioids. Purdue knew or should have known, but did not disclose, that "reformulated OxyContin is not better at tamper resistance than original OxyContin"[98] and is still regularly tampered with and abused.

137. Websites and message boards used by drug abusers, such as bluelight.org and reddit.com, report a variety of ways to tamper with OxyContin and Hysingla ER. These methods include grinding, microwaving then freezing, or drinking soda or fruit juice in which a tablet is dissolved. Further, a publicly available Citizen Petition submitted to the FDA in 2016 by a drug manufacturing firm challenged Purdue's abuse-deterrent labeling based on the firm's ability to easily prepare OxyContin to be snorted or injected.[99]

138. As discussed above, Purdue misleadingly told prescribers to look for evidence of snorting or injecting as signs of addiction when it knew oral abuse was vastly more common. Even assuming *arguendo* that Purdue's deception was accurate, the ADF properties of Purdue's drugs could be easily tampered with. One

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[98] *In re Oxycontin*, 1:04-md-01603-SHS, Docket No. 613, Oct. 7, 2013 hr'g, Testimony of Dr. Mohan Rao, 1615: 7-10.

[99] Pharmaceutical Manufacturing Research Services, Inc. (PMRS) Citizen Petition (Feb. 19, 2016)

third of the patients in a non-Purdue 2015 study defeated OxyContin's ADF mechanism and were able to continue inhaling or injecting the drug.[100] Moreover, to the extent that the abuse of Purdue's ADF opioids was reduced, those addicts simply shifted to other drugs such as heroin.

139. As in other areas, Purdue distorted its own research to support its promotional claims and bury contrary evidence. For example, a 2013 article presented by Purdue employees based on review of data from poison control centers concluded that ADF OxyContin can reduce abuse, but ignored important negative findings.[101] On close review, the study reveals that abuse merely shifted to other drugs and that, when the actual incidence of harmful exposures was calculated, there were *more* harmful exposures to opioids (including heroin) after the reformulation of OxyContin. Purdue gave copies of its misleading ADF studies to health care providers throughout the Commonwealth, and even discussed the distorted research findings directly with Pennsylvania doctors during sales calls to promote the misconception that reformulated OxyContin's abuse-deterrent properties had "fixed" the abuse problem.

140. The CDC Guideline opined on ADF and once again exposes

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[100] Theodore J. Cicero & Matthew S. Ellis, *Abuse-Deterrent Formulations and the Prescription Opioid Abuse Epidemic in the United States Lessons Learned From OxyContin.* 72(5) JAMA Psychiatry (2015), https://jamanetwork.com/journals/jamapsychiatry/fullarticle/2174541.
[101] Paul M. Coplan et al., *Changes in oxycodone and heroin exposures in the National Poison Data System after introduction of extended- release oxycodone with abuse-deterrent characteristics*, 22(12) Pharmacoepidemiol Drug Saf. (2013).

Purdue's rampant deception by confirming that "*[n]o* studies" support the notion that "abuse deterrent technologies [are] a risk mitigation strategy for deterring or preventing abuse," and noting that the technologies "do not prevent opioid abuse through oral intake, the most common route of opioid abuse, and can still be abused by non-oral routes."[102] The original FDA medical review of reformulated OxyContin stated in 2009 that "tamper resistant properties will have no effect on abuse by the oral route (the most common mode of abuse)," which represented nearly 72% of OxyContin abuse at that time.[103] In its 2012 medical office review of Purdue's application to include an abuse-deterrence claim in its OxyContin label, the FDA noted that the overwhelming majority of deaths linked to OxyContin were associated with oral consumption, and that only 2% of deaths were associated with recent injection and only 0.2% with snorting the drug.[104] In September 2015, the FDA's Director of the Division of Epidemiology stated that no data she had seen suggested that reformulated ADF OxyContin "actually made a reduction in abuse," in light of continued oral abuse, shifts to injection of other drugs (including heroin), and defeat of the ADF mechanism.[105] Even Purdue's own funded research shows

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[102] CDC Guideline at 21-22 (emphasis added).
[103] New Drug Application 22-272, OxyContin, Division Director Summary Review for Regulatory Action, at 7 (Dec. 30, 2009), available at https://www.accessdata.fda.gov/drugsatfda_docs/nda/2010/022272s000MedR.pdf
[104] *See* FDA Medical Officer Review (Nov. 14, 2012), available at https://www.accessdata.fda.gov/drugsatfda_docs/nda/2013/022272Orig1s014SumR.pdf
[105] *See* note 99, *supra*. Pharmaceutical Manufacturing Research Services, Inc. (PMRS) Citizen

that half of OxyContin abusers continued to do so orally after the reformulation rather than abuse other drugs.[106] Tom Frieden, former Director of the CDC, also warned that reformulated "abuse-deterrent" opioids are "no less addictive" than their predecessors.[107]

141. In 2015, claiming a need to further assess its data, Purdue abruptly withdrew its supplemental new drug application for reformulated OxyContin one day before FDA staff was set to release its assessment of the application. The staff review preceded an FDA advisory committee meeting related to new studies by Purdue "evaluating the misuse and/or abuse of reformulated OxyContin" and whether those studies "have demonstrated that the reformulated product has a meaningful impact on abuse."[108] Upon information and belief, Purdue still has not presented the data to the FDA, presumably because the data would not have supported claims that OxyContin's ADF properties reduced abuse or misuse. A recent report by the Institute for Clinical and Economic Review (ICER) confirms

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Petition (Feb. 19, 2016)

[106] Paul M. Coplan et al., *The effect of an abuse-deterrent opioid formulation (OxyContin) on opioid abuse-related outcomes in the postmarketing setting*, 100(3) Clin Pharmacol Ther. (2016), https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5102571/.

[107] Matthew Perrone, *Drugmakers Push Profitable, but Unproven, Opioid Solution*, Assoc. Press (Jan. 2, 2017), http://www.detroitnews.com/story/news/nation/2017/01/02/painkillersdrugmakersaddictive/96095558.

[108] Meeting Notice, Joint Meeting of the Drug Safety and Risk Management Advisory Committee and the Anesthetic and Analgesic Drug Products Advisory Committee; Notice of Meeting (May 25, 2015, 80 FR 30686), available at https://www.govinfo.gov/content/pkg/FR-2015-05-29/pdf/2015-12957.pdf.

this suspicion. In its 2017 review of the clinical effectiveness of abuse deterrent formulations of opioids, ICER concluded there was "insufficient evidence…to judge the net health benefit, at the population level, of the introduction or substitution of ADFs for non-ADF opioids." Specifically, the report found that reformulated OxyContin introduced "a shift in some cases toward other routes of administration, other prescription opioids, and heroin," potentially causing an overall "net harmful [effect] across the entire population."[109]

142. Purdue's false and misleading marketing of the benefits of its ADF opioids in Pennsylvania was calculated and aimed at a vulnerable audience. It preserved and expanded Purdue's sales by persuading Pennsylvania prescribers to write prescriptions for ADF opioids in the mistaken belief that they were safer. It also allowed prescribers to discount evidence of opioid addiction and abuse and attribute it to other, less safe opioids—*i.e.* it allowed them to believe that while patients might abuse, become addicted to, or die from other, non-ADF opioids, Purdue's opioids did not carry that risk.

143. Purdue's deceptive and misleading marketing preserved not only the price of its opioid products, but their sales volume as well. Generic versions of OxyContin, which became available in February 2011, threatened to erode Purdue's

[109] *Final Evidence Report—Abuse-Deterrent Formulations of Opioids: Effectiveness and Value*, Institute for Clinical and Economic Review (2017), available at https://icer-review.org/wp-content/uploads/2016/08/NECEPAC_ADF_Final_Report_08_08_17.pdf.

market share and the price it could charge. However, through a Citizen Petition, Purdue was able to convince the FDA in April 2013 to remove original OxyContin from the market as unsafe because it lacked abuse-deterrent properties, and secured a determination that non-ADF generic copies should no longer be sold.[110] As a result, Purdue extended its branded exclusivity for OxyContin until the patent protection on the abuse-deterrent coating expires.

144. Purdue successfully persuaded providers that the supposedly abuse-deterrent characteristics of its products were actually effective in preventing abuse. Nearly half of the 1,000 primary care physicians surveyed as part of a 2014 nationwide survey reported their belief that abuse-deterrent formulations were less addictive than their counterparts.[111]

145. In Pennsylvania and elsewhere, even after reformulating the drug with seemingly "abuse-deterrent" properties, OxyContin still remains highly sought after in illicit street sales and frequently abused through nonoral routes, such as snorting and injecting crushed or dissolved tablets. According the CDC, oxycodone (such as OxyContin) also continues to be one of the most common drugs involved

[110] *See* FDA's Federal Register Notice on Feb. 18, 2013, https://www.federalregister.gov/d/2013-09092

[111] Hwang CS et al., *Primary Care Physicians' Knowledge and Attitudes Regarding Prescription Opioid Abuse and Diversion*, 32(4) Clin. J. Pain, 279-84 (2016).

in thousands of prescription opioid overdoses and deaths annually.[112]

IV. PURDUE FAILED TO REPORT SUSPICIOUS PRESCRIBING BY PENNSYLVANIA PRESCRIBERS

146. Purdue deceptively and unfairly failed to report to Pennsylvania authorities illicit or suspicious prescribing of its opioids in Pennsylvania, even while it publicly and repeatedly touted its "constructive role in the fight against opioid abuse," including its commitment to ADF opioids and its "strong record of coordination with law enforcement."

147. Purdue's public stance long has been that "bad apple" patients and drug diversion to illicit channels are to blame for widespread opioid addiction and abuse. While opioids have been diverted through illegal prescribing and street sales, it is the regular, legitimate prescribing of opioids that created and fueled this crisis. For example, a study of 254 accidental opioid overdose deaths in Utah found that 92% of the decedents had been receiving prescriptions from health care providers for chronic pain.[113] Meanwhile, studies indicate that sales to patients who doctor-shop (visiting multiple doctors to hide illicit or over-use) constitute

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[112] CDC/National Center for Injury Prevention and Control, https://www.cdc.gov/drugoverdose/data/prescribing.html

[113] Erin M. Johnson et al., *Unintentional Prescription Opioid-Related Overdose Deaths: Description of Decedents by Next of Kin or Best Contact, Utah, 2008–2009*, 28(4) J Gen Intern Med. (2013), available at https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3599020/pdf/11606_2012_Article_2225.pdf.

approximately only 1% to 2% of opioid volume.[114]

148. Yet, as part of its campaign of deception, Purdue actively works to distract the public and medical community by keeping attention on illicit use and diversion. The Company then promotes its funding of various drug abuse and diversion prevention programs and introduction of ADF opioids as the solution to the opioid epidemic. This sleight of hand diverts attention from the real problem of widespread prescribing of opioids, which Purdue normalized, and misleadingly allows Purdue to present itself as a responsible corporate citizen doing what it can to address the opioid crisis.

149. Since at least 2008, Purdue has consistently trumpeted its partnership with law enforcement and government agencies to combat opioid abuse and diversion. The message of close cooperation features in virtually all of Purdue's recent pronouncements regarding opioid abuse.

150. For instance, while touting the benefits of ADF opioids on its website, Purdue asserts: "we 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 risk of opioid abuse

[114] Douglas C. McDonald & Kenneth E. Carlson, *Estimating the Prevalence of Opioid Diversion by "Doctor Shoppers" in the United States*, 8(7) PLOS ONE (2013), https://journals.plos.org/plosone/article?id=10.1371/journal.pone.0069241.

and misuse..."[115] Purdue's statement on "Opioids Corporate Responsibility" likewise states that "[f]or many years, Purdue has committed substantial resources to combat opioid abuse by partnering with...communities, law enforcement, and government agencies."[116] Responding to criticism of Purdue's failure to report suspicious prescribing to government regulatory and enforcement authorities, the website similarly proclaims that Purdue "[h]as a long record of close coordination with the DEA and other law enforcement stakeholders to detect and reduce drug diversion."[117]

151. These statements, among others, create the misimpression that Purdue is proactively working with law enforcement and government authorities, nationwide and in Pennsylvania, to root out drug diversion, including the illicit prescribing that can lead to diversion. It aims to portray Purdue as committed to reining in opioid abuse, thereby enhancing the image of the Company and its drugs as safe and worthy of patients' and doctors' trust.

152. Purdue can track distribution and prescriptions of its opioids down to the retail and prescriber level. It has detailed data on opioid prescribing and

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[115] *See* Purdue website, *Opioids With Abuse Deterrent Properties*, https://www.purduepharma.com/healthcare-professionals/responsible-use-of-opioids/opioids-with-abuse-deterrent-properties/

[116] *See* Purdue website, *Opioids Corporate Responsibility*, https://www.purduepharma.com/about/company-values/opioids-corporate-responsibility/

[117] *See* Purdue website, *Setting the Record Straight on Our Anti-Diversion Programs* (July 11, 2016), https://www.purduepharma.com/news-media/2016/07/setting-the-record-straight-on-our-anti-diversion-programs/

sales and, until very recently through its extensive network of sales representatives, was able to—and did—observe signs of diversion.

153. Purdue did identify doctors suspected of improper prescribing, *internally*. Since at least 2002, Purdue maintained a database of health care providers suspected of inappropriately prescribing OxyContin or other opioids. Physicians should have been internally reported by Purdue sales staff, investigated by in-house counsel, then added to this "Region 0" database based on observed indicators of illicit prescribing, such as excessive numbers of pain patients, cash transactions, patient overdoses, and unusual prescribing of the highest-strength pills. (80 mg OxyContin pills, or "80s" as they were known on the street, were a prime target for diversion.) Further, sales detailing to health care providers added to this database was supposedly prohibited, and Purdue sales staff allegedly received no compensation from their prescriptions.

154. This half-measure was little more than window dressing. While the Company may have prohibited sales visits, Purdue failed to cut off the improper prescribers' opioid supply at the pharmacy level. In other words, Purdue continued to generate sales revenues from their prescriptions, and more importantly, failed to report "Region 0" providers to state medical boards or law enforcement. For example, in an interview with the *Los Angeles Times*, which first reported the story, Purdue's former senior compliance officer acknowledged that the Company never

stopped the supply of its opioids to a pharmacy throughout five years of investigations—even where Purdue employees personally witnessed the diversion of its drugs.

155. But it was not only diverting pharmacies that Purdue chose to willfully ignore—it was prescribers as well. Despite Purdue's knowledge of illicit prescribing from one clinic since 2009, which Purdue's district manager called an "organized drug ring," Purdue did not report its suspicions until 2013—long after law enforcement shut the clinic down and the ring had prescribed more than 1.1 million OxyContin tablets.[118]

156. Pennsylvania law requires manufacturers of controlled substances, including Purdue, to monitor and report suspicious conduct.[119] On

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[118] Harriet Ryan et al., *More than 1 million OxyContin pills ended up in the hands of criminals and addicts. What the drugmaker knew*, LA Times (2016), https://www.latimes.com/projects/la-me-oxycontin-part2/.

[119] *See* 35 P.S. § 780-112(c) and 63 P.S. § 391; 21 U.S.C. § 823(e); 21 C.F.R. § 1301.74(b).

The Pennsylvania Controlled Substance, Drug, Device and Cosmetic Act, 35 P.S. § 780-112(c) and Wholesale Prescription Drug Distributors License Act, 63 P.S. § 391.6(k), incorporate 21 CFR § 1301.74(b), requiring distributors to "design and operate a system to disclose suspicious orders of controlled substances," which includes "orders of unusual size, orders deviating substantially from a normal pattern, and orders of unusual frequency." 35 P.S. § 780-112(c) and 63 P.S. § 391.6(k) additionally incorporate 21 U.S.C. § 823, requiring distributors to establish effective controls against orders which they know or should have known were likely to be diverted into the community. Importantly, 63 P.S. § 391.3 defines "Wholesale distributor of prescription drugs" as "a person who operates a facility from which a person engages in the wholesale distribution of prescription drugs, including, but not limited to, manufacturers, repackers, own-label distributors, private-label distributors or jobbers, warehouses, including manufacturers' and distributors' warehouses, chain drug warehouses and wholesale drug warehouses, independent wholesale drug traders and retail pharmacies that conduct wholesale distributions" (emphasis added).

December 27, 2007, the DEA sent a letter to manufacturers and wholesalers of opioids, including Purdue, reminding them of their legal obligation "to design and operate a system to disclose…suspicious orders of controlled substances," to inform the DEA of "suspicious orders when discovered" and to "maintain effective controls against diversion" of controlled substances. A manufacturer's or distributor's "responsibility does not end merely with the filing of a suspicious order report. Registrants must conduct an independent analysis of suspicious orders prior to completing a sale to determine whether the controlled substances are likely to be diverted from legitimate channels."

157. Purdue's failure to monitor and report this suspicious prescribing that it knew, or could and should have known, has had a catastrophic effect on Pennsylvania and constitutes both unfair and deceptive practices.

V. PURDUE TARGETED TOP PRESCRIBERS IN PENNSYLVANIA EVEN WHEN THEY WROTE ILLEGAL OR SUSPICIOUS PRESCRIPTIONS, CAME UNDER CRIMINAL INVESTIGATION AND THEIR PATIENTS DIED

158. After deceiving the professional medical community and patients about the benefits and risks of prescription opioids, Purdue focused its marketing efforts on the gatekeepers of these dangerous drugs—doctors.

159. Purdue aggressively marketed its opioids and earned millions of dollars by targeting top opioid prescribers. Knowing that in-person marketing (or

"detailing") was highly effective, the Company dispatched a small army of sales representatives to promote opioids in doctors' offices, clinics, pharmacies, and hospitals throughout Pennsylvania.[120] To make sure its sales force succeeded in this relentless promotional effort, Purdue tracked doctors' prescriptions, visited their offices hundreds of times, bought them meals, and asked physicians to "commit" to prescribing Purdue opioids to specific patients.

160. Through sales representatives, or "detailers," the Company also aggressively pushed doctors to provide savings cards to patients for its branded opioids. Purdue's savings cards gave patients discounts on their first opioid prescriptions and kept patients on Purdue drugs longer. According to the Company's internal analysis, "more patients remain on OxyContin after 90 days" when they used a Purdue opioid savings card. The risks for addiction, overdose, and death, of course, were also greater the longer patients stayed on Purdue's opioids. But despite these known and dangerous risks, savings cards became one of the most powerful (and profitable) marketing tools for Purdue—the return on investment for OxyContin savings cards alone was $4.28 for every $1 spent. The program was so critical to OxyContin's commercial success, Purdue tracked the number savings

[120] *See, e.g.*, Avinash R. Patwardhan, *Physicians-Pharmaceutical Sales Representatives Interactions and Conflict of Interest: Challenges and Solutions*, Inquiry: The Journal of Health Care Organization, Provision, and Financing (2016), available at https://journals.sagepub.com/doi/full/10.1177/0046958016667597.

cards its sales force distributed to prescribers and ranked each sales representative by the highest number of redemptions. Purdue detailers gave thousands of patient savings cards to Pennsylvania prescribers since 2008.

161. Purdue has made ***over 531,000 detailing visits*—more than 48,000 per year**—to Pennsylvania doctors and pharmacists since May 15, 2007. In addition to this astonishing effort by its detailers, Purdue rewarded top prescribers with food and gifts, as well as consulting, speaking, and other promotional deals worth thousands of dollars. From 2009 through 2017, Purdue paid Pennsylvania healthcare providers ***more than $1.5 million*** for such engagements.

162. Purdue targeted not only pain specialists, but also general and family practitioners, nurse practitioners, physician assistants, and other primary care specialties who, collectively, write/wrote the greatest volume of opioid prescriptions.[121] Purdue took advantage of these prescribers' lack of specific knowledge related to its products, fully aware that primary care doctors and non-physician providers were less able to assess Purdue's misleading statements about the risks of opioid addiction and death. And, it worked. From 2007 to 2012, opioid prescribing rates nationwide increased the most for family practice, general practice,

[121] Jan Hoffman, *Patients in Pain, and a Doctor Who Must Limit Drugs*, N.Y. Times (2016), https://www.nytimes.com/2016/03/17/health/er-pain-pills-opioids-addiction-doctors.html (citing Chen JH, et al., *Distribution of Opioids by Different Types of Medicare Prescribers*. 176(2) JAMA Intern Med., 259–261 (2016).

and internal medicine.[122]

163. Opioid abuse is killing people, tearing apart families, and ruining lives. Contrary to its duties and public pronouncements regarding vigorous cooperation with law enforcement, Purdue actively and recklessly promoted opioids to Pennsylvania doctors under investigation by law enforcement and/or other government regulatory bodies for prescribing opioids inappropriately. As demonstrated below, sales representatives continued calling on prescribers across Pennsylvania even when they wrote illegitimate prescriptions, lost their medical licenses, and their patients overdosed and died. Purdue acted without regard to the public health hazard it was creating, choosing to maximize profits while putting Pennsylvania lives at risk.

New Castle, PA

164. In early 2005, Purdue representatives began visiting Dr. Van Edward Scott, a general practitioner in New Castle. Upon information and belief, Purdue hired Detailer #1 on October 8, 1990 and assigned him to the Western Pennsylvania territory. He was the only Purdue representative assigned to Dr. Scott between February 2006 and May 2009, and visited the doctor approximately 43

[122] *See* Deborah Dowell et al., *CDC Guideline for Prescribing Opioids for Chronic Pain – United States, 2016*, 65(1) MMWR Recomm. Rep. (2016), https://www.cdc.gov/mmwr/volumes/65/rr/pdfs/rr6501e1.pdf. (citing Levy B, et al., *Trends in opioid analgesic-prescribing rates by specialty, U.S., 2007–2012*, 49 Am J Prev Med., 409-13 (2015).

times. Detailer #1 frequently won yearly bonuses in the tens of thousands of dollars due to the amount of opioids his assigned doctors prescribed to patients. From 2007 to 2016, Purdue paid him more than $360k in additional compensation for his sales performance.

165. Dr. Scott was not a pain specialist, but despite his lack of expertise, the doctor became one of the top three OxyContin prescribers in Pennsylvania. From 2007 until he lost his medical license in 2010, Scott wrote more than 12,600 OxyContin prescriptions—Purdue's most potent and addictive opioid.

166. Detailer #1 knew that Dr. Scott was prescribing opioids inappropriately but targeted him nonetheless. And, he did so frequently: the Purdue representative called on the doctor nearly twice every month over a four year period. During that time, Detailer #1 submitted three different "reports of concern" to his Purdue supervisors. These reports stated concerns from local pharmacists and other sources related to Scott's suspicious prescribing habits and an investigation by the DEA in 2006. However, Purdue did not direct its sales force to stop visiting the doctor until ***after*** criminal charges were reported in 2009.

167. Dr. Scott started questioning the validity of Purdue's information on drug abuse during Purdue's detailing visits to his office in 2007—the same year he became the Company's top prescriber in Pennsylvania. Detailer #1 ignored his concerns. Instead, the sales representative provided the doctor a booklet on the

"barriers to pain management and [opioid] medication fears" and discussed "physical dependence vs addiction and pseudoaddiction" Detailer #1 repeatedly noted goals "to titrate [Scott's patients] from OxyContin 40mg to 60mg." The doctor complied. From 2007 to 2008, no other physician in Pennsylvania prescribed more prescription opioids than Dr. Scott.

168. In April 2010, Dr. Scott and eleven of his former patients were arrested and charged with running a "pill mill." Dr. Scott was accused of overprescribing huge quantities of narcotic painkillers, including oxycodone and OxyContin. Many of these drugs were being diverted to the streets. At the time of Dr. Scott's arrest, news articles reported that: he was the top prescriber of Schedule II controlled substances in Pennsylvania (over 60% more prescriptions than any other doctor in the state); he prescribed 2.19 million doses of narcotics in just one year; charged patients a monthly fee for services; and failed to provide legitimate physical examinations.[123]

169. Purdue ignored these red flags because Dr. Scott was a high-value target. Instead of addressing Scott's suspiciously high volume of opioid prescriptions, Detailer #1 encouraged him to prescribe more Purdue opioids at higher

[123] Per local news articles, *see, e.g.,* https://www.wpxi.com/news/hearing-set-for-new-castle-doctor-accused-of-presc/289141197, https://gantdaily.com/2010/04/11/pas-highest-prescriber-of-pain-medication-and-others-arrested-in-lawrence-county/, and http://www.ncnewsonline.com/news/local_news/pain-doctor-sentenced-to-prison/article_be4406ee-4da5-55a2-8c95-9c25ab4ff186.html

doses while helping the doctor "stay out of trouble with regulators." Despite its assurances to Pennsylvanians that it was ever-vigilant about diversion, and even after multiple reports of concern, Purdue did nothing to stop or expose Dr. Scott until criminal charges were filed.

Media, PA

170. In Delaware County, Purdue singled out Dr. Lawrence Wean as a "special" target for over a decade. From 2004 until his arrest in December 2014, Purdue assigned 6 sales representatives to visit his office more than 190 times. Purdue Detailers #2 and #3 called on Dr. Wean for nearly half of those years.

171. Upon information and belief, Purdue hired Detailer #2 on June 1, 1987 and Detailer #3 on June 11, 2012, assigning them both to the Southeastern Pennsylvania region. Detailer #2 visited Dr. Wean 31 times from October 2010 until his retirement in July 2012, and reported to his supervisors that the internist was "in the perfect position [to] treat pain as well as addiction because of his certification." Detailer #3 continued to call on Dr. Wean 2-3 times per month, visiting the doctor's office 57 times between September 2012 and August 2014. Both Purdue representatives frequently won yearly bonuses in the tens of thousands of dollars due to the amount of opioids their assigned doctors prescribed to patients. From 2007 to 2012, Purdue paid Detailer #2 more than $248k in additional compensation for his sales performance. Detailer #3 earned more than $80k in bonuses from 2013 until

his termination in January 2015.

172. By 2012, Purdue knew that Dr. Wean was writing illegitimate and/or suspicious opioid prescriptions. Within a three-month period, Detailer #2 submitted two separate reports of concern to the Company after a pharmacist located next door to the doctor's office observed suspicious patients and prescribing practices. Purdue representatives not only continued calling on Dr. Wean after both reports, but Detailer #3 actually tripled his number of office visits the following year. The number of OxyContin prescriptions that Dr. Wean prescribed also increased during this time period by more than 70 percent.

173. In 2013, Detailer #3 filed a third report of concern with the Company after the doctor's own employee expressed concerns about his prescribing of pain medication to "a lot of cash" patients from out-of-state. Again, Purdue did nothing. Around this time, Dr. Wean also told Detailer #3 that "his pain patients pay cash," insurance companies "stop in from time to time," and "he was the highest oxycodone writer in the state" based on a local pharmacist's report—all clear indicators of inappropriate (or at least suspicious) opioid prescribing. Dr. Wean's assigned Purdue representative then spent several follow-up visits "reminding" and asking the doctor to switch his oxycodone patients to Purdue long-acting opioids "to avoid the issues he and the pharmacist talked about." Instead of a red flag, Detailer #3 saw a business opportunity and took advantage.

174. In August 2014, a local physician told Detailer #3 that Dr. Wean was under investigation for "mishandling opioids prescribing… a second time." Purdue finally paid attention. Only after this *fourth* report of concern did Purdue investigate and stop visiting the doctor. He was arrested four months later and charged with illegally prescribing painkillers and insurance fraud. Newspapers reported that Dr. Wean ran a "pill mill," prescribed painkillers without legitimate examinations, and treated an unusually high volume of "cash" patients.[124] Purdue, of course, had already known for years that he was dangerous but kept promoting opioids to the doctor anyway.

175. Multiple sources reported Dr. Wean's inappropriate prescribing to Purdue over the years, but the Company disregarded the warning signs and chose profits over keeping his patients safe. When Purdue finally stopped calling on the doctor, it was too late. Two of his patients had already overdosed on narcotics and died.

Bristol and Philadelphia, PA

176. Purdue targeted two other primary care specialists in Bucks and Philadelphia counties. Both physicians were top prescribers of Purdue opioids. From

[124] Per local news reports, *see, e.g.*, http://www.delcotimes.com/article/DC/20151209/NEWS/151209595, and http://www.philly.com/philly/news/20151209_Delco_doc_gets_up_to_20_years_for_drug_sales.html

2007 through 2016, they wrote more than 136,000 opioid prescriptions combined, including nearly 28,000 for OxyContin alone.

177. For almost nine years, several sales representatives promoted opioids to internist Jeffrey Bado, DO at his office in Philadelphia, including Purdue Detailers #2, #3, and #4. Upon information and belief, Purdue hired Detailer #4 on June 23, 1997 and assigned her to the Southeastern Pennsylvania territory. She visited Dr. Bado approximately 43 times between September 2005 and March 2008. Detailer #4 frequently won yearly bonuses in the tens of thousands of dollars due to the amount of opioids her assigned doctors prescribed to patients. From 2007 to 2016, Purdue paid the sales representative more than $460k in additional compensation for her sales performance.

178. On September 1, 2005, Detailer #4 began making sales calls on Dr. Bado. She learned that he was "writing for brand," meaning that Dr. Bado prescribed brand name opioids in the form of OxyContin. Not only did Dr. Bado regularly prescribe OxyContin, he did so at the request of patients who asked for it specifically, an indication of drug seeking behavior.[125]

179. Detailer #4 continued to call on Dr. Bado for over two years and she used that time to reinforce his allegiance to Purdue's opioids. Her strategy

[125] Richard W. Pretorius & Gina M. Zurick, *A Systematic Approach to Identifying Drug-Seeking Patients*, 15(4) Fam. Pract. Manag. (2008), https://www.aafp.org/fpm/2008/0400/pa3.html

worked. Dr. Bado's OxyContin prescriptions increased by 160 percent just one year after she started calling on the doctor, and by more than ***600 percent*** from 2006 through 2010. At one point, Dr. Bado told Purdue representatives that he had been a speaker for the Company and boasted that his practice had grown to 10,000 patients. Bado's practice was so busy that Purdue representatives visited him two or three times every month to review the various patient savings card incentive programs for each Purdue opioid, providing the office staff with whatever (and as many) cards as they requested.

180. At another meeting, Dr. Bado and Detailer #4 spoke about the difference between addiction and physical dependence. Dr. Bado assured the Purdue representative that he "was on top of ... how to differentiate" between the two. However, Dr. Bado clearly was not "on top of it" because on September 13, 2011, he admitted to Detailer #2 that he wrote two Butrans (another Purdue opioid) prescriptions for inappropriate patients. He first prescribed it to a heroin addict who "kicked it a while ago" but "was feeling the edge" and whose father was concerned that she might go back to it. The second patient "was taking a lot of oxycodone," a generic opioid. However, the FDA had not approved Butrans for either of these kinds of uses or individuals. Rather, Dr. Bado should have referred the former heroin addict for addiction therapy because there was no evidence she suffered from any pain. The patient ultimately went to rehab for treatment. While reviewing the call

notes from this visit, a Purdue supervisor also noted that the doctor had not prescribed the drug to "suitable" patients. After an internal review, the Company issued Detailer #2 a warning letter about Dr. Bado's off-label prescribing and disclosed several other instances where the sales representative promoted Purdue opioids inappropriately to Pennsylvania prescribers. Despite this disciplinary action, Detailer #2 pushed Dr. Bado to prescribe more Butrans at subsequent office visits.

181. By the time Dr. Bado lost his license in 2013, he charged new patients $800 per visit (cash only) and refused to accept medical insurance. His patients received at most a cursory physical examination and little other medical care or treatment. However, they did receive prescriptions for staggering amounts of opioids. In fact, when the doctor was out of the country, he directed his staff to see patients, provide them with pre-signed prescriptions, and submit fraudulent insurance claims as if he had seen the patients himself.[126]

182. Purdue representatives made 160 visits to Dr. Bado's office between January 2006 and January 2013. During this period, Purdue stopped calling on him temporarily four separate times: January 27, 2010, May 1, 2011, November 26, 2012, and finally on March 7, 2013 (when he lost his medical license).

183. On November 2, 2011, Dr. Bado told Detailer #2 that the DEA

[126] Testimony from government expert Stephen Thomas, M.D. at Dr. Bado's trial (DOJ Press Release, 12/8/16)

planned to visit his office and review his charts. During another sales visit in 2011, he told the Purdue representative that a local pharmacist had complained about the amount of pills he prescribed. At a minimum, the DEA inspection should have signaled Purdue to take a closer look at Dr. Bado's prescribing habits. Instead, Purdue did nothing. Dr. Bado kept prescribing opioids and Pennsylvanians became addicted to drugs supplied by Purdue and improperly prescribed by this physician.

184. On February 4, 2015, Dr. Bado was indicted on numerous charges including causing the death of a drug addicted person. From 2010 through 2012, he prescribed more than 3 million oxycodone pills, making him the fourth largest prescriber of that drug in the United States excluding hospitals and other large facilities.[127] Bado wrote so many prescriptions for Purdue opioids between 2007 and 2013—the year he lost his license—that he still ranked as the top prescriber of OxyContin in Pennsylvania at the time of his 2015 arrest.

185. More recently, Purdue continued to promote its opioids to a high-value target in Philadelphia with questionable and dangerous prescribing practices—family practitioner Stuart Kauffman, DO. Purdue representatives have visited the former Bristol doctor *nearly 600 times* since 1998. He was the second highest Pennsylvania prescriber of OxyContin and opioids generally from 2014 through

[127] Pennsylvania Department of State (website); *see also* Rich Lord, *Doctor says he's 'poster child' in misguided war on pain pills,* Pittsburgh Post-Gazette (2016)

2016. Dr. Kauffman wrote OxyContin prescriptions for 80mg tablets most frequently and rarely prescribed the lower dosage strengths.

186. Kauffman's opioid prescribing has been a problem since the late 1990s. Not only did Purdue representatives hear reports from local pharmacists, but they also knew firsthand that Kauffman's OxyContin prescriptions were being diverted and/or abused by his patients. During one office visit, a Purdue sales representative witnessed a "very high" patient attempting to pick up a "lost" OxyContin prescription, and at another, Purdue sales staff discovered that (non-doctor) staff had been writing the doctor's scripts. At one point, Purdue representatives also suspected patients were diverting drugs prescribed by Kauffman and stated at the time: "I think [Kauffman] is just going along with them." Even Kauffman knew his opioid prescribing was out of control. He admitted as much to a Purdue representative who noted that he said "there is a big abuse problem for oxyc[ontin] and maybe the best thing for him would be if they took his license away." Purdue ignored the doctor's confession and continued promoting opioids to him anyway.

187. Finally, in March 2004, Purdue decided to stop detailing Dr. Kauffman around the same time the Company learned of investigations by the state and medical board. However, despite this directive, sales representatives kept targeting the doctor intermittently. When they made three additional office visits in

2006 and 2007, Kauffman had already been on Purdue's "no calling" list for more than two years.

188. In 2009, five years after Purdue first ceased promoting its opioids to Dr. Kauffman, the Company resumed calling on the doctor. An email from in-house counsel did not provide a reason, but around this time, Purdue Detailer #5 noted in call notes from pharmacy visits that Dr. Kauffman's OxyContin scripts were "keeping [the pharmacy] busy" and fully stocked in "all the strengths."

189. Upon information and belief, Purdue hired Detailer #5 on April 23, 2008 and assigned him to the Southeastern Pennsylvania territory. He began targeting Dr. Kauffman aggressively from April 2009 through the end of 2017, averaging at least one weekly visit to his Philadelphia office. In total, he visited the doctor 428 times over an approximate nine-year period. Detailer #5 frequently won yearly bonuses in the tens of thousands of dollars due to the amount of opioids his assigned doctors prescribed. From 2008 to 2016, Purdue paid him nearly $400k in additional compensation for his sales performance.

190. Purdue's influence on Dr. Kauffman's opioid prescribing habits was striking. After sales representatives ceased detailing in early 2004, he essentially stopped prescribing OxyContin in any significant numbers until 2007/2008. When Purdue resumed calling the following year, Dr. Kauffman's OxyContin prescriptions skyrocketed more than ***70 percent*** in volume. Purdue could disregard Kauffman's

troubled past and his patient's safety, but not his millions in projected profits.

Gettysburg, PA

191. In 2014, Purdue Detailer #6 started visiting a new family practitioner in Adams County. Following this sales call, the Purdue representative noted that Dr. Rita Harrison was "extremely interested" in Butrans and OxyContin, and within two weeks, the representative was providing the doctor with incentive savings cards for patients and asking her to "commit" to prescribing Purdue opioids at nearly every office visit.

192. Upon information and belief, Purdue hired Detailer #6 on September 7, 2010 and assigned her to the Central Pennsylvania territory. She was essentially the only Purdue representative assigned to Dr. Harrison and visited the doctor 31 times between September 2014 and May 2016. Detailer #6 frequently won yearly bonuses in the tens of thousands of dollars due to the amount of opioids her assigned doctors prescribed. From 2011 to 2016, Purdue paid the sales representative more than $164k in additional compensation for her sales performance.

193. Detailer #6 first reported red flags to Purdue following an office visit in February 2016:

> *"Doctor recently married one of her Suboxone patients over the Christmas break. He appears to be taking an active role in the practice and had many questions for us today about our products. He told us that Dr. Harrison has been treating him for addiction. He had questions about Butrans and being able to use other immediate release opioids and if you can get the buprenorphine out of the patch. He also*

> *referenced OC vs OP OxyContin and noted that he like the former better. He asked additional questions about IP and OC and if OP was generic. He said he used to spend $1,400 a month for OxyContin and that he took it 40 mg q 6 hour. Responded that OxyContin has only been studied as a q 12 h. He made some additional comments that local pharmacies are not accepting prescriptions from Dr. Harrison. The former office manager has left the practice for undisclosed reasons…"*

Two months later, while Purdue investigated this report of concern, the sales representative returned to Dr. Harrison's office with her supervisor to continue promoting more opioids. Purdue ultimately advised its sales force they could continue calling on the doctor despite knowing that she was prescribing Purdue opioids inappropriately to her addict husband and other patients.

194. By July 2016, Dr. Harrison's practice had closed its doors. Even then, Detailer #6 reported concerns about the doctor a second time in August 2016, telling Purdue that her husband "may have undue influence on her and her prescribing habits, and that she may be treating patients at home." Purdue still did nothing. The sales representative's suspicions were confirmed later that month when Dr. Harrison was arrested and charged with numerous drug-related violations after an investigation by the Pennsylvania Office of Attorney General discovered she had treated patients while high on cocaine, illegally pre-signed prescriptions for controlled substances, allowed her office manager to prescribe opioids to patients

without examinations, and engaged in other illegal conduct.[128] Purdue never reported Dr. Harrison to law enforcement or directed its sales force to stop calling on her.

Lansdowne, PA

195. Purdue targeted yet another family practitioner in Delaware County. In 2005, Detailer #2 began calling on Dr. Lenwood Wert at his Lansdowne office. Dr. Wert considered the assigned Purdue representative "his true friend," and over the next five years, they formed a close relationship. In total, Detailer #2 visited the doctor 50 times between October 2005 and June 2010.

196. Red flags surfaced as early as August 2008, when Detailer #2 discovered that other doctors would not see Dr. Wert's patients while he was on medical leave "due to so many pain [sic] pts." A few months later, the Purdue sales representative recorded his own concerns that Wert was overprescribing opioids. Instead of reporting these incidents to Purdue, Detailer #2 began discussing documentation and appropriate patient selection with Dr. Wert under the guise of concern, friendship, and "keeping him safe." Meanwhile, he kept asking the doctor to prescribe more Purdue drugs, and at one point, "called on [their] friendship" to put patients on Ryzolt. Dr. Wert agreed to do so.

197. The more times Purdue representatives called on Dr. Wert, the

[128] *See* PA Office of Attorney General, Case Update (2/7/18), https://www.attorneygeneral.gov/taking-action/updates/case-update-adams-county-doctor-charged-with-treating-patients-while-under-the-influence-of-cocaine/

more Purdue drugs he prescribed: his OxyContin prescriptions alone increased more than 500% between 2006 and 2009. By 2010, Dr. Wert's prescriptions were being sold on the street and had triggered a visit from the DEA. Purdue continued promoting opioids to the doctor for several months and ultimately did not direct its representatives to stop calling on Dr. Wert until April 2013—only ***after*** discovering his practice had been shut down. Dr. Wert was arrested the following month on numerous drug-related charges, including prescribing opioids to a drug addicted person.[129] He lost his medical license that same year.[130]

Johnstown, PA

198. From 2006 through 2011, Purdue assigned Detailer #7 to target another high-value target in Cambria County. Family practitioner Dr. Glenn Davis marketed himself to patients as a pain specialist with various third-party pain group affiliations, identifying himself as an AAPM Diplomat, ABFP Diplomat, and AAFP Fellow.

199. Upon information and belief, Purdue hired Detailer #7 on May 20, 1991 and assigned her to the Central Pennsylvania territory. She was the only Purdue representative assigned to Dr. Davis and visited the doctor 84 times between January 2006 and August 2011. Detailer #7 frequently won yearly bonuses in the

[129] Pennsylvania Department of State (website)
[130] *Id.*

tens of thousands of dollars due to the amount of opioids her assigned doctors prescribed. From 2007 to 2016, Purdue paid the sales representative nearly $380k in additional compensation for her sales performance.

200. Purdue Detailer #7 quickly learned that OxyContin was the Johnstown doctor's "drug of choice" when he told the sales representative that it was "his most prescribed and trusted medication." Detailer #7 then visited the doctor 1-2 times every month to ensure his "continued support" and loyalty to the Company's opioids. Purdue's strategy clearly worked because Dr. Davis prescribed more and more Purdue drugs. From 2007 to 2009, he increased his number of OxyContin prescriptions by nearly eighty-five percent.

201. By 2010, Detailer #7 knew that Dr. Davis' prescribing was out of control. He wrote over 1,000 opioid prescriptions per month and nearly 300 of those scripts were for OxyContin. In June, a pharmacist told the Purdue representative that Dr. Davis was being investigated for writing a large amount of opioid prescriptions for out-of-town patients, including scripts for more than 300 oxycodone tablets as well as OxyContin. Despite reporting these concerns to Purdue, the sales representative continued visiting and promoting opioids to the doctor. In July, Detailer #7 submitted another report of concern when office staff told her that Dr. Davis "was asked for documentation on 35 charts from state Medicaid," and in September, she reported a concerning letter written by the doctor and posted in his

office waiting room. Again, despite the above, Detailer #7 kept calling on Dr. Davis and asking him to prescribe more opioids at each subsequent office visit.

202. The Purdue sales representative's decision to continue promoting opioids to Dr. Davis was particularly alarming given the contents of the letter she reported to Purdue in September 2010. In addition to admitting he was under state investigation in this letter, Dr. Davis made what were, to the Purdue representative, several false and misleading statements to patients about prescription opioid use. He specifically discussed OxyContin's reformulation, claiming the drug was ineffective at 12-hour dosing, had less of a euphoric effect, and stated other misrepresentations:

> *"[Purdue] finally got the new formulation approved [by] removing the 'kick' or surge component."*
>
> *"the active ingredient in OxyContin... is oxycodone, a powerful semi-synthetic narcotic that actually is not the active form of the drug."*
>
> *"Now, the problem: for some of you folks, the enzyme for this particular drug conversion is deficient, the overall effect being that you are partially 'oxycodone-resistant.' This can result in your body not responding as well as others do to the same amount of the drug... most especially you may not get as high a concentration and/for the lower levels will result in the drug wearing off sooner than in 12 hours."*
>
> *"we need to upgrade you to an 8-hour dosing schedule, even if that means a slight increase in your pills-per-month before the insurance company."*
>
> *"those already on... the Purdue support program... would be best served by staying on the support program, but with an increase in dosing which fortunately would be automatically granted."*

Alarmed by this "misinformation," Detailer #7 immediately sent a copy of the letter to both Purdue medical services and in-house counsel. When Purdue said nothing,

she kept calling on the doctor.

203. Purdue did not place Dr. Davis on its "no calling" list until late October 2010. During this time, and despite three pending reports of concern, Detailer #7 made two additional office visits without mentioning her concerns about the doctor's letter. Instead, she asked him about new OxyContin initiations.

204. Purdue last attempted to promote opioids to Dr. Davis on August 9, 2011—nearly a year after sales representatives were told to stop calling on him—when his office requested more OxyContin savings cards. Despite the doctor's "no calling" status, Detailer #7 visited his office again and left Butrans information for Dr. Davis. In call notes, the sales representative noted that Dr. Davis was now using lie detector tests and other unorthodox screening methods on his patients, but instead of reporting these practices as red flags, she told Purdue that his office appeared "normal." She then requested permission to resume calling on the doctor.

205. However, the authorities did not consider the doctor's prescribing behavior "normal," but rather found that his practices were dangerous. At least one patient fatally overdosed on drugs prescribed by Dr. Davis. Another sold OxyContin on the street and was arrested. By 2012, the DEA had ordered local pharmacies to stop filling his prescriptions, and in May 2013, law enforcement

raided his home and office.[131] Dr. Davis lost his medical license and was ultimately indicted on several drug-related charges for illegally prescribing narcotics. Purdue did not care that he was playing "prescription roulette" with patients' lives, because at that point, the doctor had earned the Company hundreds of thousands of dollars in profits.

Lansdale, PA

206. For more than a decade, Purdue targeted an osteopathic doctor who practiced family medicine in Montgomery County. Dr. Lawrence Miller was not a pain specialist, but he regularly treated and prescribed his patients opiates and other controlled substances for chronic pain management. Despite his lack of expertise, Purdue sent several representatives to promote its opioids to Dr. Miller from May 2004 until at least November 2016, visiting his offices more than 150 times. Purdue Detailer #4 called on Dr. Miller for the majority of that period.

207. In 2008, Detailer #4 discovered that Dr. Miller was seeing more pain management patients and started visiting his office 1-2 times every month. As a result, Dr. Miller's prescriptions for Purdue opioids increased by more than 400 percent between 2007 and 2010. By the time he lost his DEA registration in June 2018 and was arrested three months later, the Lansdale physician had prescribed

[131] Richard Gazarik, *Johnstown physician indicted for illegal narcotics prescriptions,* TribLive (2014), https://triblive.com/news/adminpage/6074414-74/davis-patients-federal

more than 103,000 pills of OxyContin. More than 75% of those pills were 80 mg tablets—Purdue's highest and most profitable dosage strength.

208. Over the years, the sales representatives assigned to market Purdue's products to Dr. Miller got to know him very well. One detailer described the doctor as a "yes man" and tried to use this to her advantage by pushing him aggressively to write more prescriptions for Purdue opioids. Specifically, Detailer #4 repeatedly noted goals to secure new patient conversions to Purdue branded drugs. In order to meet her sales targets, the sales representative frequently urged Dr. Miller to prescribe OxyContin and Butrans in opioid-naïve patients.[132] For example, on several calls Detailer #4 asked the doctor "for one new pt [sic] to initiate that was on nsaids," and even recorded in one call note: "[I] basically dared him to one [Butrans] trial." She also pushed the doctor to distribute incentive savings cards to patients to increase his opioid prescribing and to keep patients on Purdue drugs longer. By 2007, Detailer #4 was targeting Dr. Miller's elderly patient population and pressuring him to "commit" to prescribing OxyContin or Butrans at nearly every sales call. When he failed to follow through with these commitments, she confronted

[132] According to the CDC, opioid-naïve patients are at higher risk for continuing long-term opioid use after they receive an initial prescription. CDC Guideline at 11. Patients considered "opioid-naïve" are not chronically receiving opioid analgesics on a daily basis and do not meet the FDA's criteria for "opioid-tolerance." *See* U.S. Food and Drug Administration, *Extended-Release (ER) And Long-Acting (LA) Opioid Analgesics Risk Evaluation and Mitigation Strategy (REMS)*, available at https://www.fda.gov/downloads/Drugs/DrugSafety/PostmarketDrugSafetyInformationforPatientsandProviders/UCM311290.pdf.

him.

209. By 2011, Detailer #4 knew or should have known that Dr. Miller struggled with appropriate pain management practices. He prescribed exorbitant amounts of opioids, ranging from 300 to 500 prescriptions per month. He had also recently inherited multiple pain patients from a local doctor who lost his medical license for illegally prescribing opiates and other controlled substances. However, Dr. Miller was not a pain specialist. During one sales call, Dr. Miller stated he was "fed up" with patients "us[ing] him for meds" and felt his opioid prescribing was spiraling out of control. He wanted to stop prescribing opiates completely and OxyContin in particular, but rather than address Miller's concerns, Detailer #4 gave him information about "pseudo-addiction" and encouraged the doctor to prescribe Butrans instead. When Dr. Miller asked about the drug's potential for abuse or addiction, she replied "you don't know until you try." She continued to minimize concerns raised by Dr. Miller about long-term opioid use in follow-up visits.

210. In January 2012, Detailer #4 sent Purdue a "Report of Concern" about Dr. Miller's prescribing behavior. Purdue did nothing for nearly six weeks. Finally, three months after the initial report, Purdue directed its sales force to continue calling on the doctor. The directive was merely a formality, however, because Detailer #4 had promoted opioids to Dr. Miller all throughout the alleged investigation.

211. By 2017, local authorities charged Dr. Miller with overprescribing opiates and other narcotic painkillers to drug-addicted patients. When law enforcement interviewed several of his former patients and employees, they discovered that "for at least five years Dr. Miller has been illegally prescribing drugs outside the scope of his practice and without legitimate medical purpose." The authorities were too late. From 2016 until September 2018, at least nine of Dr. Miller's patients fatally overdosed on drugs he prescribed, which included OxyContin and other opioids.[133] The doctor continued to write reckless prescriptions even after learning his patients were dying while Purdue's sales representatives encouraged him to prescribe more drugs.

212. For more than two decades, Purdue spent millions of dollars targeting high-prescribing physicians to make sure they prescribed increasingly higher amounts of its drugs. Purdue deceived Pennsylvania doctors about the risks of opioids, pushed them to keep patients on Purdue drugs longer, and kept promoting opioids to prescribers who wrote illegitimate prescriptions—even when their patients became addicted or died. Purdue's strategy worked: doctors started prescribing opioids in staggering amounts, drug sales skyrocketed, and the Company earned record profits.

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[133] Kara Seymour, *Patients Loved Him, But 9 Of Them Died: The Story Of Dr. Miller*, Patch (2018), https://patch.com/pennsylvania/doylestown/patients-loved-him-9-them-died-story-dr-miller

VI. PURDUE'S DECEPTION FUELED THE OPIOID EPIDEMIC AND HARMED PENNSYLVANIA AND ITS RESIDENTS

213. The opioid addiction and overdose crisis is the worst public health and public safety emergency in Pennsylvania. From big cities to rural communities, it affects Pennsylvanians across the Commonwealth. Purdue's unlawful conduct not only reshaped the prescribing of opioids in Pennsylvania, but essentially ignited this drug epidemic. Chronic opioid therapy—the prescribing of opioids long term to treat chronic pain—has become commonplace. While previously a small minority of opioid sales were for chronic pain patients, today as many as 90% of those patients have been treated with opioids.[134] In 2015, Purdue reaped an estimated $3 billion in revenue, virtually all of it from opioids.[135] OxyContin alone has generated **at least** $35 billion in sales since launching in 1996.[136]

214. The problem of opioid abuse is largely a problem of overprescribed opioids and in particular OxyContin, which is the most commonly

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[134] Andrea M. Trescot et al., *Opioid Guidelines in the Management of Chronic Non-Cancer Pain*, 9(1) Pain Physician (2006), http://www.painphysicianjournal.com/current/pdf?article=NTI0&journal=27.

[135] *See, e.g.,* Alex Morrell, *The OxyContin Clan: The $14 Billion Newcomer to Forbes 2015 List of Richest U.S. Families*, Forbes (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/#ee72f9575e02

[136] Patrick Raddon Keefe, *The Family That Built an Empire of Pain*, The New Yorker (2017), available at https://www.newyorker.com/magazine/2017/10/30/the-family-that-built-an-empire-of-pain.

abused prescription opioid. Often, the use of opioids begins with acute pain—a sport or work-related injury, dental surgery or a car accident—for which the patient is prescribed opioids. The doctor and patient, made comfortable about the safety and effectiveness of the product by Purdue's educational efforts and in-person assurances, continues to use opioids for lingering pain needs and demands. Others begin and stay with opioids for common chronic pain conditions, such as low back pain and arthritis. Either way, as a consequence of long term use, they may become addicted.

215. Despite Purdue's massive 2007 civil settlements and its executives' criminal guilty pleas, Pennsylvania has continued to experience significant increases in opioid use. In fact, the greatest increase in opioid use occurred *after* 2007. By 2017, oxycodone, a class of opioids that includes OxyContin, was reported most frequently within the prescription opioid category in toxicology reports of drug-related overdose decedents in Pennsylvania.[137]

216. The dramatic rise in heroin use is the direct result of the over-use and over-supply of prescription opioids for chronic pain. Opioid users who begin with prescription pills often move on to heroin, either because their doctors refuse to continue prescribing, or because they can no longer afford the medication.

[137] Pennsylvania DEA Opioid Threat Report 2018

Research has shown that 75% of heroin users in treatment started their addiction through the use of prescription medication.[138] An individual addicted to opioid painkillers is 40 times more likely to abuse or develop a heroin addiction.[139] In fact, a recent study from the National Bureau of Economic Research attributes the recent quadrupling of heroin death rates specifically to the "abuse-deterrent" formulation (ADF) of OxyContin in 2010. While opioid abuse rates have declined since the reformulation (and OxyContin in particular), Purdue's changes were too little too late. Instead of reducing opioid mortality, opioid deaths prevented by the reformulation were replaced with heroin deaths. Sadly, "the benefits of the reformulation are easily undone when there are readily available substitutes" in a high-demand market for opioids as a class of drugs—a demand created by Purdue.[140]

217. 5,456 Pennsylvanians died as a result of drug abuse in 2017—more than any other state.[141] That number was 4,643 the year before, and at least 85% of those drug-related fatalities involved opioids.[142] In addition to overdose deaths, the Pennsylvania Health Care Cost Containment Council reports that the

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[138] Theodore J. Cicero et al., *The changing face of heroin use in the United States: a retrospective analysis of the past 50 years*, 71(7) JAMA Psychiatry (2014).
[139] CDC/National Survey on Drug Use and Health (NSDUH), 2011-2013, https://www.cdc.gov/vitalsigns/heroin/infographic.html#use
[140] William N. Evans et al., *How the Reformulation of Oxycontin Ignited the Heroin Epidemic*, Review of Economics and Statistics, Forthcoming (2018), available at https://ssrn.com/abstract=3195807.
[141] Pennsylvania DEA Opioid Threat Report 2018
[142] *Id.*; *see also* https://www.overdosefreepa.pitt.edu/wp-content/uploads/2017/07/DEA-Analysis-of-Overdose-Deaths-in-Pennsylvania-2016.pd_-1.pdf

number of opioid-related hospitalizations in Pennsylvania increased 103.6% between 2008 and 2015. Nearly 1 in 37 hospital admissions in the Commonwealth were related to opioids in 2017 alone. This number does not include emergency room visits for opioid intoxications and other opioid encounters that did not result in a hospital admission.[143]

218. Between 2008 and 2015, the number of inpatient hospital stays involving opioids more than doubled from 14,711 admissions to 29,958. In 2017 alone, there were 36,712 opioid-related hospitalizations, with hospital admissions for opioid use disorder amounting to an estimated $32 million in hospital payments at an average cost of $10,321 per stay related to prescription opioid overdoses.[144]

219. Opioid abuse and addiction is not only devastating, but also expensive, and taxpayers often foot the bill through programs like Medicaid. The Pennsylvania Medicaid program spent millions on Purdue drugs from 2007 to the present. In 2017, Medicaid was the anticipated payer for 44.3% of opioid-related hospitalizations—the largest percentage among insurance payer groups. As a comparison, Medicaid comprised only 16.9% of all hospitalizations that same year.[145]

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[143] Pennsylvania Health Care Cost Containment Council, http://www.phc4.org/reports/researchbriefs/overdoses/101618/docs/researchbrief_overdoses101618.pdf and http://www.phc4.org/reports/researchbriefs/overdoses/17/docs/researchbrief_overdoses2017.pdf

[144] *Id.*

[145] *Id.*

220. Purdue's campaign of deception has imposed various categories of harm in Pennsylvania including spending on: (a) prescribing and using opioids for chronic pain as a result of Purdue's deceptive marketing—from the drugs themselves to doctor visits and toxicology screens—by the Commonwealth through its public health insurance program and the Commonwealth's employee health plans and by consumers and other third party payors; (b) health care utilization related to the physical and medical consequences of opioid prescribing, from opioid- induced constipation to addiction and opioid use disorder treatment, to the treatment of Hepatitis C, sepsis, endocarditis, and neonatal abstinence syndrome, among others; (c) the non-medical costs of opioids, such as greater and more expensive levels of disability (since many patients on long-term opioids will become less active and more subject to other illnesses, including obesity, depression, diabetes, and accidents), law enforcement and correction expenses (including but not limited to opioid related arrests, court costs, incarceration, and treatment), Child Welfare and Youth Services expenses (because parental substance misuse and abuse is a significant contributing factor to increased rates of child abuse and neglect), education and special education (because approximately 20% of children diagnosed with NAS subsequently receive special education services due to identified disabilities), and decreased productivity and revenue due to opioid addiction and death.

COUNT I

VIOLATIONS OF UNFAIR TRADE PRACTICES AND CONSUMER PROTECTION LAW

(Against All Defendants)

221. The Commonwealth incorporates the preceding paragraphs herein as though they were fully set forth.

222. By reason of the foregoing, Defendants misrepresented the nature of their opioid product(s) as non-addictive, appropriate for use against chronic pain, and effective for a twelve hour dosing period when in fact this is not the case.

223. By misrepresenting and/or omitting correct, scientifically supported contrary evidence concerning their opioid products, Defendants offered a product and/or service that was materially different from what it purported to be in the marketplace.

224. The foregoing acts and practices constitute unfair methods of competition and unfair or deceptive acts or practices in the conduct of trade or commerce in violation of the Consumer Protection Law, 73 P.S. §201-3, as defined by Section 201-2(4) by, among other things:

- Causing likelihood of confusion or of misunderstanding as to the source, sponsorship, approval or certification of goods or services;
- Causing likelihood of confusion or misunderstanding as to affiliation, connection or association with, or certification by, another;

- Representing that goods or services have sponsorship, approval, characteristics, ingredients, uses, benefits or quantities that they do not have or that a person has a sponsorship, approval, status, affiliation, or connection that he does not have;
- Representing that goods or services are of a particular standard, quality or grade, or that goods are of a particular style or model, if they are of another; and
- Engaging in any other fraudulent or deceptive conduct which creates a likelihood of confusion or misunderstanding.

73 P.S. §§ 201-2(4) (ii), (iii), (v), (vii), and (xxi)

PRAYER FOR RELIEF

WHEREFORE, the Commonwealth respectfully requests this Honorable Court to issue an Order:

A. Declaring Defendants' conduct to be in violation of the Consumer Protection Law;

B. Permanently enjoining Defendants, their agents, successors, assigns, and employees acting directly or through any corporate device from engaging in the aforementioned acts, practices, methods of competition, or any other practice violative of the Consumer Protection Law;

C. Directing Defendants to comply with the Consumer Protection Law and any amendments thereto;

D. Directing Defendants, pursuant to Section 201-8(b) of the Consumer Protection Law, to pay civil penalties in the amount of One Thousand and

00/100 Dollars ($1,000.00) for each and every violation of the Consumer Protection Law, which will increase to Three Thousand and 00/100 Dollars ($3,000.00) for each violation involving a victim sixty (60) or older;

E. Directing the Defendants to disgorge and forfeit all profits they have derived as a result of their unfair and deceptive acts and practices as set forth in this Complaint;

F. Directing Defendants, pursuant to Section 201-4.1 of the Consumer Protection Law, to restore any moneys which may have been acquired by means of any violation of the Consumer Protection Law;

G. Directing Defendants to pay the Commonwealth for the costs of its investigation and prosecution of this action;

H. Directing Defendants to forfeit their right or franchise to engage in business within the Commonwealth of Pennsylvania until such time as all monies have been paid for restitution, costs, and civil penalties; and

I. Providing such other relief as the Court may deem necessary and appropriate.

Respectfully Submitted,

COMMONWEALTH OF PENNSYLVANIA
OFFICE OF ATTORNEY GENERAL

JOSH SHAPIRO
Attorney General

JAMES A. DONAHUE, III
Executive Deputy Attorney General

Date: May 2, 2019

By: _____

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IN THE COMMONWEALTH COURT OF PENNSYLVANIA

COMMONWEALTH OF PENNSYLVANIA by ATTORNEY GENERAL JOSH SHAPIRO	:	**Case No.:**
PLAINTIFF,	:	**CIVIL ACTION**
v.	:	
PURDUE PHARMA L.P., PURDUE PHARMA INC., and THE PURDUE FREDERICK COMPANY	:	
DEFENDANTS.	:	

VERIFICATION

I, Rebecca Zehring, hereby state that I am a Consumer Protection Agent Supervisor with the Pennsylvania Office of Attorney General, Health Care Section, and am authorized to make this verification on behalf of the Plaintiff in the within action. I hereby verify that the facts set forth in the foregoing Complaint are true and correct to the best of my knowledge or information and belief.

I understand that the statements contained herein are subject to the penalties of 18 Pa. C.S. § 4904 relating to unsworn falsification to authorities.

Date: 5/1/2019

Rebecca M. Zehring

Rebecca Zehring
Consumer Protection Agent Supervisor

IN THE COMMONWEALTH COURT OF PENNSYLVANIA

COMMONWEALTH OF PENNSYLVANIA by ATTORNEY GENERAL JOSH SHAPIRO	:	**Case No.:**
PLAINTIFF,	:	**CIVIL ACTION**
v.	:	
PURDUE PHARMA L.P., PURDUE PHARMA INC., and THE PURDUE FREDERICK COMPANY	:	
DEFENDANTS.	:	

CERTIFICATE OF COMPLIANCE

I certify that this filing complies with the provisions of the *Public Access Policy of the Unified Judicial System of Pennsylvania: Case Records of the Appellate and Trial Courts* that require filing confidential information and documents differently than non-confidential information and documents.

Date: May 2, 2019

By: _____

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