STATE OF NORTH CAROLINA		IN THE GENERAL COURT OF JUSTICE SUPERIOR COURT DIVISION
WAKE COUNTY		FILE NO.
STATE OF NORTH CAROLINA, ex rel. JOSHUA H. STEIN, ATTORNEY GENERAL, **Plaintiff,** **v.** **PURDUE PHARMACEUTICALS L.P.; PURDUE PHARMA INC.; PURDUE PHARMA OF NORTH CAROLINA L.P.; PURDUE PHARMA TECHNOLOGIES INC.; PURDUE PHARMA MANUFACTURING L.P.; PURDUE PHARMA MANUFACTURING (NEW YORK) INC.; and THE PURDUE FREDERICK COMPANY,** **Defendant.**	)	**COMPLAINT** JURY TRIAL DEMANDED

Plaintiff, the State of North Carolina, by and through its Attorney General, Joshua H. Stein, brings this action against Defendants PURDUE PHARMACEUTICALS L.P.; PURDUE PHARMA INC.; PURDUE PHARMA OF NORTH CAROLINA L.P.; PURDUE PHARMA TECHNOLOGIES INC.; PURDUE PHARMA MANUFACTURING L.P.; PURDUE PHARMA MANUFACTURING (NEW YORK) INC.; and THE PURDUE FREDERICK COMPANY (collectively "Purdue" or "Defendants") pursuant to North Carolina's Unfair or Deceptive Trade Practices Act, N.C.G.S. §§ 75-1.1, *et seq*., and alleges as follows:

INTRODUCTION AND SUMMARY

Prescription opioids are at the core of an epidemic of drug addiction, overdose, and death that is ravaging communities and families all across North Carolina and throughout the United

States. In recent years, the crisis has grown in intensity to the point that it has become, by many measures, one of the greatest public health emergencies North Carolina has ever experienced.

While statistics can only tell a small part of the story, the numbers are striking. For example:

- In 1999, 109 people in North Carolina died from accidental opioid overdoses. By 2016, the annual number of deaths had increased by more than ten times, to 1,384.[1]
- Since 1999, more than 13,000 North Carolinians have died from opioid-related overdoses, and more than 19,000 North Carolinians have received opioid-related substance abuse treatment.[2]
- During 2017 alone, emergency medical technicians administered naloxone – a medication that can reverse the effects of an opioid overdose – to more than 15,000 people across North Carolina during 2017 alone.
- Also in 2017, North Carolinians received emergency room treatment for an opioid overdose approximately 5,800 times. That marked a 38% increase over the year before.
- Since 2012, as thousands of children across the State have lost parents to drug overdoses and addiction, North Carolina has seen a 25% increase in the number of children in foster care.

[1] Susan M. Kansagra and Mandy K. Cohen, *The Opioid Epidemic in NC: Progress, Challenges, and Opportunities*, North Carolina Medical Journal 79:157 (May-June 2018), available at http://www.ncmedicaljournal.com/content/79/3/157 full.pdf+html.

[2] Substance Abuse and Mental Health Services Administration, *2015 State Profile – United States and Other Jurisdictions, National Survey of Substance Abuse Treatment Services (N-SSATS)*, available at https://wwwdasis.samhsa.gov/dasis2/nssats/n2015_st_profiles.pdf.

- From 2004 to 2016, as opioid addiction surged in the population, the number of newborns in North Carolina who required hospital treatment because they experienced drug withdrawal increased by 922%.
- According to one estimate, just for 2015, the cost of unintentional opioid-related overdose deaths, without even counting other negative impacts, totaled at least $1.3 billion.[3]

The root cause of this public health crisis was a dramatic surge in the use of prescription opioids that began in the 1990s. Between 1999 and 2014, sales of prescription opioids almost quadrupled nationwide. By 2010, 20% of all doctors' visits resulted in an opioid prescription, and 254 million opioid prescriptions were filled – enough to medicate every adult in the United States around the clock for a month.[4] In recent years, some counties in North Carolina have seen close to 200 opioid prescriptions written annually for every 100 residents.[5]

It is no coincidence that by 2014, after years of surging opioid prescriptions, almost two million Americans were suffering from opioid abuse or dependence. Indeed, studies have shown that the rate of opioid prescriptions and the rate of opioid abuse are closely linked. Since pharmaceutical manufacturers began promoting prescription opioids in the late 1990s, more than half a million Americans have died from drug overdoses.[6]

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[3] North Carolina Department of Health and Human Services, *Opioid-Related Overdoses* (2017), available at https://files nc.gov/ncdhhs/Opioid_Overdose_Factsheet_FINAL_06_27_17.pdf.

[4] Matthew Daubresse et al., *Ambulatory Diagnosis and Treatment of Non-Malignant Pain in the United States, 2000-2010*, Medical Care 51:10 (Oct. 2013), available at https://www.ncbi nlm nih.gov/pmc/articles/ PMC3845222/.

[5] North Carolina Department of Health and Human Services, Injury & Violence Protection Branch, Injury Epidemiology and Surveillance Unit, *Opioid Prescribing Rates (Prescriptions Per 100 Residents) by County, CDC: N.C. Residents, 2006-2016* (Dec. 20, 2017), available at http://www.injuryfreenc ncdhhs.gov/DataSurveillance/ poisoning/CDC-OpioidPrescribingRates-2006-2016.pdf .

[6] Substance Abuse and Mental Health Services Administration, *Results from the 2012 National Survey on Drug Use and Health: Summary of National Findings*, NSDUH Series H-46, HHS Publication No. (SMA) 13-4795; American Society of Addiction Medicine, *Opioid Addiction 2016 Facts & Figures*, available at https://www.asam.org/docs/ default-source/advocacy/opioid-addictiondisease-facts-figures.pdf.

While millions have suffered from the opioid crisis, pharmaceutical companies have made record-breaking profits, grossing an estimated $8 billion from opioid sales in 2012 alone. Of that amount, $3.1 billion went to Purdue for its sale of OxyContin. By 2015, prescription opioids were generating nearly $10 billion in annual revenue for pharmaceutical companies, up from less than $1 billion in sales in 1992.

The opioid epidemic is a human-made disaster. It did not occur because patients suddenly started experiencing more pain, as patients' premedication reports of pain have not materially changed. Rather, much of the fuel for this epidemic came from the fact that pharmaceutical companies – including Purdue, the maker of OxyContin and other opioid pain-relief products – were willing to overlook the harm their actions and decisions were certain to cause other people. Indeed, Purdue built its sales campaign around systematic deception. Purdue repeatedly deceived people about its products and thereby increased Purdue's profits, at a staggering human cost.

Purdue's decisions and actions played a pivotal role in igniting and spreading the opioid epidemic in North Carolina. In an effort to achieve its goal of ever-expanding opioid sales growth, Purdue designed an aggressive, expensive, multi-faceted marketing campaign, deployed across many platforms, spokespeople, and media. Purdue was caught and penalized for deceptive marketing in 2007, after three executives also pleaded guilty to criminal charges, but this appears to have had no impact on its willingness to cross the line in marketing its opioid products.

At the heart of Purdue's campaign has been a host of statements that are intended to overcome, through deception, concerns that prescribers and patients have about Purdue's opioid products, including downplaying the risks of addiction, and exaggerating the safety and benefits of Purdue's products, including in comparison to other pain medications. Purdue has spread these deceptive messages in a variety of ways including, among other things, branded and

unbranded marketing materials provided to patients and prescribers in North Carolina, extensive sales calls to prescribers in North Carolina, and paying doctors and outside organizations to repeat Purdue's party line.

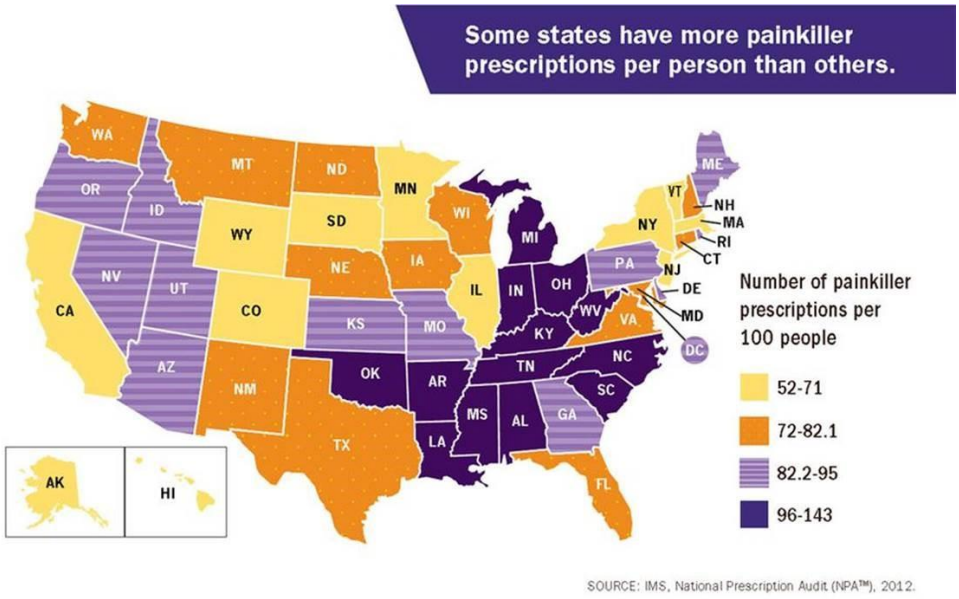
For example:

- As part of its effort to downplay the risk of addiction, Purdue pushed an invented concept – "pseudo-addiction" – which has no valid scientific basis. Portraying this made-up term as a real medical phenomenon, Purdue aggressively marketed the idea that many times it is the pain itself, not the addiction, that causes people to engage in desperate drug-seeking behavior. Even some of Purdue's own doctor-promoters eventually acknowledged that pseudo-addiction was a baseless concept, "an excuse to give patients more medication," that had "led us down a path that caused harm."
- To combat competition from makers of non-opioid NSAID[7] pain relievers, such as aspirin, acetaminophen, and ibuprofen, Purdue repeatedly claimed that NSAIDs are actually riskier than opioids for chronic pain. As with "pseudo-addiction," there is no valid science to substantiate this claim.
- To doctors who were concerned about dosage levels of OxyContin, Purdue spread the false information that there actually are no maximum dosage limits for OxyContin. According to Purdue, the only real limit is when the patient experiences side effects like respiratory depression, a potentially life-threatening condition that requires immediate medical attention.

Through these and many other deceptive statements, repeated thousands of times in numerous forms over many years, Purdue and others in the pharmaceutical industry achieved

[7] NSAID means "non-steroidal anti-inflammatory drug."

what marketers often dream of, but rarely pull off: a comprehensive transformation in the attitudes, habits, and practices of the consuming public. Ultimately, Purdue's false statements played a major role in moving North Carolina out of a world in which opioid use was sharply limited, due largely 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. The opioid epidemic has devastated thousands of North Carolina families and has overwhelmed treatment providers, law enforcement, employers, State family services, charitable organizations, the court system, and other support services throughout the State.



North Carolina's Unfair or Deceptive Trade Practices Act (UDTPA), N.C.G.S. § 75-1.1 *et seq.*, 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 North Carolina commerce. Since the UDTPA was enacted in 1969, few commercial situations have been created within North Carolina that have caused as much harm to as many members of the public as the opioid epidemic. Through this legal action, the Attorney General of North

Carolina seeks to hold Purdue accountable for its wrongful and illegal actions, and to put a stop to them.

PARTIES

1. Plaintiff, the State of North Carolina ("the State"), acting on relation of its Attorney General, Joshua H. Stein, brings this action pursuant to Chapters 75 and 114 of the North Carolina General Statutes. The State, by and through the Attorney General, is charged with, *inter alia*, enforcing North Carolina's Unfair or Deceptive Trade Practices Act, N.C.G.S. §§ 75-1.1, *et seq*.

2. Defendant Purdue Pharmaceuticals L.P. is a foreign limited partnership incorporated in Delaware with its principal place of business in Connecticut. The registered agent for Purdue Pharmaceuticals L.P. is Corporation Service Company at 2626 Glenwood Avenue, Suite 550, Raleigh, NC 27608.

3. Defendant Purdue Pharma Inc. is a foreign corporation incorporated in New York, and conducts business in North Carolina with its principal place of business in Connecticut. The registered agent for Purdue Pharma Inc. is Corporation Service Company at 2626 Glenwood Avenue, Suite 550, Raleigh, NC 27608.

4. Defendant Purdue Pharma of North Carolina L.P. is a foreign limited partnership incorporated in Delaware. The registered agent for Purdue Pharma of North Carolina L.P. is Corporation Service Company at 2626 Glenwood Avenue, Suite 550, Raleigh, NC 27608.

5. Defendant Purdue Pharma Technologies Inc. is a foreign corporation incorporated in Delaware with its principal place of business in Connecticut. The registered agent for Purdue

Pharma Technologies Inc. is Corporation Service Company at 2626 Glenwood Avenue, Suite 550, Raleigh, NC 27608.

6. Defendant Purdue Pharma Manufacturing L.P. is a foreign limited partnership incorporated in Delaware with its principal place of business in Connecticut. The registered agent for Purdue Pharma Manufacturing L.P. is Corporation Service Company at 2626 Glenwood Avenue, Suite 550, Raleigh, NC 27608.

7. Defendant Purdue Pharma Manufacturing (New York) Inc. is a foreign corporation incorporated in New York with its principal place of business in Connecticut. The registered agent for Purdue Pharma Manufacturing (New York) Inc. is Corporation Service Company at 2626 Glenwood Avenue, Suite 550, Raleigh, NC 27608.

8. Defendant The Purdue Frederick Company is a foreign corporation incorporated in Delaware. The Purdue Frederick Company has not designated and does not maintain a resident agent within the State of North Carolina. Pursuant to N.C. Gen. Stat. § 55D-33(b), Defendant The Purdue Frederick Company may be served with process by serving the North Carolina Secretary of State at 2 South Salisbury Street, Raleigh, NC 27601, as its agent.

9. At all relevant times, Defendants were engaged in trade or commerce in the State of North Carolina and are subject to North Carolina's Unfair or Deceptive Trade Practices Act, N.C.G.S. §§ 75-1.1, *et seq*.

10. Upon information and belief, the Purdue Defendants were engaged in a common unfair and/or deceptive course of conduct, carried out by each Defendant entity named herein.

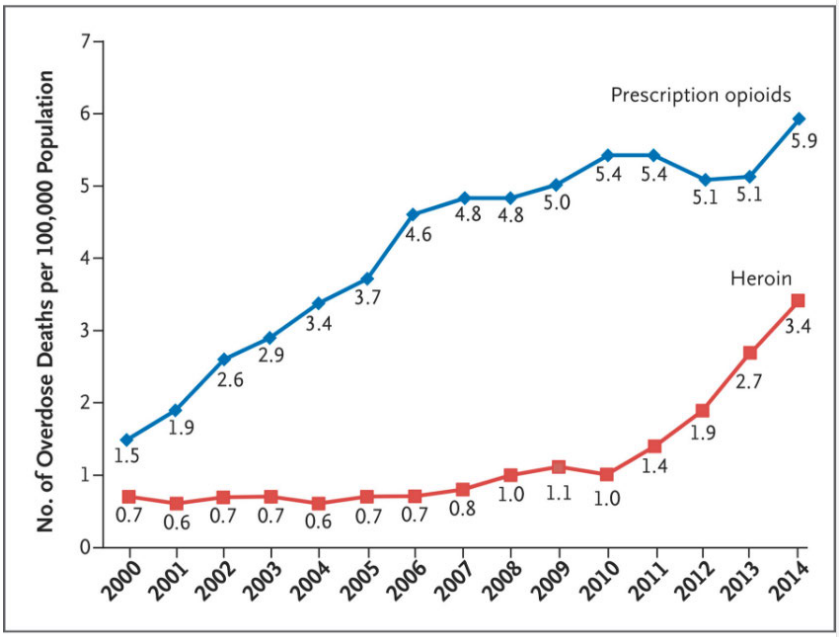
FACTUAL ALLEGATIONS

A. The Opioid Crisis in North Carolina

11. Through a years-long campaign of deceptive statements, Purdue helped drive a nearly four-fold increase in the number of annual opioid prescriptions nationwide between 1999 and 2014. That upsurge included thousands of opioid prescriptions that were medically inappropriate, involving patients who should not have been prescribed opioids at all, as well as patients who should not have been given such high doses.

12. This rising flood of new prescriptions, fueled in large part by Purdue's campaign of unfair or deceptive statements, led to thousands of instances of opioid misuse, addiction, overdose, and death in North Carolina. It also contributed to a sharp increase in the use of even more powerful drugs such as fentanyl and heroin, which are sometimes used by themselves and other times used in combination with prescription opioids.[8] Purdue's conduct as detailed in this Complaint proximately caused harm from opioid misuse, including prescription opioids and heroin.

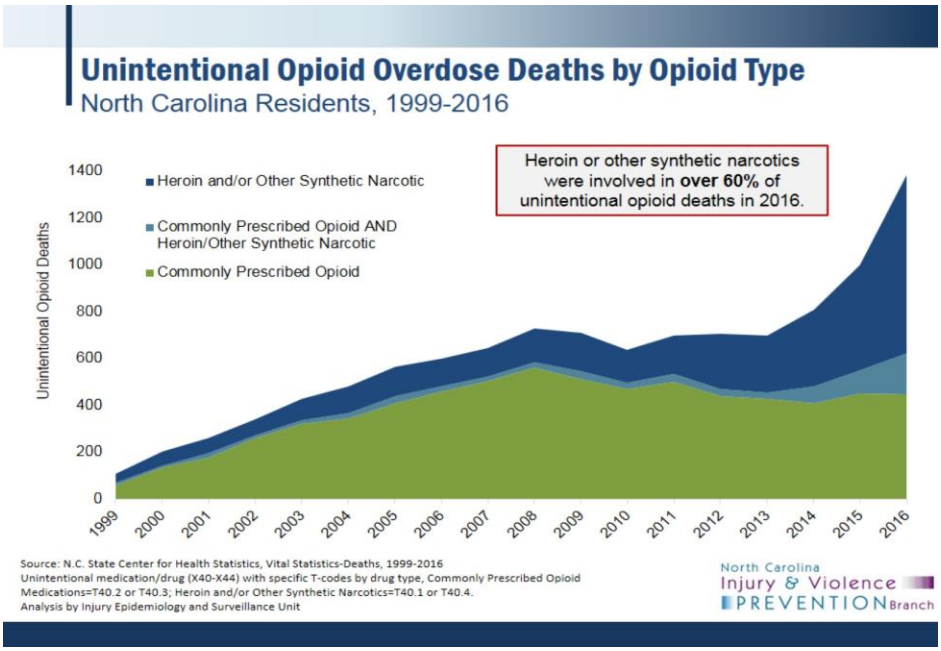
[8] Wilson Compton et al., *Relationship Between Nonmedical Prescription-Opioid Use and Heroin Use*, New England Journal of Medicine 374:154-163 (Jan. 14, 2016), available at https://www nejm.org/doi/full/10.1056/NEJMra1508490; Theodore Cicero et al., *Increased Use of Heroin as an Initiating Opioid of Abuse*, Addictive Behaviors 74:63-66 (Nov. 2017), available at https://www.sciencedirect.com/science/article/abs/pii/S0306460317302083.



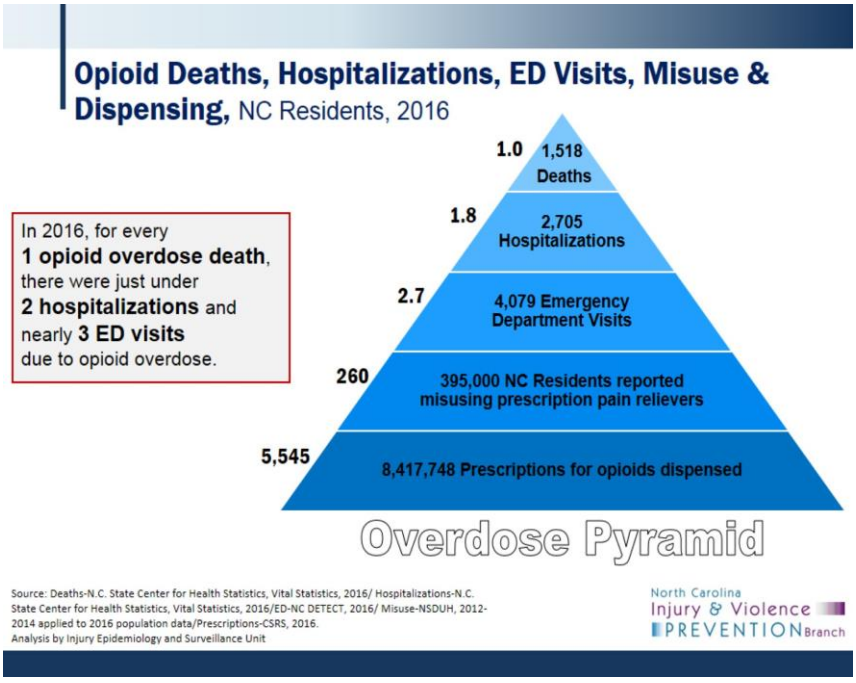
Centers for Disease Control and Prevention: Age-Adjusted Rates of Death Related to Prescription Opioids and Heroin Drug Poisoning in the United States, 2000-2014.

13. During the 2000s, prescription opioids have increasingly served as a "gateway" to heroin. Studies have shown that approximately 75% of opioid misusers began their misuse with prescription opioids. One peer-reviewed study of injection-drug users found that, by 2008-09, 86% reported having first misused opioid pain relievers obtained primarily from family, friends, or directly from prescribers. This was a marked change from past decades, when heroin was typically the first opioid experience for most opioid misusers.

14. Between 1999 and 2016, more than 12,000 North Carolinians died from opioid overdoses. The annual number of deaths from all opioids increased sharply during those years, from 109 in 1999 to 1,384 in 2016. For prescription opioids alone, the annual number of deaths increased more than seven-fold, from fewer than 100 in 1999 to 738 in 2016. Because of the upsurge in opioid overdoses, drug poisoning now causes more deaths in North Carolina than motor vehicle accidents.



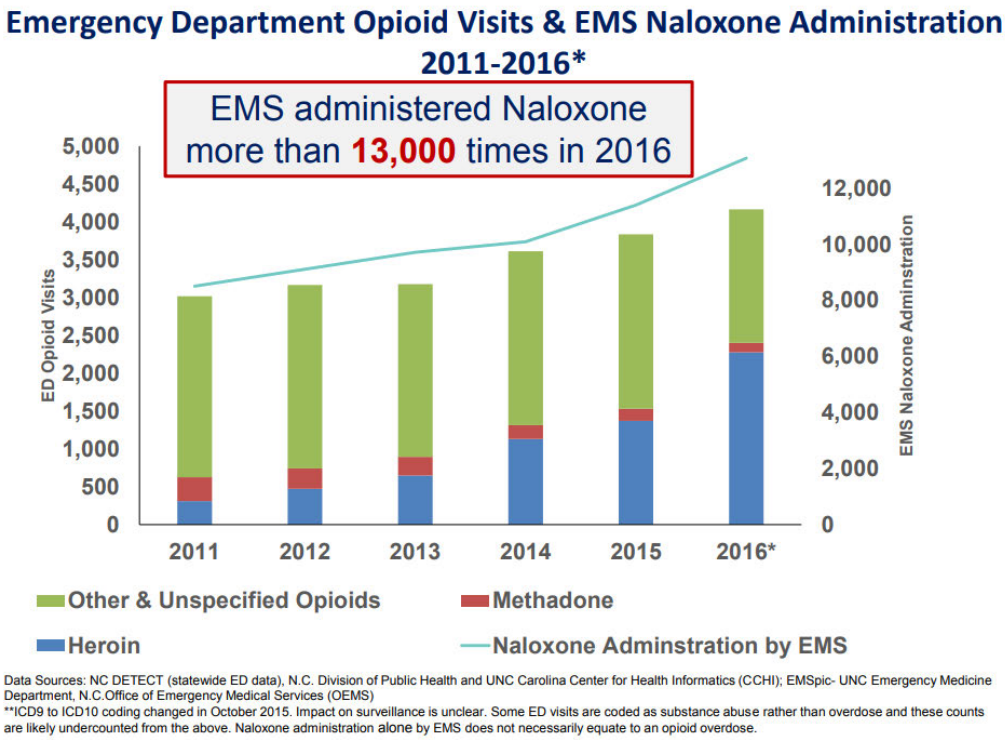
15. During 2016 in North Carolina, for every 5,545 opioid prescriptions, there were 260 instances of opioid misuse, an average of 2.7 emergency room visits, 1.8 hospitalizations, and one death.



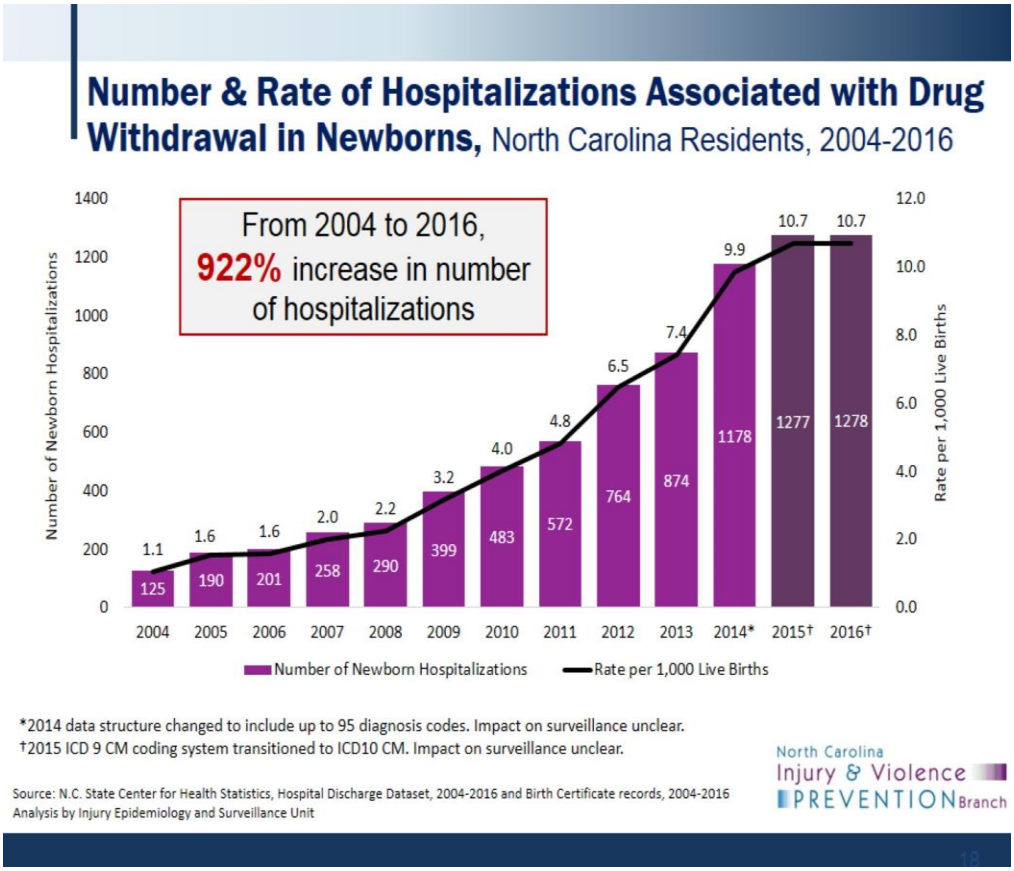
16. In 2017, the number of confirmed opioid-related poisonings increased from one month to the next during every month of the year. From 2006 to 2016, poisoning deaths involving opioids increased almost every year, and more than doubled overall, from 782 in 2006 to 1,584 in 2016. Notably, during this same span of years, poisoning deaths not involving opioids remained steady.

17. From 2010 to 2016, heroin and fentanyl poisoning deaths skyrocketed. For heroin, there were 47 deaths in 2010, compared to 573 in 2016. For fentanyl, the numbers for those same years went from 118 to 543. Controlling for North Carolina's population growth, that is an increase from 1 heroin death for approximately every 200,000 people in 2010, to 11.2 per 200,000 in 2016; and from 2.4 to 10.6 deaths per 200,000 people for fentanyl.

18. Death rates would be far higher but for the administration of Naloxone by first responders and emergency medical personnel. Naloxone, a synthetic drug that blocks opioid receptors in the nervous system, reverses the effects of an opioid overdose – effectively bringing people back from the dead, as some Emergency Medical Service ("EMS") workers describe it.



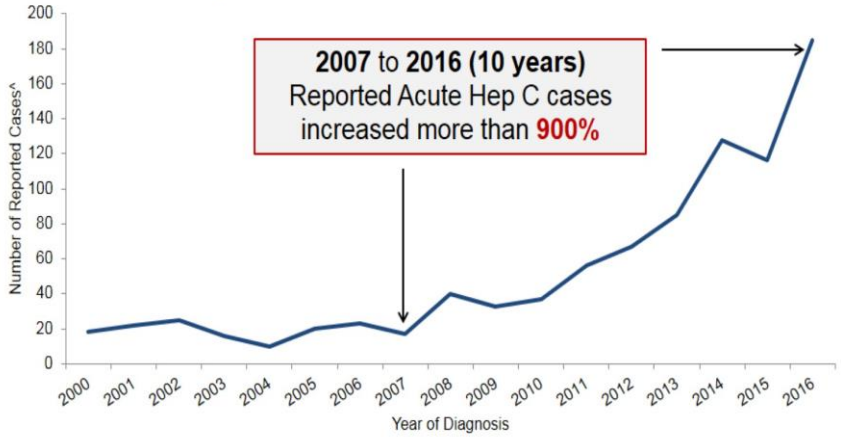
19. North Carolina has also seen a steep increase in the incidence of drug withdrawal in newborns, which frequently results from maternal use of opioids during pregnancy. In 2004, 1 out of every 909 infants in North Carolina was born drug-dependent. By 2016, the frequency had increased to 1 out of every 93 infants.



20. Sharing needles used in drug injections is associated with the spread of hepatitis C, as well as with infections of the heart-valve (endocarditis) and bloodstream (sepsis). In North Carolina, new hepatitis C infections increased by more than 900% from 2007 to 2016. Since 2010, endocarditis has increased by more 1300%, and sepsis by 400%. While hepatitis C can also be spread in other ways, it is notable that the largest increases in acute hepatitis C during this time period have occurred in the same geographic regions and demographic groups that have the highest rates of opioid overdose deaths.

Increase in Acute Hepatitis C Cases^

North Carolina, 2000–2016



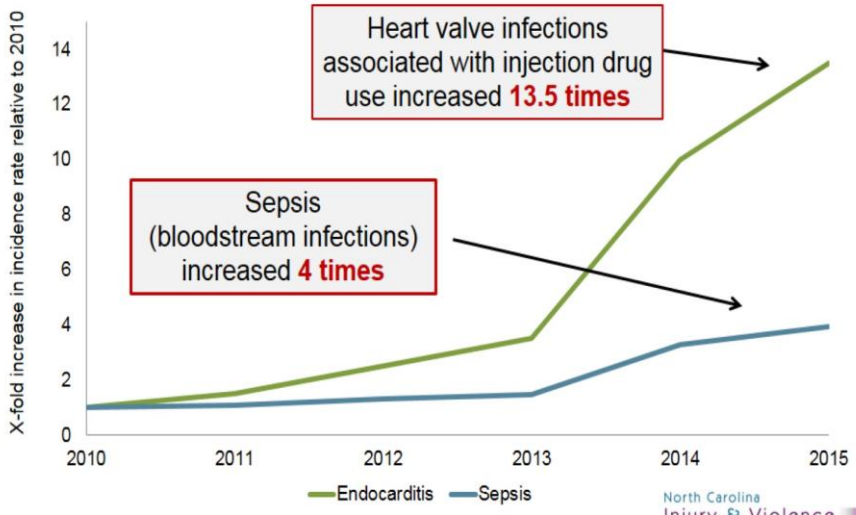
Note: Case definition for acute Hepatitis C changed in 2016.

^ Estimated true number 10–15x higher than number of reported cases

Source: NC Electronic Disease Surveillance System, 2000-2016
Analysis by NC DPH Epidemiology Section, Communicable Disease Branch

North Carolina Injury & Violence PREVENTION Branch

Endocarditis & Sepsis Among People Likely Using Drugs, North Carolina, 2010–2015



Source: N.C. State Center for Health Statistics, Hospital Discharge Dataset, 2010-2015
Analysis by NC DPH Epidemiology Section

North Carolina Injury & Violence PREVENTION Branch

21. The economic cost to North Carolina just of the opioid-caused deaths for one year (2015) – without accounting for addiction, overdoses, and other maladies caused by opioids – has been estimated at more than $1.3 billion.

22. Meanwhile, Purdue has enjoyed enormous profits from its opioid sales in North Carolina.

B. Purdue's Campaign of Deception

23. The addictive risks of opioids have been well-understood for decades, if not centuries. Because of those risks, until the mid-1990s, opioids were typically prescribed in American medicine in very limited situations, including for relief of severe pain related to cancer or surgery, or for palliative (*i.e.*, end-of-life) care.

24. Purdue, however, saw healthcare providers' caution in prescribing opioids not as a sensible constraint based on concern for patients' well-being, but as an obstacle to ever-expanding sales growth and profit for Purdue. In 1996, Purdue launched OxyContin, the first oral extended-release opioid on the market. Purdue knew that in order to boost sales of OxyContin, it would have to overcome doctors' reticence in prescribing opioids. To pursue that goal, Purdue set out on an ambitious, multi-faceted marketing campaign with the aim of fundamentally changing attitudes, practices, and culture around pain management. Paying little heed to scientific evidence, Purdue's campaign repeatedly made unsubstantiated claimed to prescribers and patients alike, including, for example, that pain is undertreated; that long-term use of OxyContin was appropriate to treat moderate to severe chronic pain, such as back-pain; that OxyContin had no maximum dose and that doctors could continue to increase the potency of a prescription without posing an added risk of addiction; and that OxyContin is superior to other pain medications in a number of ways.

25. To prime the pump for OxyContin in its first few years on the market, Purdue implemented a starter-patient coupon program for OxyContin that provided patients with a free limited-time prescription for a 7- to 30-day supply. From 1996 until 2001, when the program ended, approximately 34,000 coupons were redeemed nationally.

26. According to the Drug Enforcement Administration (DEA), Purdue's distribution of branded promotional items and other aggressive marketing tactics for OxyContin were unprecedented for drugs listed as Schedule II Controlled Substances – which are defined as drugs for which there is a "high potential for abuse."[9]

27. By 2007, Purdue's aggressive marketing had attracted legal attention, including criminal and civil charges arising from misbranding of OxyContin as less addictive, less likely to be abused or diverted, and less likely to cause tolerance and withdrawal. Purdue agreed to pay the United States government $635 million – at the time, one of the largest payments by a drug company to settle claims of marketing misconduct – and settled with 27 states, including North Carolina, for a total of $19.5 million.

28. Rather than changing its ways, however, Purdue seems to have considered these sanctions simply as a cost of doing business. After 2007, Purdue not only continued, but widened, its aggressive and deceptive sales tactics.

C. Purdue's Promotional Partners

29. Purdue's primary promotional tool in spreading its marketing messages was a common one in the pharmaceutical industry: the use of hundreds of sales representatives to visit health care providers, distribute marketing materials, and promote the use of Purdue's products.

[9] United States General Accounting Office, *Prescription Drugs: OxyContin Abuse and Diversion and Efforts to Address the Problem*, Publication GAO-04-110 (2003), available at https://www.gpo.gov/fdsys/pkg/GAOREPORTS-GAO-04-110/pdf/GAOREPORTS-GAO-04-110.pdf.

30. Between 2006 and 2017, Purdue employed [redacted] sales representatives in North Carolina who logged sales calls to physicians.

31. Between 2006 and 2017, Purdue sales representatives made at least [redacted] sales calls – or [redacted] calls per day, on average – to healthcare providers in North Carolina. 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 marketing materials in their interactions with North Carolina providers.

32. Through thousands of interactions with providers, Purdue's sales force spread misinformation about, among other things, the risks of opioid addiction, the efficacy of opioids in treating chronic pain, the phenomenon and prevalence of "pseudo-addiction," the supposed ease of preventing addiction, the safety of high dosages and indefinite opioid use, and the benefits of opioids relative to other pain relievers.

33. In addition to direct engagement with providers, Purdue also sponsored and maintained a promotional website called "In the Face of Pain" – www.inthefaceofpain.com. Purdue used this 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 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.

34. The "In the Face of Pain" website was launched in 2001, and continued in operation until Purdue deactivated it effective October 1, 2015.

35. Another tool Purdue used to spread deceptive information was to recruit and pay organizations that would promote its products, yet appear to be acting in the name of an independent organization focused on pain relief. Through these organizations, Purdue widely distributed pamphlets and other reading materials containing information about opioids. To lead these groups, Purdue often picked doctors who had served as paid speakers for it, and had touted Purdue and its opioid products. The pamphlets distributed by these nominally independent groups typically did not carry Purdue branding, and were deceptively made to appear as though their publishers were neutral third-party sources.

36. One such organization was the American Pain Foundation, whose media and political lobbying strategy was often steered by Purdue. Purdue was one of the Foundation's main sponsors, and [redacted]

37. In 2009, a pro-opioid media campaign by the American Pain Foundation, which was "made possible through a grant from Purdue," eventually reached 450,000 people in six states, including North Carolina. Among the media "hits" were television and radio interviews in Charlotte.

38. 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.[10]

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

D. Purdue's Deception Works

39. Using these deceptive marketing tactics, Purdue made OxyContin a revenue giant. In doing so, Purdue had embarked on a campaign of deception that led thousands of doctors to believe that opioids could be safely prescribed in more situations, more frequently, and in higher doses, than had previously been considered appropriate. In 1996, its first year on the market, OxyContin's sales totaled $48 million. By 2006, annual OxyContin sales had grown to $800 million, and by 2010, annual OxyContin sales exceeded $3 billion. By 2013, OxyContin constituted roughly 30% of the entire market for prescription pain relievers.[11] From June 2007 to December 2016, Purdue had sold [redacted] worth of prescription opioids nationwide, a significant portion of which were sold in North Carolina.

40. Purdue followed on the commercial success of OxyContin by introducing other extended release/long-acting prescription opioids, including products sold under the brand names Butrans, Hysingla, Ryzolt, and Targiniq.

41. For years, Purdue has used these channels of communication and these deceptive practices to spread among the public (including residents of North Carolina) repeated untruths about opioid medications. Those deceptive representations include, without limitation, the following: (a) deceptively minimizing the risk of opioid addiction; (b) touting the invented concept of "pseudo-addiction"; (c) claiming that OxyContin has no appropriate maximum dose; (d) providing false comfort about the ease of preventing opioid misuse and addiction; (e) targeting vulnerable populations; (f) withholding relevant information about the short- and long-term harms caused by opioids; (g) relentlessly repeating deceptive comparative claims; and (h) repeatedly overstating the appropriateness of opioids for treating chronic pain.

[11] Timothy W. Martin, *Generic OxyContin Pains the FDA*, The Wall Street Journal (Apr. 14, 2013).

a. Purdue repeatedly minimizes the risks opioid addiction

42. Time and again, over many years, Purdue has repeatedly minimized the risk of becoming addicted to opioids through the use of its products. Relatedly, Purdue has also frequently claimed to North Carolina doctors and patients that opioids are safe at higher doses, failing to disclose that the higher doses Purdue is touting carry even greater risks of addiction and overdose.[12]

43. Purdue frequently included in its promotional and educational materials a false and deceptive claim that opioids are not addictive. As support for this claim, Purdue repeatedly cited the highly reputable *New England Journal of Medicine*. What Purdue failed to disclose, however, is that the claim about addiction in the *New England Journal of Medicine* was not made in a peer-reviewed or otherwise scientifically validated article, but was instead just a one-paragraph "letter to the editor" dating back to 1980.[13]

44. Purdue repeatedly cited to this 1980 letter as if it were an authoritative, scientifically valid source, even though Purdue knew full-well that it was not. A June 2017 study by the *Journal* concluded that this deceptive citation had "contributed to the North American opioid crisis by helping to shape a narrative that allayed prescribers' concerns about the risk of addiction associated with long-term opioid therapy."[14]

45. To further its campaign of deception about the risks of opioids, Purdue often used paid third-party promoters such as the American Pain Foundation. In the Purdue-funded

[12] Concerning the higher risks connected to higher doses, *see* National Institute on Drug Abuse, *Opioid Prescribers Can Play a Key Role in Stopping the Opioid Overdose Epidemic* (2017), available at https://www.drugabuse.gov/publications/improving-opioid-prescribing/improving-opioid-prescribing.

[13] Jane Porter and Hershel Jick, *Correspondence: Addiction Rare in Patients Treated with Narcotics*, New England Journal of Medicine 302:123 (1980), available at https://www nejm.org/doi/pdf/10.1056/NEJM198001103020221.

[14] Pamela Leung et al., *A 1980 Letter on the Risk of Opioid Addiction*, New England Journal of Medicine 376:2194-95 (June 1, 2017), available at https://www nejm.org/doi/full/10.1056/NEJMc1700150.

publication, "A Policymaker's Guide to Understanding Pain & Its Management," the American Pain Foundation made the unsubstantiated claim that the risk of addiction is "low for the vast majority of individuals when using opioids for the long-term management of chronic pain." The same publication also claimed that "[l]ess than 1 percent of children treated with opioids become addicted."

46. The American Pain Foundation also published a Purdue-funded pamphlet entitled "Treatment Options: A Guide for People Living With Pain." This publication purported to be "a comprehensive resource that would explain various treatment options and help [patients] navigate their pain care." The pamphlet further claimed that opioids are "often under-used" despite their "great benefits," that under-use of opioids had led to "much unnecessary suffering," and that "myths and misunderstandings" about addiction and misuse should "not get in the way of effective pain control."

47. When Purdue pushed these claims, it knew full well that its opioid products posed a risk of addiction even for patients without a history of substance abuse, and that prolonged opioid use made the risk even higher. In addition to the fact that Class II opioids by definition carry a "high risk of abuse," Purdue had also received a warning letter from the FDA in 2003 for failing to disclose the risks of addiction in its advertisements for OxyContin.[15] In addition, numerous scientific studies have demonstrated the high risk of addiction from prescription opioids.

b. Purdue purveyed the concept of "pseudo-addiction"

[15] Letter from Thomas W. Abrams, Director, Division of Drug Marketing, Advertising, and Communications, FDA, to Michael Friedman, Executive Vice President and Chief Operating Officer, Purdue Pharma L.P., The Purdue Frederick Company (January 17, 2003), available at https://wayback.archive-it.org/7993/20170112130229/http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm367726 htm

48. Purdue touted the concept of "pseudo-addiction" widely to healthcare providers and patients concerned about the addictive properties of opioids. Purdue used the concept of "pseudo-addiction" to justify continuing to prescribe opioids even after a patient begins to show signs of addiction, including, in the words of third-party promoters, "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 "pseudo-addiction," 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.

49. "Pseudo-addiction" was coined by Dr. J. David Haddox in 1989, who later was hired as a paid promoter of OxyContin, and then became Purdue's Vice-President of Health Policy at Purdue. He is still employed by Purdue.

50. In 2007, Purdue sponsored a book entitled *Responsible Opioid Prescribing: A Physician's Guide* (2007),[16] edited 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 others– were signs not of real addiction, but of "pseudo-addiction."

51. This "physician's guide" has been distributed to [redacted] physicians practicing in North Carolina.

52. In 2007, Purdue published a pamphlet entitled "Providing Relief, Preventing Abuse," which was intended to serve as a brief reference guide for prescribing practices. This

[16] Federation of State Medical Boards of the United States, *Responsible Opioid Prescribing: A Physician's Guide* (Scott M. Fishman ed., 2007).

publication also referred to "pseudoaddiction," and claimed that doctors often misinterpret "behaviors in patients who have pain that has not been effectively treated" as risky "behaviors aimed at obtaining pain medication."

53. [redacted] copies of "Providing Relief, Preventing Abuse" [redacted] to prescribers or pharmacists in North Carolina. [redacted]

54. Purdue also discussed "pseudoaddiction" in its publication "Clinical Issues in Opioid Prescribing." [redacted]

55. In 2010, [redacted] an article entitled "Opioid Prescribing: Clinical Tools and Risk Management Strategies," which purported to inform healthcare providers that when patients exhibit aberrant behavior (including calls or unscheduled clinic visits, unsanctioned dose escalation, obtaining opioids from multiple sources, or forging prescriptions), the first diagnosis should be to consider whether these behaviors were being caused not by addiction, but by uncontrolled pain that was not treated to the right degree.

56. Purdue sales representatives repeatedly emphasized "pseudo-addiction" [redacted]

- [redacted]
- [redacted]

- [redacted]
- [redacted]
- [redacted]
- [redacted]

57. Starting in 2006, Purdue began providing health care providers in North Carolina with copies of a CDROM entitled "FACETS (Focused and Customized Education Topic Selections) in Pain Management." Over the years, there were multiple volumes of this presentation, which asserted that "aggressive complaining about the need for higher doses" was not predictive of addiction or other drug-related behaviors.

58. [redacted]

59. Purdue also actively evangelized the deceptive statements in FACETS through live or webinar presentations to healthcare providers and to organizations like [redacted]

60. [redacted]

61. Purdue also disseminated a CDROM entitled "Complexities of Caring for People in Pain." In it, Purdue characterized untreated and undertreated pain as an "epidemic," and falsely attributed this under-treatment of pain to "pseudoaddiction."

62. [redacted]

63. In 2009 and 2010, Purdue distributed copies of the "Complexities of Caring for People in Pain" CDROM to North Carolina health care providers.

64. Purdue also distributed copies of a CDROM 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 pseudo-addictive behaviors "resolve when pain is effectively treated."

65. [redacted]

66. Upon information and belief, Purdue knew that the concept of "pseudo-addiction" was misleading and deceptive. A number of physicians with close ties to Purdue—and who had helped spread earlier marketing messages to other physicians—have since acknowledged that "pseudo-addiction" is not a valid concept. Dr. Lynn Webster, a Utah pain specialist and former president of the American Academy of Pain Medicine, conceded that pseudo-addiction "obviously became too much of an excuse to give patients more medication. It led us down a path that caused harm. It is already something we are debunking as a concept." Likewise, Dr.

Russell Portenoy, the executive director of the MJHS Institute for Innovation in Palliative Care, admitted: "The term has taken on a bit of a life of its own. That's a mistake."[17]

c. Purdue claimed that opioids had "no maximum dose"

67. Another deceptive claim that Purdue has made repeatedly is that its opioid medications have no maximum dose. Purdue has made this claim in a variety of ways, including through its own publications, through publications by paid promoters, and through sales calls directly to healthcare providers. By repeating this deceptive claim over and over, Purdue has led providers and patients to believe that it would be safe to prescribe opioids in ever-increasing doses, subject only to pain and individual side-effects experienced by the patient. Purdue failed to inform these providers and patients that prescribing higher doses significantly raises the likelihood of addiction and overdose.

68. The "Treatment Options" publication referenced above stated that opioid doses "can be gradually increased over time. There is no ceiling dose as there is with the NSAIDs." Failing to note that continued use of opioids substantially increases the risks of addiction, the publication stated that opioid medications can "continue to be useful unless side effects occur."

69. In 2008 alone, more than 14,000 copies of "Treatment Options" were distributed nationwide.

70. Another Purdue pamphlet, entitled "Clinical Issues in Opioid Prescribing," advised healthcare providers that with "pure" opioids, including OxyContin, "there is no defined maximum dose." But this Purdue pamphlet took it one step further, suggesting that higher doses

[17] John Fauber, *Painkiller boom fueled by networking*, Milwaukee Journal Sentinel (Feb. 18, 2012), available at http://archive.jsonline.com/watchdog/watchdogreports/painkiller-boom-fueled-by-networking-dp3p2rn-139609053.html/.

of opioids could actually decrease adverse effects experienced at lower dosages: "Even if opioid doses need to be gradually increased in a patient, common adverse effects may often decrease."

71. While this "Clinical Issues" pamphlet noted that high doses of opioids carry some risks, it listed various "side effects," which it said could range from minor conditions such as constipation to more serious events like respiratory depression. Purdue made no mention in this pamphlet of the dangerously high risks of addiction and overdose that are posed by ever-increasing doses.

72. Purdue distributed [redacted] copies of "Clinical Issues" to healthcare providers in North Carolina during [redacted] Upon information and belief, in 2008 and later, Purdue distributed many more copies of this pamphlet in North Carolina, [redacted]

73. Purdue also encouraged providers to increase dose levels – or "titrate up." Federal Centers for Disease Control (CDC) guidelines published in 2016 state that providers should avoid doses over 90 MMEs[18] per 24-hour period. But one OxyContin 40 mg tablet taken as prescribed (i.e., every 12 hours) equates to 120 MMEs in a 24-hour period — 33% more than what the CDC has determined to be safe and effective. Between [redacted], more than [redacted] of all [redacted] prescribed in North Carolina, totaling [redacted], were [redacted] tablets.

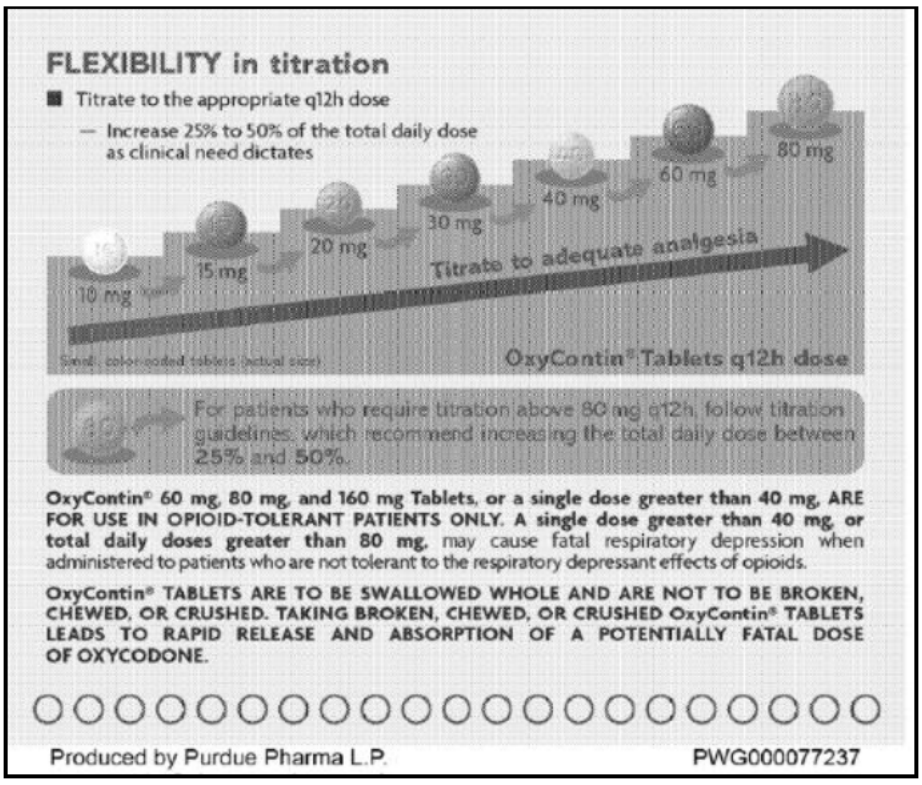
74. Another deceptive document, distributed from at least 2006 until 2014 by Purdue's "Medical Services" division, also advanced the claim that "there is no established or fixed upper limit on the dosage of full, single entity, opioid agonists such as oxycodone." This document, entitled "Maximum Dose of OxyContin Tablets," stated that "with increasing doses

[18] MME stands for morphine milligram equivalent, and is used as a standardized unit of opioid potency.

[of OxyContin] there is increasing analgesia [*i.e.*, pain relief], unlike with . . . non-opioid analgesics, where there is a limit to the analgesic effect with increasing doses." The document contained no warnings about the increased risk of addiction and overdose that arises from increased doses of opioids.

75. On many occasions, Purdue sales representatives reinforced these deceptive messages during sales calls to North Carolina providers. Call notes reflect instances in which Purdue sales representatives:

- [redacted] the provider that [redacted]
- [redacted]
- [redacted] providers that [redacted]
- [redacted]
- [redacted]
- [redacted]
- Instructed prescribers to "[i]ncrease 25% to 50% of the total daily dose as clinical need dictates" without any mention of the increased risk of addiction at higher doses.



Source: Purdue's Conversion and Titration Guide for OxyContin

d. Purdue provided false comfort about the ease of preventing opioid misuse and addiction

76. Another aspect of Purdue's deceptive marketing campaign was to make it seem easier than it actually is for providers to monitor and control the risk of opioid addiction. Purdue spread this idea in several different ways.

77. One way was to mischaracterize the warning signs of addiction. For example, the publication "Providing Relief, Preventing Abuse" identified several signs of possible drug abuse, including indications like injection marks (complete with images of skin popping and track marks), constricted pupils, perforated nasal septum, loss of appetite, nausea, drowsiness, and possession of drug paraphernalia. The publication ignored the drug-seeking behaviors that are also tell-tale — and common — signs of opioid addiction.

78. Similarly, in a 2010 presentation for healthcare providers entitled "Addressing Substance Abuse Prevention," Purdue listed signs associated with substance abuse as including unkempt appearance, red face and palms, track marks, and pinpoint pupils.

79. Purdue used messages such as these to spread the false idea that the signs of opioid addiction are blatant, striking, and largely match the signs of abuse of illicit intravenous or nasally ingested drugs. Upon information and belief, Purdue did so in order to encourage doctors to dismiss more subtle – but nevertheless significant – signs of prescription opioid abuse and addiction.

80. Another way Purdue tried to deceive healthcare providers into believing that they could spot and stop opioid addiction was by promoting the use of certain "tools" to monitor potential abuse.

81. In 2011, for example, Purdue created and funded a presentation entitled "Managing Patient's Opioid Use: Balancing the Need and the Risk" in which it compared and contrasted assessment tools that healthcare physicians used to measure the "potential risk for opioid misuse." After that presentation, some conference attendees were persuaded to rely on these tools and indicated that they would use these tools in the future.

82. Purdue promoted these assessment tools, including an "Opioid Risk Tool" developed by one of its third-party paid promoters, as reliable methods by which healthcare providers could assess a patient's risk of abusing opioids. However, clinical reviews determined that these tools were not reliable. A 2014 report by the Agency for Healthcare Research and Quality found that the Opioid Risk Tool was "extremely inconsistent." [19]

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

83. Yet another way Purdue gave false comfort to opioid prescribers was by claiming that its opioid products were subject to greater protections against abuse than other opioids, including by exaggerating the benefits of being "crush-resistant."

84. As early as 2010, in response to concerns about the propensity for opioid abuse, Purdue sought FDA approval for the first "abuse-deterrent" version of OxyContin. This version of OxyContin was different in that it was designed with properties intended to make it more difficult to crush, snort, or inject intravenously.

85. The term "abuse-deterrent," however, is a misnomer, as it implies that opioid abuse is most likely to come through intravenous use or nasal ingestion. In fact, the most common form of opioid abuse is—and always has been—ingesting pills orally. The CDC's 2016 Guideline for Prescribing Opioids for Chronic Pain warned that, although such crush-resistant characteristics are "expected to make manipulation of opioids more difficult or less rewarding, they do not prevent opioid abuse through oral intake, the most common route of opioid abuse, and can still be abused by nonoral routes." The CDC also warned: "The 'abuse-deterrent' label does not indicate that there is no risk for abuse." The CDC found no studies assessing the effectiveness of "abuse-deterrent" characteristics as a strategy for deterring or preventing abuse, let alone any that concluded that these strategies actually worked.[20]

86. [redacted] In 2009, the FDA had informed Purdue that "while the reformulation [of OxyContin] is harder to crush or chew, possibly mitigating some accidental misuse, oxycodone HC1 is still relatively easily extractable." Furthermore, because the

[20] *Id.*

reformulation did not alter the ability of a patient taking OxyContin to abuse it orally, which is "the most common mode of abuse," the reformulation only had a "limited, incremental effect on abuse and misuse."[21]

87. [redacted]

88. Still, before the FDA approved of using the descriptor "abuse-deterrent" on OxyContin labels in 2015, and despite the fact that Purdue knew of the limited value of its "abuse-deterrent formulation," it embarked on a campaign to promote OxyContin's "abuse-deterrent" effects through its own marketing material as well as presentations and pamphlets created by Purdue's paid promoters.

89. In January 2015, *The Atlantic* magazine published a Purdue-sponsored article by Dr. Gerald Aronoff, a paid promoter and the medical director of Carolina Pain Associates in Charlotte, called "Take My Pain Away." That article claimed that opioids with abuse-deterrent properties "will make certain forms of abuse much more difficult."[22] Dr. Aronoff's article was viewed 26,236 times by 21,998 unique visitors to *The Atlantic*'s website.

90. Purdue promoted this article, including by emailing it to healthcare providers. One such email encouraged providers to read and share Dr. Aronoff's article and touted Purdue's

[21] FDA Center for Drug Evaluation and Research, Division of Anesthesia, Analgesia, and Rheumatology Products, *Summary Review for Regulatory Action* (Dec. 30, 2009), available at https://www.accessdata.fda.gov/drugsatfda_docs/nda/2010/022272s000MedR.pdf.

[22] Gerald Aronoff, *Take My Pain Away*, The Atlantic (Jan. 9, 2015), available at https://www.theatlantic.com/sponsored/purdue-health/take-my-pain-away/202/.

"recent technological approaches to developing opioid medications with abuse-deterrent properties."

91. Purdue's sales representatives marketed OxyContin, including to many healthcare providers in North Carolina on multiple occasions, as [redacted]

92. On at least one occasion, Dr. Haddox, Purdue's Vice President of Health Policy who had invented the term "pseudo-addiction," asserted that opioids with abuse-deterrent properties were harder to abuse and therefore should be prescribed more often in order to *combat* the opioid crisis—a claim for which Purdue had no evidence.

93. 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.[23]

e. Purdue targeted vulnerable populations

94. Purdue sales representatives targeted vulnerable patient populations, without disclosing the unique harms it knew were critical to safe and appropriate treatment. Upon information and belief, Purdue sales representatives made more than [redacted]ales calls since 2006 to family doctors in North Carolina. In calls to family medicine doctors, Purdue sales representatives encouraged prescribing OxyContin, pushed their Dispense As Written ("DAW") campaign, providing coupons, and touted the benefits of extended-release opioids over short acting pain relievers.

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[23] Catherine S. Hwang, et al., *Primary Care Physicians' Knowledge and Attitudes Regarding Prescription Opioid Abuse and Diversion*, Clin. J. Pain, Vol, 32(4), pp. 279-84 (2016), *available at* https://www.ncbi.nlm.nih.gov/pubmed/26102320.

95. Purdue focused on these prescribers because family doctors tend to see a high volume of patients reporting moderate-to-severe pain of some kind, but also tend not to have independent expertise in pain management – thus, they are often more reliant on the accuracy of Purdue's marketing messages about the safety and efficacy of opioids. [redacted]

96. Purdue sales representatives also targeted vulnerable patient populations like the elderly and veterans, who tend to suffer from chronic pain. For example, a 2009 American Pain Foundation publication, *Exit Wounds*, funded, again, by the "generous support" of Purdue, reads as a personal narrative by a veteran and purports to "offer[] veterans and their families comprehensive and authoritative information on acute and chronic pain syndromes afflicting veterans, treatment options, and strategies for self-advocating for optimal pain care and medical resources inside and outside the VA system." The book warns of "the dangers of untreated chronic pain" and praises opioids for their "unsurpassed" "pain-relieving properties," calling them "the 'gold standard' of pain medication."

97. The book laments that opioids are "often underused" because of unwarranted concerns that a patient will become addicted; according to *Exit Wounds*: "Long experience with opioids shows that people who are not predisposed to addiction are unlikely to become addicted

to opioid pain medications. When used correctly, opioid pain medications *increase* a person's level of functioning; conversely, when a drug is used by somebody who is addicted, his or her function *decreases*." This statement runs counter to prevailing medical knowledge of the time.

98. Although the book provided 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.

99. The publication also failed to disclose that interactions between opioids and anti-anxiety medications (taken by many veterans for PTSD), can be fatal.[24]

100. Purdue sales representatives specifically targeted veterans in North Carolina and promoted them as good candidates for opioids to prescribers. Call notes from over [redacted] sales calls from 2007 to 2015 reference the availability and coverage of OxyContin by Tricare, a health care program for U.S. Armed Forces military personnel, military retirees, and their dependents.

101. In addition, between 2006 and 2015, Purdue sales representatives promoted OxyContin specifically for elderly patients in approximately [redacted] sales calls, even though the risks of long-term opioid use are significantly greater for the elderly. 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

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[24] Dasgupta et al., *Cohort Study of the Impact of High-Dose Opioid Analgesics on Overdose Mortality,* Pain Medicine 17:85-98 (2016), available at https://academic.oup.com/painmedicine/article/17/1/85/1752837; Karen H. Seal, *Opioids in Chronic Pain and PTSD: Liability or Potential Therapy,* presentation available at https://www.hsrd.research.va.gov/for_researchers/cyber_seminars/archives/791-notes.pdf.; *see also* Karen H. Seal et al., *Association of Mental Health Disorders with Prescription Opioids and High-Risk Opioid Use in US Veterans of Iraq and Afghanistan*, JAMA 307(9):940-47 (Mar. 7, 2012), available at https://jamanetwork.com/journals/jama/fullarticle/1105046

medication errors; and they are more likely to have additional medical conditions that require medications that could interact with opioids.[25] CDC Guideline for Prescribing Opioids for Chronic Pain indicates that providers "should use additional caution and increased monitoring … to minimize risks of opioids prescribed for patients aged ≥65 years."[26] OxyContin's label even recognizes that respiratory depression, as a side effect of OxyContin, "is a particular problem in elderly or debilitated patients."

102. Still, Purdue sales representatives encouraged prescribers to consider OxyContin for their elderly patients, [redacted]

103. Purdue even instructed sales representatives [redacted]

104. As evidenced by a sales call to a family practitioner in Wilmington, North Carolina, Purdue specifically targeted providers with elderly patients, at least in part, because Medicare Part D had favorable coverage for some of Purdue's opioid products – not because opioids were necessarily indicated or appropriate. [redacted]

[25] United States Centers for Disease Control and Prevention, *Applying CDC's Guideline for Prescribing Opioids*, Module 4, available at https://www.cdc.gov/drugoverdose/training/reducingrisk/accessible/index.html.
[26] United States Centers for Disease Control and Prevention, *CDC Guideline for Prescribing Opioids for Chronic Pain — United States, 2016*, available at https://www.cdc.gov/mmwr/volumes/65/rr/rr6501e1.htm.

105. Another sales representative instructed a prescriber [redacted]

106. This focused targeting of vulnerable patient populations generated a substantial uptick in sales: From 1996 to 2012, the number of opioid prescriptions provided to older patients increased 9-fold. More alarming, 35% of patients aged 50 or older who experienced chronic pain reported misuse of their opioid prescriptions within 30 days of the survey. The hospitalization rate for geriatric misuse of opioids has quintupled in the past 20 years alone.[28]

f. Purdue withheld information about harms caused by opioids

107. Purdue withheld from prescribers and patients information about the short- and long-term harms that opioid use frequently causes. Instead, Purdue held opioids out to be the safest choice for pain management in its branded and non-branded promotional materials.

108. At least since 2012, it has been widely accepted that the duration of opioid use is strongly associated with the prevalence of certain mental health conditions and other distress. Numerous studies have shown that, the longer a patient uses opioids, the higher the prevalence of

[27] [redacted]

[28] Uma Suryadevara *et al.*, *Opioid Use in the Elderly*, 35(1) Psychiatric Times (Jan. 30, 2018), available at http://www.psychiatrictimes.com/special-reports/opioid-use-elderly.

mental health conditions including depression, anxiety, post-traumatic stress disorder, and substance abuse, increased psychological distress, and the need for increased care.[29]

109. Moreover, it has been widely documented that long-term opioid use also leads to a decline in general health and social function. In fact, over time, opioid use fails to control pain because of the tolerance patients develop to these potent drugs with long-term use.[30] Indeed, there is no evidence that long-term opioid use provides pain relief or increased function without incurring serious risk of overdose, dependence, or addiction.[31]

110. In addition to tolerance, another known risk of long-term opioid use that Purdue obscured from patients and healthcare providers is hyperalgesia. Hyperalgesia causes patients to experience increased sensitivity to certain painful stimuli over time, hormonal or endocrine dysfunction, a decline in immune function, mental clouding, confusion and dizziness, increased falls and fractures, neonatal abstinence syndrome, and dangerous (sometimes fatal) interactions with alcohol or benzodiazepines.[32]

111. Purdue also concealed from healthcare providers the difficulty of withdrawing from opioids. Purdue knew that patients experiencing opioid-withdrawal would suffer intense physical and psychological pain, including anxiety, nausea, headaches, and delirium. Purdue

[29] U.S. Department of Health and Human Services, National Institute on Drug Abuse, *Comorbidity: Addiction and Other Mental Illnesses* (2008, rev. 2010), available at https://www.drugabuse.gov/sites/default/files/rrcomorbidity.pdf; R. Deyo et al., *Opioids for Back Pain Patients: Primary Care Prescribing Patterns and Use of Services*, Journal of the American Board of Family Medicine 2011:24(6), available at https://www ncbi.nlm.nih.gov/pmc/articles/PMC3855548/.

[30] A. Rubenstein, *Are we making pain patients worse*, Sonoma Medicine (2009), available at http://www.nbcms.org/about-us/sonoma-county-medical-association/magazine/sonoma-medicine-are-we-making-pain-patients-worse.aspx?pageid=144&tabid=747.

[31] Gary M. Franklin, *Opioids for Chronic Noncancer Pain: A Position Paper for the American Academy of Neurology*, Neurology 83:1277-84 (2014), available at http://n.neurology.org/content/83/14/1277.

[32] Food and Drug Administration, *FDA Announces Safety Labeling Changes and Postmarket Study Requirements for Extended-Release and Long-Acting Opioid Analgesics* (Sep. 10, 2013). Archived press release and letter to extended-release/long acting opioid application holders available at https://www.fda.gov/Drugs/DrugSafety/InformationbyDrugClass/ucm363722 htm.

knew that patients experiencing withdrawal symptoms might be unwilling or unable to give up opioids which, in turn, heightens the risk of addiction.[33] But Purdue did not disclose these risks to the healthcare providers or the patients to whom Purdue was hawking opioids. Instead, Purdue promoted long-term opioid use as a safe and effective method of pain management.

112. In addition to its direct-to-physician outreach by its sales representatives, Purdue deployed third-party publications and Purdue-funded internet sites to create the false impression that the prevailing medical opinion was that opioids were a safe alternative to other pain therapy.

113. These third-party publications, which were funded by Purdue, described the "most common" side effects of opioids as constipation, nausea, vomiting, sleepiness, mental cloudiness, and itching. These publications further asserted that "most side effects go away after a few days." These third-party paid promoters did not reference other known serious side effects, including addiction.

g. Purdue's deceptive comparisons

114. Purdue has long pushed the notion that OxyContin's 12-hour dosing regimen sets it apart from competitors, and has done so because that claim is key to OxyContin's market dominance and price premium. The belief that OxyContin is superior to less expensive, immediate-release opioids (as its competitors Vicodin and Percocet operate) was a key advantage to cornering more of the pain management marketplace. In response to a 2004 citizen's petition from the State of Connecticut, Purdue told the FDA that the 12-hour dosing regimen served as a "significant competitive advantage of OxyContin over other products."

[33] Thomas R. Kosten and Tony P. George, *The Neurobiology of Opioid Dependence: Implications for Treatment*, Science & Practice Perspectives v.1(1), p. 13 (July 2002), available at https://www.ncbi nlm nih.gov/pmc/ articles/PMC2851054/; The American Society of Addiction Medicine, *National Practice Guideline for the Use of Medications in the Treatment of Addiction Involving Opioid Use* (June 2015), available at https://www.asam.org/ docs/default-source/practice-support/guidelines-and-consensus-docs/asam-national-practice-guideline-supplement.pdf; Harriet Ryan, *"You want a Description of Hell?": OxyContin's 12-Hour Problem*, Los Angeles Times (May 5, 2016), available at http://www.latimes.com/projects/oxycontin-part1/.

115. As a result, [redacted]

116. In sales training materials, Purdue informed sales representatives that they could not make comparative claims against Purdue's competitors. [redacted]

117. Still, Purdue tiptoed around these restrictions, [redacted]

118. Purdue's sales representatives were instructed on how to make an end-run around FDA restrictions, while communicating to North Carolina healthcare providers that OxyContin's "extended release" formulation had greater benefits over Purdue's competitors' products. Sales representatives:

- [redacted]
- [redacted]

- [redacted]
- [redacted]
- [redacted]
- [redacted]
- [redacted]
- [redacted]

h. Purdue overstated the appropriateness of opioids for treating chronic pain

119. Knowing that the market for end-of-life and acute short-term patients was limited, Purdue aggressively pushed the idea that opioids are appropriate – and indeed, optimal – for treating chronic pain, while downplaying the significant risks of such treatment.

120. Purdue, through the American Pain Foundation, frequently claimed that long-acting opioids provide a better quality of life for those suffering from chronic pain: In the Purdue-funded "A Policymaker's Guide to Understanding Pain & Its Management," the American Pain Foundation claimed "[L]ong-acting opioids, in particular, are effective in

improving: Daily function[;] Psychological health[;] Overall health-related quality of life for people with chronic pain."

121. "A Policymaker's Guide" also asserted that "[m]ultiple clinical studies" had found that opioids were effective at improving the quality of life for those who suffered from chronic pain, but failed to reference even one such study to support its claim.

122. The American Pain Foundation's "Treatment Options" pamphlet claimed that opioids can be "an important part of the management of persistent pain unrelated to cancer. . . . It is a myth that opioids like morphine should only be used at the final stages of a seriously painful disease. When pain is severe, opioids should be considered." "Treatment Options" lamented that opioids are classified as narcotics since that only "places emphasis on their potential [for] abuse" and expressed concern that "myths and misunderstandings" about opioids could "get in the way of effective pain control."

123. In fact, substantial scientific evidence supports the view that opioids are not suitable for long-term chronic pain management. A number of studies have found that "no evidence exists to support long term use – longer than four months – of opioids to treat chronic pain." Indeed, the National Safety Council found: "Despite the widespread use of opioid medications to treat chronic pain, there is no significant evidence to support this practice." Additionally, the CDC's 2016 Guideline for Prescribing Opioids for Chronic Pain notes: "Experts agreed that opioids should not be considered first-line or routine therapy for chronic pain" in light of the "small to moderate short-term benefits, uncertain long-term benefits, and potential for serious harms." The CDC Guideline recommends that both "nonpharmacologic therapy and non-opioid pharmacologic therapy are preferred for chronic pain."

124. As noted in the journal *Neurology* in 2014, "there is no substantial evidence for maintenance of pain relief or improved function over long periods of time without incurring serious risk of overdose, dependence, or addiction."[34]

125. The CDC Guidelines stressed 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."

FIRST CAUSE OF ACTION

(Violations of the Consumer Protection Act, N.C.G.S. § 75-1.1)

126. The allegations contained in paragraphs 1-125 are incorporated by reference as if they were set out at length herein.

127. Purdue, in the course of promoting and marketing its extended release/long acting opioid-containing prescription drugs, made numerous statements about the risks and benefits of opioid products which have the capacity, tendency, or effect of deceiving or misleading consumers and prescribers. Pursuant to North Carolina's Unfair or Deceptive Trade Practices Act, such statements and omissions constitute unfair or deceptive trade practices that are prohibited by N.C.G.S. § 75-1.1. Purdue's unfair or deceptive statements, omissions, acts, and practices include, but are not limited to, the following:

a. Minimizing and failing to disclose the risks of opioid addiction;

b. Pushing the concept of "pseudo-addiction," and other unsubstantiated claims about the risks and benefits of opioid medications;

c. Claiming that its opioid products have no maximum dose;

[34] Gary M. Franklin, *Opioids for Chronic Noncancer Pain: A Position Paper for the American Academy of Neurology*, Neurology 83:1277-84 (2014), available at http://n.neurology.org/content/83/14/1277.

d. Falsely suggesting that opioid misuse and addiction among prescription opioid users can be readily monitored and prevented;

e. Overstating the benefits and appropriateness, and downplaying the risks, of using prescription opioids to treat chronic pain;

f. Exaggerating the benefits and downplaying the risks of Purdue's products in comparison to other products, including both competing opioid medications and non-opioid pain relievers such as aspirin, ibuprofen, and acetaminophen;

g. Withholding information about the harms and risks created by opioids;

h. Targeting vulnerable populations, including injured veterans and the elderly, for opioid sales, without disclosing the unique harms associated with its products;

i. Creating an "echo chamber" of self-referential misinformation about opioids, in which unsubstantiated claims were repeated and spread, and then cited as a basis for further statements to lead prescribers and patients to increase opioid use.

JURY DEMAND

The State demands trial by jury on all issues so triable.

REQUEST FOR RELIEF

WHEREFORE, the State respectfully requests:

1. A permanent injunction to restrain Purdue, its agents, servants, employees, and all other persons and entities, corporate or otherwise, in active concert or participation with any of them, from engaging in unfair or deceptive trade practices in the promotion and

marketing of prescription opioid pharmaceutical products pursuant to N.C.G.S. § 75-1.1, including but not limited to those identified above;

2. Equitable relief to cure Purdue's deceptive practices;

3. Civil penalties pursuant to N.C.G.S. § 75-15.2;

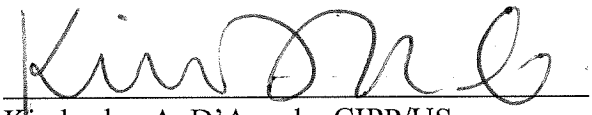
4. Disgorgement of Purdue's profits from its unfair or deceptive acts and practices;

5. The State's reasonable attorneys' fees and costs incurred by the investigation and litigation of this matter pursuant to N.C.G.S. § 75-16.1; and

6. Any and all further legal and equitable relief as the Court deems the State is entitled to receive.

This the 15th day of May, 2018.

JOSHUA H. STEIN
Attorney General



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