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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.	**COMPLAINT**
RICHARD SACKLER; MORTIMER D.A. SACKLER; JONATHAN SACKLER; KATHE SACKLER; ILENE SACKLER LEFCOURT; BEVERLY SACKLER; THERESA SACKLER; and DAVID SACKLER,	JURY TRIAL DEMANDED
Defendants.	

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WAKE CO., C.S.C.
BY

Plaintiff, the State of North Carolina, by and through its Attorney General, Joshua H. Stein, brings this action against Defendants RICHARD SACKLER; MORTIMER D.A. SACKLER; JONATHAN SACKLER; KATHE SACKLER; ILENE SACKLER LEFCOURT; BEVERLY SACKLER; THERESA SACKLER; and DAVID SACKLER (collectively, the "Sackler Defendants") pursuant to North Carolina's Unfair or Deceptive Practices Act, N.C.G.S. § 75-1.1, *et seq*., and alleges as follows:

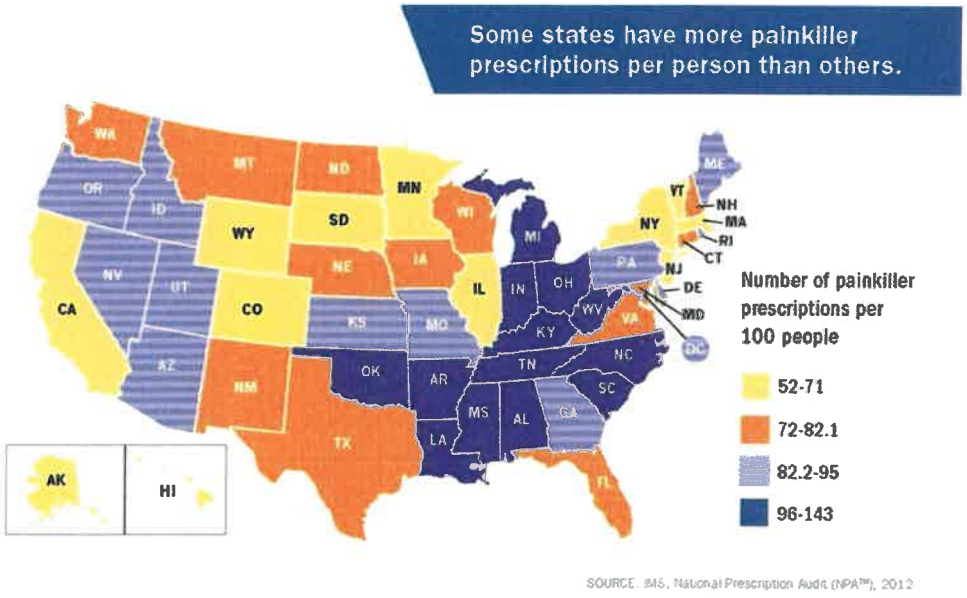
INTRODUCTION AND SUMMARY

The Sackler Defendants are the driving forces behind Purdue Pharma, the family-owned company that developed and marketed the addictive opioid known as OxyContin. The State of North Carolina brings this lawsuit against the Sackler Defendants to obtain redress for the deceptive actions they took over many years in marketing and selling OxyContin. Those deceptive actions led to billions of dollars in profits for the Sackler Defendants, but helped create

and foster an epidemic of prescription opioid addiction that has caused devastating harm to thousands of North Carolinians.

Prescription opioids are now 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.

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.



The fuel for this epidemic came from the actions of individuals including the Sackler Defendants, who were so consumed with generating billions of dollars for themselves from opioid sales that they disregarded the harm their actions and decisions were causing other people.

OxyContin contains oxycodone, a type of opioid that is chemically similar to morphine, but more potent, and is derived from the opium poppy plant. Because of its addictiveness,

OxyContin has a limited number of approved medical uses, such as for acute post-surgical and end-of-life pain management. The Sackler Defendants, however, were not content with the limited profits those limited uses would allow. So they supervised and directed deceptive marketing campaigns that disregarded those limitations on OxyContin's use, and that downplayed the addictive and dangerous qualities of the drug while overplaying its benefits. The Sackler Defendants also browbeat Purdue employees to max out sales of OxyContin regardless of the consequences. Once those consequences became impossible to ignore, the Sackler Defendants refused to accept responsibility for their role in sparking the crisis, and instead sought to blame the victims of addiction.

In 2007, an affiliate of Purdue Pharma that was also owned by the Sackler family pleaded guilty to federal criminal charges arising from marketing misrepresentations about OxyContin. However, instead of ensuring that the conduct of their family opioid business would stay within the bounds of the law, the primary lesson the Sackler Defendants appear to have taken from the 2007 conviction was that they needed to protect the billions that their family business was generating for them from the legal liability that their continued unlawful conduct would inevitably create. Thus began a run of nearly a decade in which the Sackler Defendants pulled billions of dollars in profits out of Purdue, while continuing to pump up sales through their unfair and deceptive tactics.

The Sackler Defendants tightly controlled and often micromanaged the deceptive sales and marketing campaigns that created those billions. They were directly involved in developing the guiding principles of the campaigns, demanded and received frequent, detailed reports regarding their impact on sales, and mercilessly harassed employees if insufficient profits were being generated. When confronted with information regarding risks and harms OxyContin was

creating, the Sackler Defendants continually disavowed responsibility. Often, they seemed to consider themselves the victims of the opioid crisis confronting the country, rather than the main financial beneficiaries of it.

Based on the facts set forth below, the State of North Carolina seeks appropriate penalties against the Sackler Defendants, as well as appropriate injunctive relief designed to ensure that the Sackler Defendants do not engage in this type of misconduct in North Carolina again.

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 Attorney General is charged with, *inter alia*, enforcing North Carolina's Unfair or Deceptive Practices Act, N.C.G.S. § 75-1.1, *et seq*.

2. Defendant Richard Sackler is a natural person residing in Florida. Richard Sackler served on the Board of Purdue Pharma Inc. from at least May 15, 2007 until July 24, 2018. Richard Sackler was the head of research and development at Purdue from at least 1990 through 1999. In 1999, Richard Sackler became the CEO of Purdue. He served in that role through 2003.

3. Defendant Mortimer D.A. Sackler is a natural person residing in New York. Mortimer D.A. Sackler served on the Board of Purdue Pharma Inc. from at least May 15, 2007 until January 16, 2019. On and before May 31, 2007, Mortimer D.A. Sackler also served as a Vice President of Purdue Pharma Inc. and Purdue Pharma L.P.

4. Defendant Jonathan Sackler is a natural person residing in Connecticut. Jonathan Sackler served on the Board of Purdue Pharma Inc. from at least May 15, 2007 until December 8, 2018. On and before May 31, 2007, Jonathan Sackler also served as a Senior Vice President of Purdue Pharma Inc. and Purdue Pharma L.P.

5. Defendant Kathe Sackler is a natural person residing in Connecticut. Kathe Sackler served on the Board of Purdue Pharma Inc. from at least May 15, 2007 until September 27, 2018. On and before May 31, 2007, Kathe Sackler also served as a Senior Vice President of Purdue Pharma Inc. and Purdue Pharma L.P.

6. Defendant Ilene Sackler Lefcourt is a natural person residing in New York. Ilene Sackler Lefcourt served on the Board of Purdue Pharma Inc. from at least May 15, 2007 until October 9, 2018.

7. Defendant Beverly Sackler is a natural person residing in Connecticut. Beverly Sackler served on the Board of Purdue Pharma Inc. from at least May 15, 2007 until October 17, 2018.

8. Defendant Theresa Sackler is a natural person residing in the United Kingdom. Theresa Sackler served on the Board of Purdue Pharma Inc. from at least May 15, 2007 until 2018.

9. Defendant David Sackler is a natural person residing in New York. David Sackler served on the Board of Purdue Pharma Inc. from July 19, 2012 until August 14, 2018.

10. 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 Practices Act, N.C.G.S. §§ 75-1.1, *et seq.*

11. None of the Defendants are current members of the Board of Directors at Purdue.

12. Each of the Sackler Defendants is subject to the jurisdiction of this Court. Upon information and belief, the Sackler Defendants were each individually involved in directing, approving, and participating in the unfair and/or deceptive sales and promotion of opioids in North Carolina that resulted in the widespread harms alleged in this Complaint.

FACTUAL ALLEGATIONS

A. The Sackler Defendants' Campaign of Deception.

13. The addictive risks of opioids have been known 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.

14. The Sackler Defendants,[1] 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 their family business, Purdue. In 1996, Purdue launched OxyContin, the first oral extended-release opioid on the market. OxyContin contains Oxycodone, a type of opioid that is chemically similar to morphine and is derived from the opium poppy plant. The Sackler Defendants knew that in order to boost sales of OxyContin, they would have to overcome doctors' traditional reticence in prescribing opioids. To pursue that goal, the Sackler Defendants directed Purdue sales representatives to make false and unsubstantiated claims regarding OxyContin.

15. The detail-oriented nature of the Sackler Defendants' supervision of Purdue is unusual even for a family-owned, privately held company. Throughout Purdue's history, Sackler family members, including the Sackler Defendants, have, among other things, held executive positions at Purdue, run its operations, developed corporate policy, developed compensation programs, made key decisions, instructed sales managers and employees, served on its Board,

[1] Each of the Sackler Defendants were Board members from at least 2007 to various times in 2018. The allegations in this Complaint, when they refer to the Sackler Defendants generally during this time period, refer to all defendants. To the extent that any allegations apply primarily to certain of the defendants, the allegations state to whom such allegations apply.

engaged in complex financial transactions between themselves and with Purdue and related corporate entities, and received enormous personal profits from the business. They met regularly on the Board, receiving detailed information from the staff and providing exhaustive direction to the staff, not just on general matters, but on specific activities regarding the operation of the sales force.

1. The initial wave of deceptive marketing results in both civil and criminal liability for the family business.

16. The initial wave of deceptive marketing pursued by the Sackler Defendants and the family business prior to 2007 included the misbranding of OxyContin as less addictive, less likely to be abused or diverted, and less likely to cause tolerance and withdrawal. These deceptive claims attracted legal attention and investigation, resulting in criminal and civil action in 2007. Purdue Frederick 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.

17. Sackler Defendants Richard, Ilene, Jonathan, Kathe, and Mortimer each certified in writing to the federal government that they had read and understood the provisions contained in a Corporate Integrity Agreement Purdue entered into with the Office of Inspector General of the U.S. Department of Health and Human Services that were designed to ensure compliance with the law.

18. Purdue Frederick and three of its executives also pleaded guilty to federal criminal charges and in the plea agreement admitted to a number of misrepresentations that sales representatives had made. The criminal information filed contemporaneously with the plea agreement charged that certain Purdue Frederick "supervisors and employees, with the intent to defraud or mislead, marketed and promoted OxyContin as less addictive, less subject to abuse

and diversion, and less likely to cause tolerance and withdrawal than other pain medications." Purdue Frederick agreed that everything in the information, including the above allegation, was "true and correct." The plea agreement stated: "Purdue is pleading guilty as described above because Purdue is in fact guilty."

2. Despite the 2007 criminal conviction of the family business, the Sackler Defendants continue and even expand the aggressive and deceptive promotion of opioids.

19. The 2007 criminal conviction and civil settlement did not deter the Sackler Defendants. Instead of changing their ways and reforming the family business, the Sackler Defendants continued, and even widened, their aggressive and deceptive sales tactics through the family business entities Purdue Pharma Inc. and Purdue Pharma L.P. In addition to promoting and selling OxyContin, the Sackler Defendants followed on the commercial success of that drug by introducing other extended release opioids, such as Butrans, Hysingla, Ryzolt, and Targiniq.

20. After the criminal plea, the Sackler Defendants continued to be heavily involved with the family business, where they dominated and controlled the Board and closely supervised marketing and sales activities. In 2007, there were nine individuals on the Board, and all nine were Sackler family members. From 2008 to 2018, the numbers varied, but there were always more Sacklers on the Board than non-Sacklers. Upon information and belief, in addition to controlling the Board and directing activities and corporate policy from that vantage point, some of the Sackler Defendants worked at the Purdue headquarters on a daily basis, directing activities and corporate policy in person.

21. In April 2008, after the criminal investigation that almost reached the Sacklers, Richard wrote that it was crucial to install a CEO at Purdue Pharma who would be loyal to the family: "People who will shift their loyalties rapidly under stress and temptation can become a liability from the owners' viewpoint."

22. The Sackler Defendants continued to focus particular attention on sales, fostering the belief among staff and sales employees that it was important to increase opioid sales at all costs.

23. The Sackler Defendants used deceptive practices to spread among the public, including residents of North Carolina, repeated untruths about opioid medications. Those deceptive practices included, without limitation, the following: (a) directing Purdue employees to target suspicious prescribers and patients as lucrative targets for its opioid products, knowing that these prescribers and patients were likely to divert and abuse opioids; (b) directing employees to deceptively promote Purdue opioid products as being safer or otherwise better than other pain products; (c) directing Purdue employees to target vulnerable populations, including the elderly and veterans; (d) directing Purdue employees to withhold critical information about the harms caused by opioids; (e) directing Purdue to focus on selling higher-dose—and more dangerous—opioids because they were more profitable; and (f) directing Purdue employees to influence and direct the work of Purdue's paid promotional partners, who likewise disseminated deceptive information about opioids.

24. Some of these tactics were similar to tactics the family business had engaged in beginning in the late 1990s, but they continued well past 2007, and well after the company had entered into its criminal plea and settlement with the United States Department of Justice. What follows are specific examples of unfair and/or deceptive misconduct committed by the Sackler Defendants.

25. The Sackler Defendants tightly controlled the Purdue sales force and pushed Purdue sales employees to make deceptive representations about the risks and benefits of Purdue's opioid products. Through their actions and statements, the Sackler Defendants

conveyed to those employees that increasing sales took precedence over compliance with the law.

26. As described in more detail below, at one point, after Richard Sackler had shadowed sales representatives on sales pitches in the field, he criticized them for providing a legally required warning about opioids, because he was concerned that doing so could reduce sales.

27. The Sackler Defendants significantly ramped up the sales force in the years immediately following the criminal guilty plea including in North Carolina. In June 2014, they removed Purdue's vice president of sales and pushed his replacement to sell even more opioids at an even faster rate. In September 2017, the Sackler Defendants approved a target number of sales representative visits to healthcare providers that was almost double the target number for 2010.

28. The Sackler Defendants also demanded detailed information regarding activities of the sales force. The Sackler Defendants tracked the exact number of visits sales representatives made to healthcare providers, and knew what drugs were promoted to which healthcare providers, how many visits a certain representative averaged per day, and the total cost of these visits.

29. The Sackler Defendants often expressed frustration by the approaches taken by Purdue's sales and marketing employees when they were not meeting their preconceived notion of what sales results should be. For instance, in March 2008, the year after Purdue Frederick had pleaded guilty to criminal charges, Richard complained that the sales forecast was "almost certainly overly conservative" and suggested that he and Mortimer re-do the forecast and prepare a five-year plan. This frustration caused the Sackler Defendants to push sales employees to take even more aggressive approaches.

30. A year later, Richard remained unsatisfied with OxyContin sales and demanded a plan to "boost" them. After staff presented such a plan to the Sackler Defendants, Richard questioned the approach and demanded the raw data underlying that presentation.

31. Such a demand was not uncommon. Richard frequently made these sorts of requests, even for reports and information that Purdue did not keep readily available. Richard would demand prompt responses to these requests, even those that were made outside of business hours, and would communicate his anger if staff protested that responding to the requests would take longer than Richard believed to be warranted.

32. Richard was not the only Sackler who demanded details into Purdue's sales and marketing of OxyContin and its other opioid products, thereby sending the signal to employees that sales needed to be higher and they needed to be taking more aggressive approaches. After Kathe and Richard were designated by the Board to review sales projections in November 2009, the two Sackler Defendants asked staff to "identify specific programs that Sales and Marketing will implement to profitably grow the OER [extended-release oxycodone] market and OxyContin in light of competition; provide analytics around why/how the proposed increase in share-of-voice translates into sales and profitability growth; clarify the situation with respect to OxyContin being used by 35% of new patients, but only retaining 30% of ongoing patients;" and give the Sacklers a copy of a report from McKinsey on tactics to increase OxyContin sales. The McKinsey report instructed sales reps to maximize profits by "emphasizing [the] broad range of doses"—which was essentially coded language for pushing the doses that were highest and most profitable (but also most dangerous to patients).

33. The following July, Kathe ordered staff to circulate details regarding Purdue's sales and marketing efforts before a Board meeting.

34. Like Kathe and Richard, Mortimer also made periodic requests for information about Purdue's sales and marketing efforts, and, particularly, what specific efforts Purdue was undertaking to increase its sales. Mortimer, like Richard, grew frustrated and impatient when his requests were not answered immediately.

35. In January 2011, Richard attended the launch meeting for Butrans and discussed promotion of the opioid with sales representatives. Soon after the drug was launched, Richard requested a "briefing on the field experience and intelligence regarding Butrans. How are we doing, are we encountering the resistance that we expected and how well are we overcoming it and are the responses similar to, better, or worse than when we marketed OxyContin® tablets?"

36. In June 2011, Richard asked to be included in a meeting with district managers, who were the immediate supervisors of the sales representatives who called on, and made sales pitches to, healthcare providers.

37. In June 2011, Richard shadowed sales representatives in the field as they called on various healthcare providers. After his time in the field, Richard complained that sales representatives were providing a legally required warning about opioids. Richard wrongly claimed that the language "implies a danger of untoward reactions and hazards that simply aren't there." Notwithstanding the legal requirement, Richard insisted there should be "less threatening" ways to describe Purdue's opioids.

38. The next February, Richard suggested that Purdue cancel its annual January sales meeting to allow sales representatives to resume calling on healthcare providers more quickly in the new year and thereby avoid a post-holidays slump in sales of OxyContin. Purdue's compliance officer forwarded that suggestion to his staff, commenting: "Oh dear."

39. In January 2012, Jonathan joined other family members in requesting weekly sales updates from Purdue staff. Richard had initially requested these sales reports starting in October 2009; at that time, no one at the company was receiving them with that frequency.

40. Purdue implemented the Sackler Defendants' demand for ever-increasing sales by hiring more and more sales staff to aggressively push Purdue's opioid products. At a Board meeting in July 2010, the Sackler Defendants approved the hiring of over 100 additional sales representatives, 16 new district managers, and 2 new regional managers.

41. In July 2014, in response to the FDA's requirement to conduct studies to determine the effects of opioids due to growing concerns about them, Richard called Purdue staff to complain about the FDA. Richard emphasized that the Sackler Defendants felt the FDA requirement was unfair and expressed concern about the potential implication of the results of these studies. Richard and the other Sackler Defendants were worried that studying the effects of opioids would undermine Purdue's opioid sales. Staff tried to reassure Richard that the studies would take "several years to complete, thereby keeping our critics somewhat at-bay during this time."

42. In December 2014, Richard initiated a confidential sales and marketing project to aggressively increase opioid prices. On New Year's Eve, he demanded that staff prepare to meet with him regarding this project.

43. Purdue responded to the Sackler Defendants' frequent inquiries by continuing to expand its sales force and directing the sales force to make deceptive statements to the public to increase sales.

44. The Sackler Defendants' practice of emphasizing sales at all costs and putting undue pressure on sales employees inevitably led to deceptive marketing. The Sackler Defendants not only were aware of the deceptive marketing, but directed and encouraged it.

45. For example, the Sackler Defendants encouraged staff to deceptively promote Butrans, demanding to know why Purdue was not claiming that Butrans was effective for seven days in its marketing materials, despite the lack of data to support that claim.

46. In April 2011, Jonathan complained to Purdue's CEO that the efforts currently underway to promote Butrans would not be enough to generate sufficient sales of that opioid. Jonathan was concerned that sales numbers were "starting to look ugly." Richard echoed that concern in June 2014, after the Sackler Defendants had forced out a vice president of sales at Purdue. Richard pushed the new sales executive to increase opioid sales quickly, particularly Butrans. Richard lamented that it was "very late in the day to rescue the failed launch" of Butrans, which was not making as much money as he desired.

47. The Sackler Defendants knew that Purdue employees were spreading false information and had sought to conceal their actions. For example, in July 2011, sales staff were prohibited from communicating sales pitches to prescribers by email, out of concern that it would create written evidence. After a sales representative had violated this mandate, the vice president of sales, following the Sackler Defendants' directives, ordered, "Fire her now!"

48. The Sackler Defendants directed Purdue sales staff to repeat the deceptive claim that its opioid medications have no maximum dose. This claim was made in a variety of ways, including through Purdue publications, through publications by paid promoters, and through sales calls directly to healthcare providers. By repeating this deceptive claim over and over, Purdue sales representatives, acting under the direction and control of the Sackler Defendants,

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. Consistent with the Sackler Defendants' directions, Purdue did not inform these providers and patients that prescribing higher doses significantly raises the likelihood of addiction and overdose.

49. In addition, Purdue staff followed the Sackler Defendants' direction to fund an organization called the American Pain Foundation. Purdue was one of the Foundation's main sponsors, and the company viewed the Foundation as having "a responsibility to make sure that [Purdue's] dollars go to initiatives and have recognition for Purdue that make sense." In addition, Purdue often steered the media and political lobbying strategy for this organization.

50. The American Pain Foundation's "Treatment Options" pamphlet 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."

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

52. The deceptive nature of the marketing carried out under the direction and control of the Sackler Defendants is also evident through another Purdue pamphlet, entitled "Clinical Issues in Opioid Prescribing." That document 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 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."

53. 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.

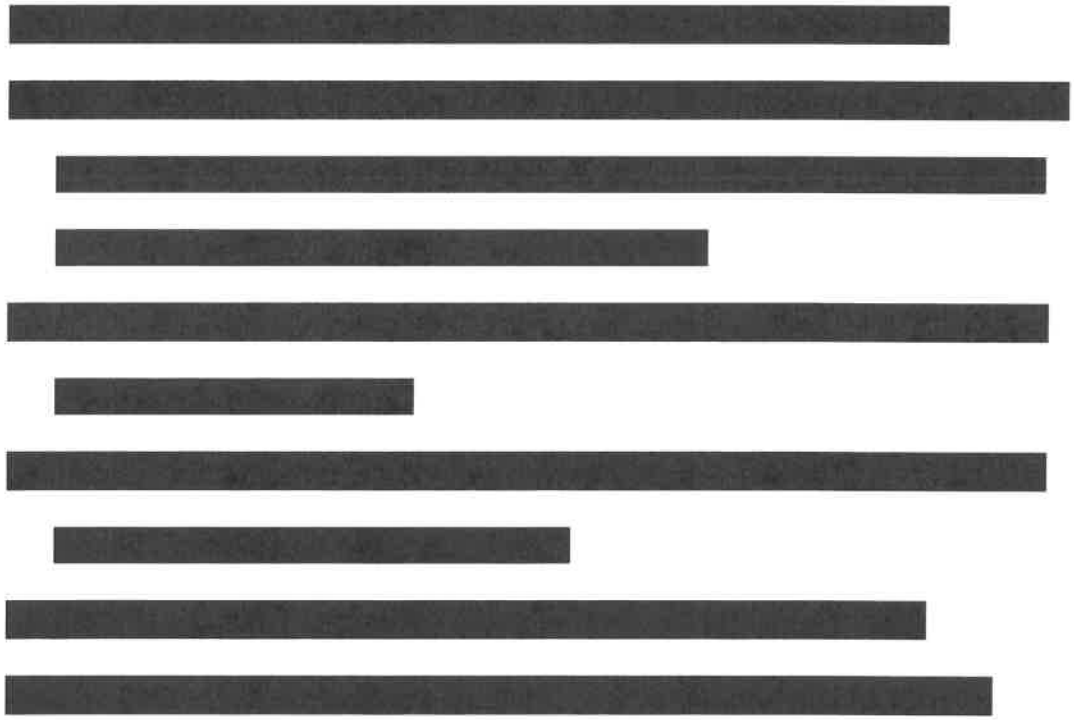
54. Purdue distributed more than 1,000 copies of "Clinical Issues" to healthcare providers in North Carolina during 2006 and 2007. Upon information and belief, in 2008 and later, acting in furtherance of the Sackler Defendants' direction to continue the same kinds of deceptive marketing that had led to civil and criminal liability, Purdue distributed many more copies of this pamphlet, including in North Carolina, as it placed an order for 10,000 copies of "Clinical Issues" in March 2008.

55. 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[2] 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 2008 and 2017, more than 40% of all OxyContin pills prescribed in North Carolina, totaling nearly 51 million pills, were 40mg or higher tablets. This extraordinary number of high-dosage OxyContin prescriptions in North Carolina was a result of the Sackler Defendants' insistence on aggressive promotion of these products.

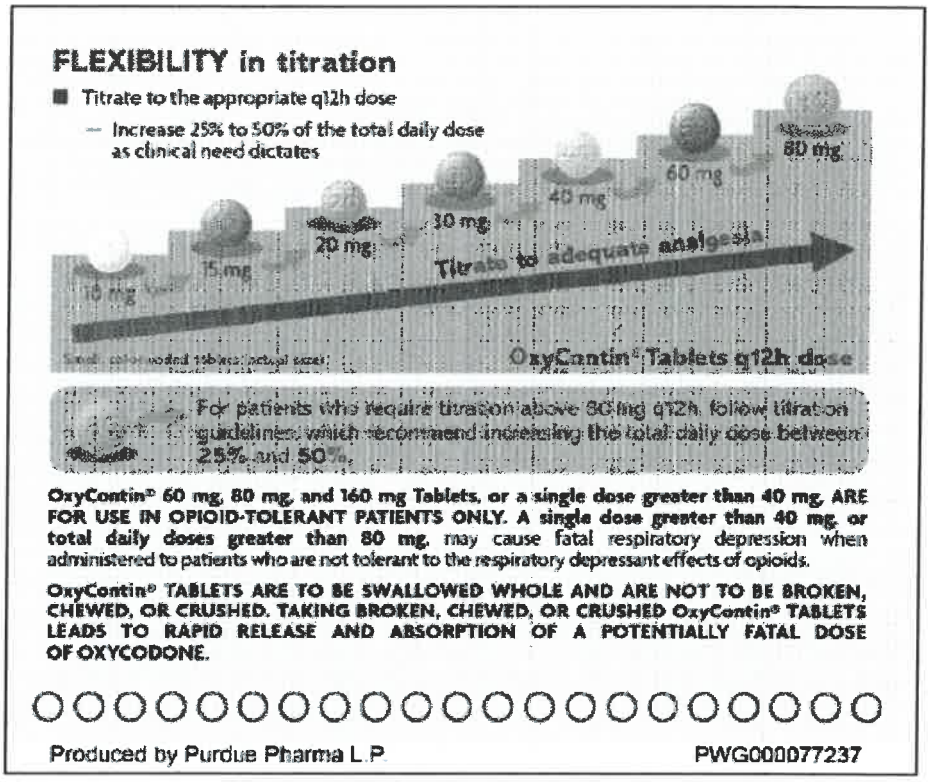
[2] MME stands for morphine milligram equivalent, and is used as a standardized unit of opioid potency.

56. 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 [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.

57. 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:



- 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

3. "Region Zero"—the Sackler Defendants direct Purdue to target suspicious prescribers as targets for its opioid products.

58. The lengths to which the Sackler Defendants went in pushing sales of addictive opioids regardless of the risks to public health are evident from its treatment of prescribers who fell under its "Region Zero" classification. In an effort to expand the sales of OxyContin—and thus the profits that could be shared with the family—the Sackler Defendants directed Purdue to expand the healthcare providers whom they typically targeted for promotion. This included, remarkably, *prescribers who had been flagged as possible diverters or abusers of opioids.*

59. Purdue's list of healthcare providers suspected of diversion or abuse of opioids was referred to as "Region Zero." At a July 2010 Board meeting in Bermuda, the Sackler Defendants expressed great interest in the Region Zero list. However, they were not interested in it from a public health or prevention standpoint, but from the opportunity to generate and increase sales. The Sackler Defendants asked Purdue staff about sales generated by the healthcare providers on this list. Staff assured the Sackler Defendants that Purdue would continue to track prescriptions written by healthcare providers on this list, including the specific number of prescriptions, units, and dollars from each prescription. Staff told the Board that Purdue had identified [redacted] prescribers in North Carolina as likely involved in diversion and abuse. Staff gave the Board a list of all of the prescribers in Region Zero that included the exact number of prescriptions and dollars of revenue each prescriber provided to Purdue and, by extension, the Sacklers.

60. Purdue employees complied with the direction they received from the Sackler Defendants and pursued sales from health care providers from Region Zero.

61. In June 2011, Kathe Sackler suggested that Purdue analyze the characteristics of those patients who switched to OxyContin from another pain reliever in order to identify common traits that might help identify additional patients who could convert to OxyContin. Notably, the focus was not on what needs a particular patient presented, from a health standpoint, but rather whether he or she fit a common profile for sales purposes.

4. The Sackler Defendants direct employees to deceptively promote Purdue opioid products as safer than other pain products.

62. The Sackler Defendants also directed Purdue to deceptively promote opioid products as being safer or otherwise better than other pain products, in order to boost sales.

63. For example, in response to the saturation of competing opioid products on the market, Richard, in 2009, ordered the staff prepare a list of "OxyContin's clinical advantages vs. Opana ER, MS Contin, Kadian, Exalgo, Avinza, Nucynta and Duragesic." In addition, Richard demanded to know "[h]ow are these differences communicated?" In response, staff reported to all the Sackler Defendants a list of purported advantages of OxyContin over competing products, including that OxyContin purportedly reduces pain faster, has less variability in blood levels, and works for more pain conditions than competing drugs. On information and belief, none of these claims were backed by valid or reliable data. In fact, these were all improper, unfair, and/or deceptive claims that Purdue had admitted were prohibited.

64. The Sackler Defendants were aware of the plan to tout these unsubstantiated benefits, and directed the family business to move forward with publicly disseminating these falsehoods.

65. There are many other examples where Purdue has pursued similar deceptive promotion pitches in response to direction from the Sackler Defendants, including the immense pressure to increase sales. For example, Purdue has long pushed the notion that OxyContin's 12-hour dosing regimen sets it apart from competitors. Purdue 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 (such as Vicodin and Percocet) was a key advantage to cornering more of the pain management marketplace.

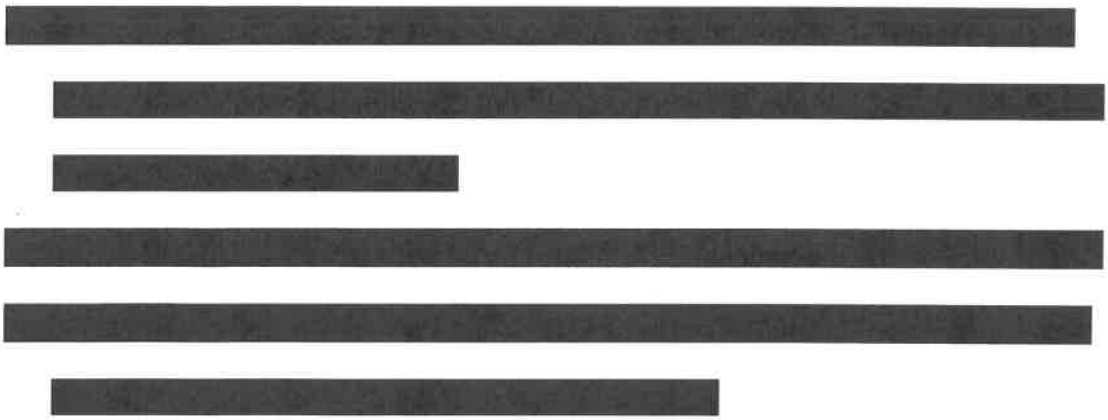
66. In some settings, Purdue acknowledged reality. Purdue informed its paid physician speakers that claims that a patient will benefit from an extended-release drug were not supported by clinical studies: "We do not have evidence of convenience, safety, less pills are

better, sleep through the night, etc." And Purdue informed its speakers that it was not aware of a single study comparing immediate-release drugs to any of its products.

67. In sales training materials, Purdue informed sales representatives that they could not make comparative claims against Purdue's competitors. Specifically, Purdue noted that sales representatives should stop claiming that there was "[s]moother release of active ingredient," "[f]ewer peaks and valleys," and "[m]ore advantageous blood levels or plasma concentration curves."

68. However, despite these acknowledgements, Purdue danced around these restrictions, training its sales representatives to urge healthcare providers to prescribe the extended-release OxyContin to patients in lieu of multiple doses of an immediate-release drug like Vicodin or Percocet in a 24-hour period because doing so would "provid[e] analgesia with fewer doses" and "be more convenient" for the patient.

69. 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:



70. As late as December 2015, Kathe and Mortimer demanded that Purdue staff break out, for each opioid sold by the company, productivity data by clinical indication with the corresponding specialty of the prescriber so as to best identify prescriber and patient populations that would be particularly susceptible to Purdue's tactics.

71. At the same time, Jonathan asked Purdue staff to brief him on how public health efforts to prevent opioid addiction, including the CDC guidelines, would affect OxyContin sales.

72. At no point did any of the Sackler Defendants instruct Purdue staff to stop spreading deceptive statements about Purdue's products or issue corrective instructions to sales staff about the true risks and limited benefits of prolonged opioid use.

5. The Sackler Defendants direct Purdue employees to target vulnerable patients, including the elderly and veterans.

73. Purdue staff also carried out the Sackler Defendants' direction in other ways, including making deceptive comparisons with competitive products, and touting OxyContin as being appropriate for treating chronic pain, particularly for vulnerable patients.

74. These deceptive statements often targeted vulnerable populations without disclosing the unique harms it knew were critical to safe and appropriate treatment. Upon information and belief, in carrying out the sales and marketing campaigns that were supervised and directed by the Sacklers, Purdue sales representatives made more than 69,000 sales 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.

75. 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. One prescriber from Asheville, North Carolina, who specialized in family medicine told a sales representative that he had prescribed doses as high as 80mg every 12 hours—2.5 times the CDC's upper threshold for safe and efficacious dosing of prescription opioids. The call notes from this visit indicate that the sales representative merely "[r]eminded him to increase 25-50%," and left some laxative samples. In contrast, an oncologist from Elkin, North Carolina, who likely has far more day-to-day experience treating severe pain, recognized, in a message to a Purdue sales representative, that "80mg q12h is a whopping dose!"

76. 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 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."

77. 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.

78. 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.

79. The publication also failed to disclose that interactions between opioids and anti-anxiety medications (taken by many veterans for PTSD), can be fatal.[3]

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[3] 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

80. Purdue sales representatives specifically targeted veterans in North Carolina and promoted them as good candidates for opioids to prescribers. Call notes from over 4,000 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.

81. In addition, between 2006 and 2015, Purdue sales representatives promoted OxyContin specifically for elderly patients in approximately 4,900 sales calls, even though the risks of long-term opioid use are significantly greater for the elderly. The 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.[4] The 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."[5] OxyContin's label even

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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.

[4] 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.

[5] 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.

recognizes that respiratory depression, as a side effect of OxyContin, "is a particular problem in elderly or debilitated patients."

82. Still, Purdue sales representatives encouraged prescribers to consider OxyContin for their elderly patients, frequently using an "example of elderly patient with compression fractures/osteo arthritis" or the "little old lady who is suffering from" arthritis as good candidates to start on OxyContin.

83. Purdue even instructed sales representatives to "have a specific business plan in place" for prescribers who provided long-term care for elderly patients (*i.e.*, in nursing homes), that "should be geared toward appropriately maximizing demand for Ryzolt, OxyContin Tablets, and Colace Capsules."

84. 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. When one prescriber asked if OxyContin would be appropriate for her elderly patients, the sales rep, without any mention of the risks associated with opioid use in older patients, responded, "yes with Med[icare Part] D coverage."

85. Another sales representative instructed a prescriber in Asheboro "to continue to write [prescriptions of OxyContin] for little old lady in pain"[6] and assured a primary care physician in Kernersville that Purdue's opioid products are "[w]ell studied in elderly" populations, typically covered by Medicare, and provide patients with a bridge while they wait for a specialist referral. Rather than outlining the risks for elderly patients, another sales

[6] This "little old lady" example is used at least 177 times in the call notes.

representative emphasized the "[s]afety and efficacy" of opioids for the "[g]eriatric population" when meeting with a prescriber.

86. 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.[7]

6. The Sackler Defendants direct Purdue employees to withhold critical information about the harms caused by opioids.

87. From the inception of the company, the Sackler Defendants directed Purdue to deceive healthcare professionals, patients, and the public at large about the risks, harms, and benefits of opioids. As set forth above, some of these deceptions resulted in the family business pleading guilty to federal criminal charges and admissions of fraudulent misrepresentations.

88. More recent examples where the Sackler Defendants directed employees to withhold other information about opioids, include the following:

- 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 mental health conditions including

[7] 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.

depression, anxiety, post-traumatic stress disorder, and substance abuse, increased psychological distress, and the need for increased care.[8]

- 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.[9] 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.[10]
- 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

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[8] 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/.

[9] 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.

[10] 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.

abstinence syndrome, and dangerous (sometimes fatal) interactions with alcohol or benzodiazepines.[11]

89. Purdue, acting under the direction of the Sackler Defendants, also concealed from healthcare providers the difficulty of withdrawing from opioids. Purdue and the Sackler Defendants knew that patients experiencing opioid-withdrawal would suffer intense physical and psychological pain, including anxiety, nausea, headaches, and delirium. Purdue and the Sackler Defendants also knew that patients experiencing withdrawal symptoms might be unwilling or unable to give up opioids which, in turn, heightens the risk of addiction.[12] But Purdue and the Sackler Defendants did not disclose these risks to the healthcare providers or the patients to whom Purdue was hawking opioids. Instead, they continued to promote long-term opioid use as a safe and effective method of pain management.

90. 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.

91. These third-party publications, which were funded by Purdue, described the "most common" side effects of opioids as constipation, nausea, vomiting, sleepiness, mental cloudiness,

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[11] Food and Drug Administration, *FDA Announces Safety Labeling Changes and Postmarket Study Requirements for Extended-Release and Long-Acting Opioid Analgesics* (Sep. 10, 2013), available at https://www.fda.gov/Drugs/DrugSafety/InformationbyDrugClass/ucm363722.htm.

[12] 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/.

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.

92. When the tide of public knowledge about the harms opioids cause appeared to be turning against the Sackler Defendants and Purdue, the Sackler Defendants retaliated by pumping more disinformation to the public. In November 2015, Purdue staff gave the Sackler Defendants a presentation on the [redacted]

7. The Sackler Defendants direct Purdue to focus on selling higher-dose—and more dangerous—opioids because they were more profitable.

93. The Sackler Defendants encouraged staff and sales employees to deceptively push the sale of its more dangerous, higher-dose opioids, to the detriment of patients. Purdue and the Sackler Defendants stood to make more profits from the sale of these drugs.

94. In May 2013, the Sackler Defendants had an in-depth meeting with Purdue's vice president of sales to discuss various strategies to sell and promote the higher-dose opioids. These strategies included having sales representatives promote these drugs to prescribers, instituting a rebate card to help patients cover their costs of these drugs, and promoting the drugs using an

"Individualize the Dose" marketing campaign. The intent and purpose of that marketing campaign was, in fact, to *increase* the dose of particular patients—and the Sackler Defendants knew this.

95. Likewise, the Sackler Defendants directed Purdue to use rebate cards to promote the use of Purdue's opioids. These rebate cards would help attract new patients with an offer for an introductory discount on the prescription price of high-dose opioids. Because these opioids are so highly addictive, patients who filled initial prescriptions at the discounted price had a high chance of suffering withdrawal symptoms if they stopped taking the high-dose opioids. The Sackler Defendants knew this and it was part of their strategy to hook new patients. By June 2008, the Sackler Defendants had authorized a savings card program that would give patients a discount for their first five prescriptions. These five initial prescriptions were understood by the Sackler Defendants to be sufficient to ensure that there would be a significant chance of withdrawal if a patient were to discontinue taking opioids after having filled the first five prescriptions. Over a quarter of the patients who used these cards filled all five prescriptions.

96. The Sackler Defendants were also intently focused on increasing Purdue's share of the market for higher-dose opioids, regardless of whether increased availability and use of these higher-dose opioids was harming the public. For instance, in June 2011, Jonathan proposed that Purdue study changes in the market share of opioids, focusing on dose strength. The Sackler Defendants remained focused on Purdue's market share of the higher-dose opioids. More than two years later, in October 2013, Mortimer requested additional information about market share, including a "breakdown on OxyContin market share by strength."

97. In April 2016, the Sacklers considered exactly how much money was riding on their strategy of pushing higher doses of opioids. In March of that year, the CDC had announced

guidelines to try to show the epidemic of opioid overdose and death. The CDC urged prescribers to avoid doses higher than 30mg of Purdue's OxyContin twice per day. The CDC discouraged twice-a-day prescriptions of all three of Purdue's most profitable strengths: 40mg, 60mg, and 80mg. Staff studied how much money Purdue was making from its high dose strategy and told the Sacklers that [redacted] in revenue was at risk in North Carolina each year.

8. The Sackler Defendants direct Purdue employees to influence and direct the work of Purdue's paid promotional partners.

98. Another tool the Sackler Defendants directed and controlled Purdue in using to spread deceptive information was to recruit and pay organizations that would promote Purdue's 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 promoted doctors who had served as paid speakers for it, and had touted Purdue and its opioid products. These doctors were viewed as "Key Opinion Leaders," who could influence other doctors to prescribe more opioids. 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.

99. The Sackler Defendants were intimately involved in the coordination between Purdue and these Key Opinion Leaders. The Sackler Defendants, in their quest to increase sales and boost opioid prescription and use, encouraged coordination between Purdue and Key Opinion Leaders to ensure a synergistic messaging campaign that would induce healthcare professionals to prescribe opioids.

100. The Sackler Defendants were hungry for details about the strategy and tactics that the Purdue sales staff used to influence the Key Opinion Leaders: "Provide the Board with more

information on the strategy/tactics with respect to KOLs, how they are identified, how do we plan to interact with them, how do we see them helping build appropriate utilization of Butrans - and any other relevant information that will/could influence the prescribing of the product."

101. Purdue staff followed the Sackler Defendants' direction. 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.

102. 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."

103. "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.

104. 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."

105. 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, 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."

106. 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."[13]

107. 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."

108. 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.[14]

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[13] 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.

109. Despite the Sackler Defendants' efforts to pump into the public discourse deceptive information about the appropriate uses of opioids, by 2013, the medical community and public health advocates had begun sounding the alarm about the dangers of opioids. Instead of instructing Purdue's promotional partners to correct the literature and information they were providing to the healthcare professionals and the public, Richard complained that there was too much public information about the dangers of opioids. After he had set up a Google alert to send him news about OxyContin, he objected to a Vice President at the company: "Why are all the alerts about negatives and not one about the positives of OxyContin tablets?"

B. The Sackler Defendants Knew That Their Conduct Created Enormous Risks That Would be Borne By the Public.

110. The Sackler Defendants were well aware that their conduct created extraordinary risks for public health.

1. The Sackler Defendants knew that their opioid product caused a public health crisis.

111. As early as 2001, the Sackler Defendants knew that their opioid product was resulting in a health crisis. In February of that year, a federal prosecutor reported that 59 people in a single state had died from overdosing on OxyContin. When the Sackler Defendants learned of this, Richard wrote to Purdue executives that "[t]his is not too bad. It could have been far worse."

112. The Sackler Defendants were also well aware that Purdue's opioid product was being diverted and widely abused, including in North Carolina. In fact, by at least 2006, the Sackler Defendants were receiving daily news-summary emails. These summary emails

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[14] 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.

contained daily news stories on "diversion and abuse"—including many emails containing articles that included North Carolina sources.

113. In October 2008, the Sackler Defendants were informed that data monitored by Purdue indicated a "wide geographic dispersion of abuse and diversion cases involving OxyContin throughout the United States." Staff informed the Sacklers that "availability of the product" and "prescribing practices" were among the factors driving increasing abuse and diversion of OxyContin.

114. On the same day that information about widespread abuse and diversion of OxyContin was delivered to the Sackler Defendants, the Sackler Defendants were also given information about Purdue's new "Toppers Club sales contest" for sales representatives to earn bonuses. The bonuses would be based in part on the representative's "ability to grow Oxycodone scripts, Brand and generics." This is just one striking example of the Sackler Defendants supervising Purdue's providing financial rewards to its sales force for making money for them by encouraging the same kinds of prescribing practices by healthcare providers that were increasing the risk of diversion and abuse across the country, including in North Carolina.

115. On that same day in October 2008, Purdue staff also told the Sackler Defendants that Purdue's compliance hotline had received 163 tips during the third quarter of 2008—but that Purdue had not reported any of them to the authorities. This failure to report tips made to the compliance hotline to appropriate authorities would become a trend—and one that the Sacklers knew about. For instance:

- In July 2008, staff told the Sackler Defendants that Purdue's compliance hotline had received 93 tips in the second quarter of 2008, and that Purdue had not reported any to the authorities.

- In April 2009, staff told the Sackler Defendants that Purdue's compliance hotline had received 122 tips in the first quarter of 2009, and that Purdue had only reported one to the authorities.
- In May 2011, staff told the Sackler Defendants that Purdue's compliance hotline had received 88 calls in the first quarter of 2011, and that Purdue had not reported any of them to the authorities.

116. Purdue's failure to alert authorities of calls made to its compliance hotline is at odds with the 2007 Consent Judgment, which obligated Purdue to provide notice of "potential abuse or diversion to appropriate medical, regulatory or law enforcement authorities."

117. As recently as 2014, the Sackler Defendants were provided even more comprehensive information about how their products were causing widespread harm. That year, Richard, Kathe, and staff presented the rest of the Sackler Defendants a report on the "market" of people addicted to opioids. The findings showed that the number of people addicted had doubled from 2009 to 2014. In fact, opioid addiction had grown at a compound annual growth rate of 20% between 2000 and 2010.

118. That same year, as press coverage and scrutiny around the opioid epidemic grew, Jonathan became concerned that the coverage might implicate the Sackler Defendants. He reviewed the recent press coverage and asked Purdue staff to assure him that journalists covering the opioid epidemic were not focused on the Sackler Defendants.

119. In response to the chorus of alarm growing ever louder about the opioid epidemic, the Sackler Defendants made no moves to direct the company to stop deceptively representing that opioids were safe and minimizing the risk of addiction. Rather, they retaliated. In October 2017, Cigna removed OxyContin from their list of covered medications. Upon learning of

Cigna's decision, Richard asked Purdue's CEO if the company was considering dropping Cigna as an insurance provider for Purdue's health plan. The intended implication of Richard's question was that Purdue should in fact drop Cigna.

2. The Sackler Defendants direct Purdue to provide false comfort about the risks of addiction.

120. The Sackler Defendants repeatedly directed Purdue to minimize the risk of addiction from opioids by pursuing a theory that responsible use of opioids could not lead to addiction—a theory for which the Sackler Defendants had no evidence.

121. In particular, Richard insisted for years that people who become addicted to opioids are criminals who lack personal responsibility. In 2001, Richard wrote that it was important to "hammer on the abusers in every way possible. They are the culprits and the problem. They are reckless criminals."

122. The insistence that addiction to opioids was caused by criminal behavior—rather than the Sackler Defendants' and Purdue's own irresponsible and deceptive misstatements about the risks of opioid abuse—pervaded Richard's interactions with both Purdue staff and the public at large. Richard complained to a friend about articles that painted OxyContin in a negative light: "This vilification is shit." Richard went on to claim that people addicted to opioids are "criminals, and they engage in it with full, criminal intent. Why should they be entitled to our sympathies?" When the friend suggested that a host of factors, including genetics, might lead to addiction, Richard responded: [redacted]

123. In an attempt to distinguish responsible "patients" from "abusers," the Sackler Defendants even went so far as exploring the possibility of using PET scans to demonstrate supposed differences between "pain patients and drug abusers in their reaction to opioids."

124. Purdue implemented the Sackler Defendants' false messaging about people addicted to opioids by making unsupported distinctions between "patients," who were purportedly not addicted and should be prescribed opioids, and "abusers," who were purportedly addicted and should not be prescribed opioids. It was Purdue and the Sackler Defendants' goal to ensure that the largest number of patients—even those who exhibited signs of addiction—were thought to be appropriate candidates for continued opioid prescriptions. At the same time, Purdue and the Sackler Defendants aimed to ensure that only the few patients who exhibited signs of intravenous drug use dependence and similar symptoms were deemed inappropriate candidates for opioid prescription.

125. To further this goal, Purdue mischaracterized 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.

126. 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.

127. Purdue used messages like 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.

128. 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.

129. In 2011, for example, Purdue created and funded a presentation entitled "Managing Patient's Opioid Use: Balancing the Need and the Risk," which 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 the tools in the future.

130. 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."[15]

131. The Sackler Defendants knew that the theory of addiction they directed Purdue to push was based on falsehoods. As just one example, during a Board meeting in 2014, Kathe, Richard, and Purdue staff made a presentation to the remaining Sackler Defendants informing them—once more—that "[p]ain treatment and addiction are naturally linked." As a result,

[15] 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.

addiction "can happen to anyone—from a 50 year old woman with chronic lower back pain to an 18 year old boy with a sports injury, from the very wealthy to the very poor."

C. After Helping Cause an Addiction Crisis, the Sackler Defendants Seek Further Profit from the Addiction-Treatment Market.

132. Not content with simply dominating the brand-name market for opioid products by disseminating false statements and inducing the company to commit deceptive acts, the Sackler Defendants sought to also *expand* their footprint by entering the markets for generic opioid products and opioid treatments. In other words, they sought to profit further off of the very problem they created by providing treatment drugs for the persons who had become addicted to OxyContin, the addictive drug that the Sackler Family Defendants and Purdue had deceptively marketed as safe and with low risk of addiction.

133. In June 2011, Mortimer inquired about Purdue launching a generic version of OxyContin so as to move into that market and "capture more cost sensitive patients." By doing so, the Sackler Defendants hoped to introduce yet another revenue stream and increase their personal fortunes even more.

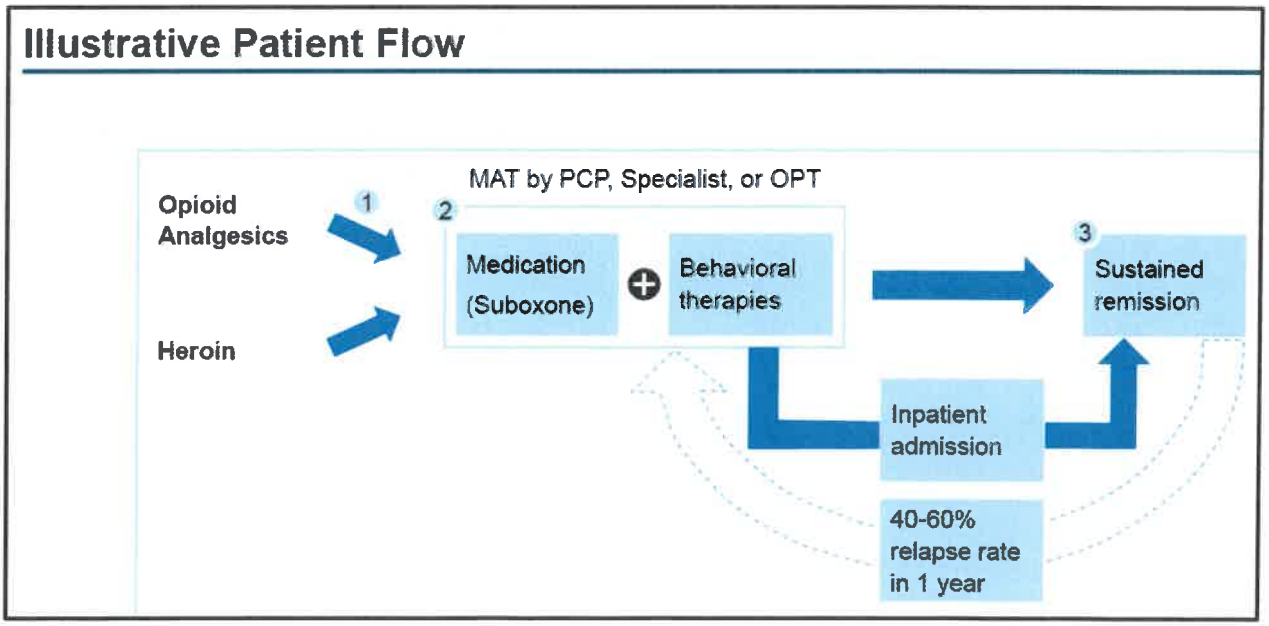
134. As early as 2007, Richard took steps to apply for a patent for a method to treat opioid addiction. In the application, he recognized that opioids are addictive, but referred to addicts as "junkies," failing to take into account the serious risks of addiction that attach to opioid use. Richard was eventually awarded the patent in 2018.

135. Richard was not alone in recognizing the monster the Sackler Defendants had created in opioid addiction. Instead of modifying Purdue's business practices, however, Richard and Kathe sought to profit off of the problem the family had created. Richard and Kathe worked with Purdue staff to create a presentation in which they characterized addiction treatment as "an attractive market," where there was a "large unmet need" to treat victims of addiction. The

presentation further declared that: "[a]ddiction treatment is a good fit and next natural step for Purdue."

136. The family embarked on a plan to corner the opioid-treatment market and named it Project Tango.

137. By February 2015, the leaders of Project Tango, Kathe and Richard, were ready to present to the rest of the Sackler Defendants their plan under Project Tango. At a business development committee meeting, the Sackler Defendants were presented with a plan for a joint-venture controlled by the Sackler Defendants to sell suboxone, an opioid-treatment pharmaceutical. Suboxone was expected to give the Sackler Defendants the "market lead[] in the addiction medicine space." The presentation also mapped out for the Sackler Defendants the full addiction ecosystem: patients would first get addicted to OxyContin and then become consumers of Purdue's treatment drug. The presentation noted the opportunity Suboxone had to capture customers for life, as 40-60% of Suboxone users were predicted to relapse and need the medication again.



Source: Purdue Presentation Explaining "Project Tango" Patient Flow

138. The Sackler Defendants' plan for Purdue to become a vertically integrated company in the opioid-addiction market was not without its detractors. In December 2015, Jonathan asked for follow-up briefing from staff about how public health efforts to prevent opioid addiction would affect the sales for OxyContin. Presumably, Purdue's own entry into the opioid-addiction market would also affect OxyContin sales.

139. In the end, however, Jonathan's concerns were assuaged. By June 2016, the Sackler Defendants met to consider a revised version of Project Tango in which the company would also sell the opioid-addiction pharmaceutical NARCAN. NARCAN was estimated to provide a growing source of revenue and triple in sales volume from 2016 to 2018.

140. In December 2016, Jonathan, Mortimer, and Richard held a call with Purdue staff to discuss another version of the Project Tango plan that would call for the Sackler Defendants and Purdue to acquire a company that treated addiction with implantable drug pumps. Jonathan and Mortimer commented that this acquisition would be a "strategic fit" because it treated the "strategically adjacent indication of opioid dependence."

141. At no point did the Sackler Defendants consider abandoning their business and marketing practices related to Purdue's sales of OxyContin and other opioids, however. While millions of people died because of opioid-dependence-related causes—including thousands in North Carolina—the Sackler Defendants continued to profit mightily. Upon information and belief, by 2018, the Sackler Defendants had extracted almost $11 billion in profits from Purdue. A substantial portion of that profit was derived from sales into North Carolina, including sales that were generated by deceptive marketing tactics described in this Complaint.

D. The Sackler Defendants Were Involved in the Day-to-Day Operations of Their Facilities in North Carolina.

142. The Sackler Defendants were involved in numerous aspects of the family business, including the day-to-day operations of Purdue's manufacturing facilities in the Treyburn Corporate Park in Durham and in Wilson. Those facilities were the only sites that handled the manufacturing of Purdue's solid oral-dose medications, including OxyContin.[16] The Wilson facility was opened in 2000 and employed roughly 200 people. The Treyburn facility opened in 2017 in order to support the Wilson plant and employed fewer than 80 people until it was sold earlier this year.

143. At various times over the relevant time period, the Sackler Defendants were informed about [redacted]. In addition, in April 2011, Richard Sackler learned that a Purdue executive [redacted].

144. In July 2012, soon after David Sackler joined the Board of Purdue, he asked a Purdue senior executive for ways in which he could [redacted] The executive suggested that [redacted].

145. The Sackler Defendants selected Treyburn as the location for another North Carolina facility in September 2013 after considering other options in the state. When that facility [redacted].

146. In November 2013, staff informed the Sackler Defendants that the Wilson plant [redacted]

[16] https://www.stamfordadvocate.com/business/article/OxyContin-maker-Purdue-Pharma-to-close-North-14281934.php.

[redacted].

147. In addition to having first-hand knowledge of and participating in the operations of Purdue's facilities in North Carolina, the Sackler Defendants were also, as noted above, knowledgeable about Purdue's efforts to get its opioid products on the formulary for North Carolina Medicaid. A November 2015 executive committee presentation detailed these efforts as part of a [redacted].

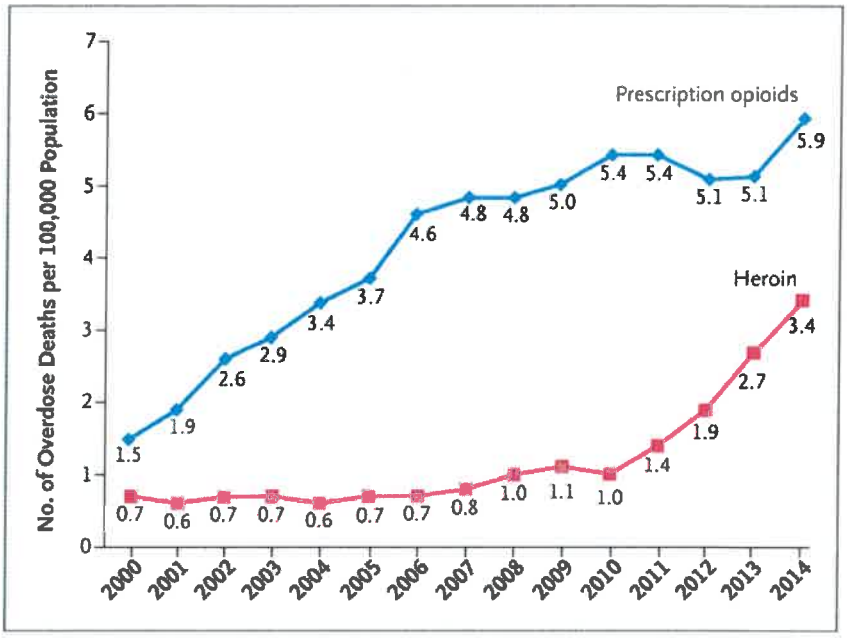
E. The Opioid Crisis in North Carolina.

148. The Sackler Defendants' deceptive acts have come at an enormous cost to North Carolina.

149. Through a years-long campaign of deceptive statements, the Sackler Defendants 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.

150. This rising flood of new prescriptions, fueled in large part by the Sackler Defendants' campaign of unfair and/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.[17]



Source: 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.

151. 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.

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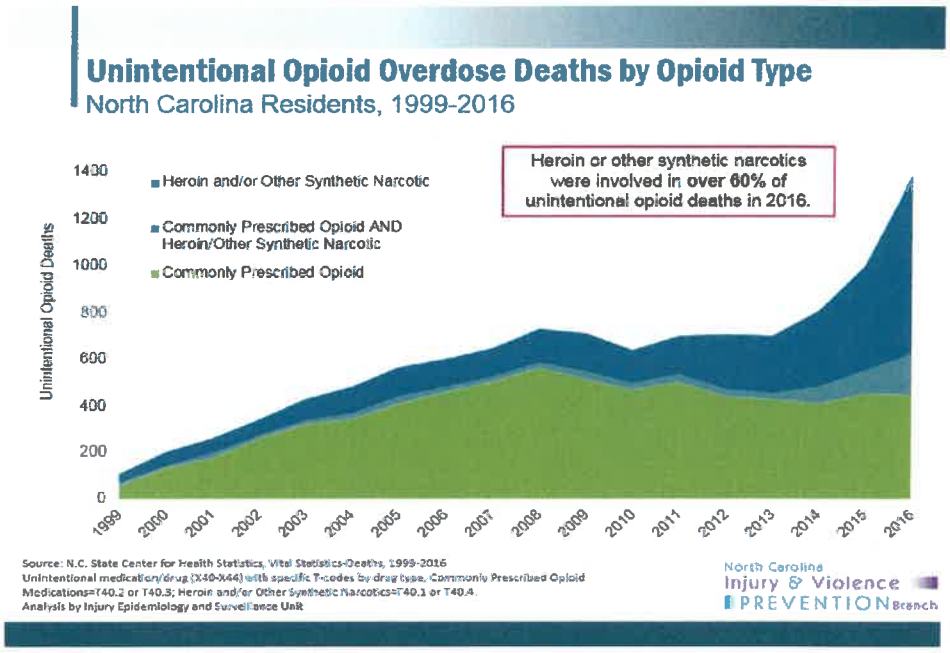
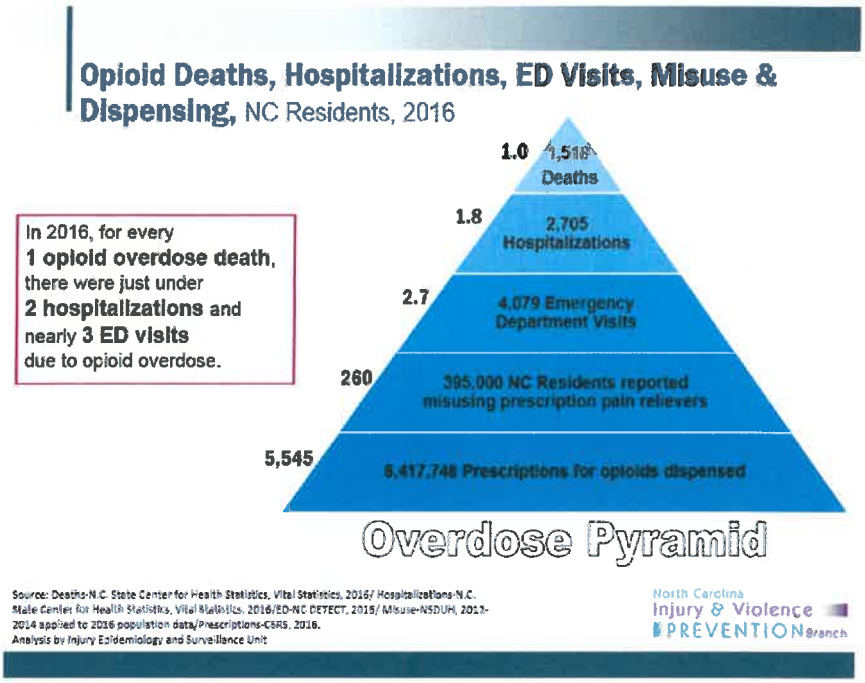
[17] Wilson Compton et al., *Relationship Between Nonmedical Prescription-Opioid Use and Heroin Use*, New England Journal of Medicine 374:154-163 (Jan. 14, 2016), available at https://www.nejm.org/doi/full/10.1056/NEJMra1508490; Theodore Cicero et al., *Increased Use of Heroin as an Initiating Opioid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

152. 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.



153. 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.

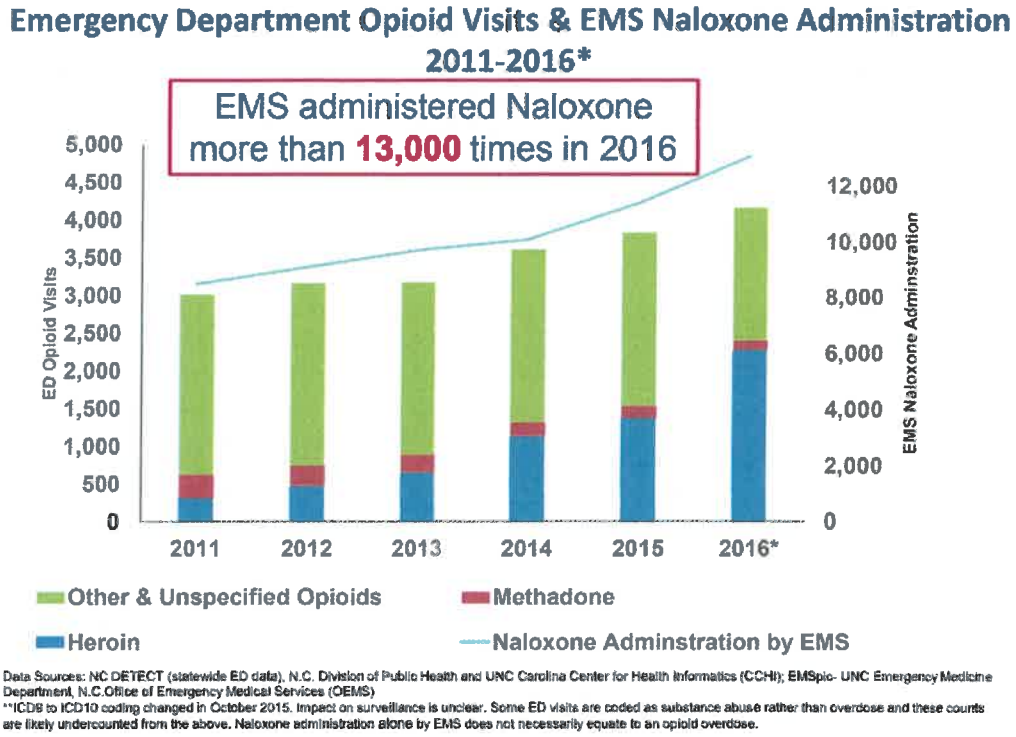


154. In 2017, the number of confirmed opioid-related poisonings increased from one month to the next during every month of the year. From 2006 to 2016, poisoning deaths involving opioids increased almost every year, and more than doubled overall, from 782 in 2006 to 1,584 in 2016. Notably, during this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

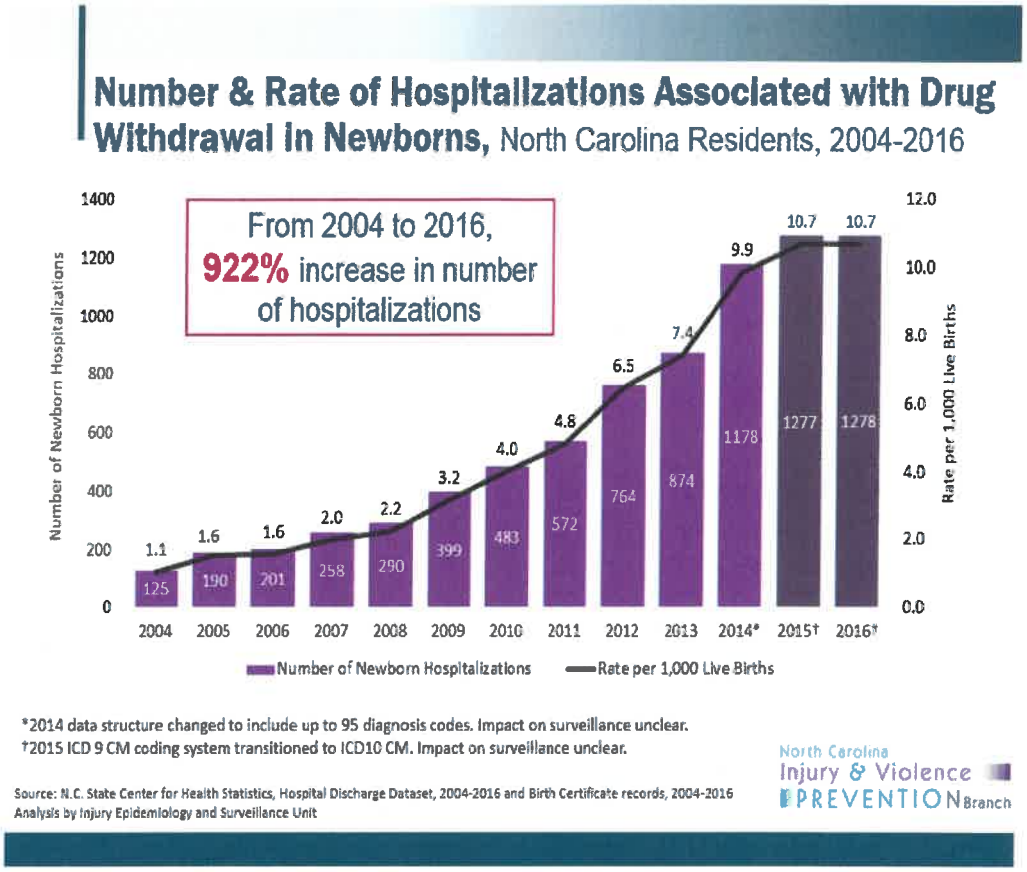
155. From 2010 to 2016, heroin and fentanyl poisoning deaths skyrocketed. For heroin, there were 47 deaths in 2010, compared to 573 in 2016. For fentanyl, the numbers for those same years went from 118 to 543. Controlling for North Carolina's population growth, that is an increase from 1 heroin death 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.

156. 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.



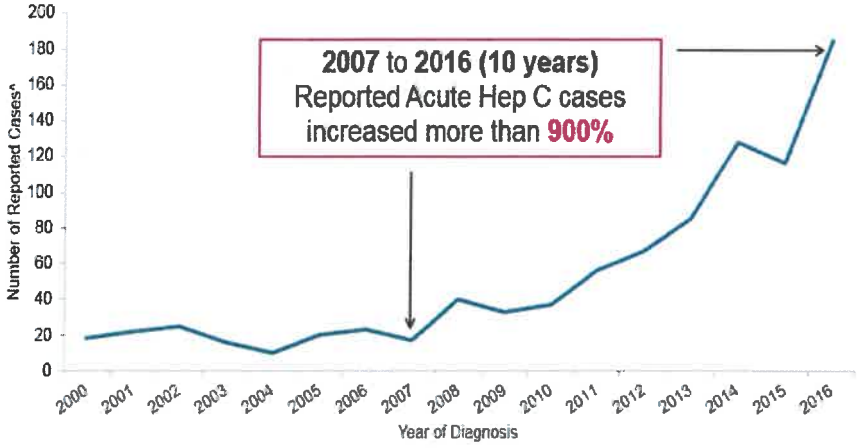
157. North Carolina has also seen a steep increase in the incidence of drug withdrawal in newborns, which frequently results from maternal use of opioids during pregnancy. In 2004, 1 out of every 909 infants in North Carolina was born drug-dependent. By 2016, the frequency had increased to 1 out of every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



158. 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



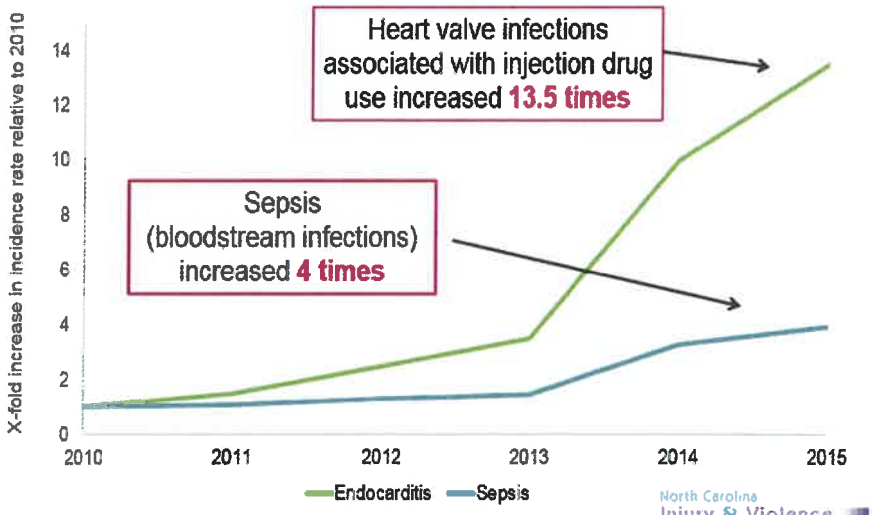
Note: Case definition for acute Hepatitis C changed in 2016.

^ 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

159. 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.

160. Meanwhile, the Sackler Defendants have enjoyed enormous profits from the company's opioid sales in North Carolina.

FIRST CAUSE OF ACTION

(Violations of the North Carolina Unfair or Deceptive Practices Act, N.C.G.S. § 75-1.1)

161. The allegations contained in paragraphs 1-160 are incorporated by reference as if they were set out at length herein.

162. The Sackler Defendants, in the course of directing Purdue, promoted and marketed opioid-containing prescription drugs, directed and made numerous statements and omissions in commerce in North Carolina about the risks and benefits of opioid products, which have the capacity, tendency, or effect of deceiving or misleading consumers. Pursuant to North Carolina's Unfair or Deceptive Practices Act, such statements and omissions constitute unfair and/or deceptive practices that are prohibited by N.C.G.S. § 75-1.1. The Sackler Defendants' unfair and/or deceptive statements, omissions, acts, and practices include, but are not limited to, the statements and omissions detailed above in this Complaint, including but not limited to the following, all undertaken to promote the sale of Purdue's products, and resulting profit for themselves:

a. Directing and encouraging employees to make false and misleading representations about the benefits, safety, dangers, addictive qualities, and other characteristics of OxyContin and other opioids;

b. Unfairly targeting for sales prescribers who were known to be likely diverters or abusers of opioids, and attempting to sell them even more;

c. Directing and encouraging employees to make false and misleading claims about Purdue's opioid products, including comparisons regarding opioids or pain products manufactured and/or promoted by other companies;

d. Unfairly targeting vulnerable populations such as elder consumers and veterans;

e. Directing and encouraging employees to withhold critical information from the public about the harms caused by opioids;

f. Directing and encouraging employees to unfairly and deceptively promote more dangerous, higher-dose—and more profitable—opioids; and

g. Directing employees to influence and direct the work of Purdue's paid promotional partners with knowledge that they would disseminate false information about opioids and increase Purdue's sales.

163. The Sackler Defendants' unfair and/or deceptive statements, omissions, acts, and practices harmed North Carolina consumers, including by proximately causing actual injury from opioid misuse, including prescription opioids and heroin, to North Carolina consumers.

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 the Sackler Defendants, their 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 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:

a. Promoting, marketing, or directing the promotion or marketing of any opioid products in the state of North Carolina;

b. Making, or encouraging or directing any other entity to make, false or deceptive statements or representations, about opioid products in the state of North Carolina;

2. Equitable relief to cure the Sackler Defendants' deceptive practices;

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

4. Disgorgement of profits that the Sackler Defendants have gained from their 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

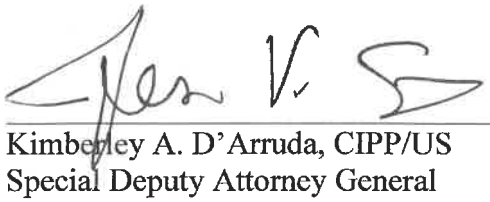
6. Any and all further legal and equitable relief as the Court deems the State is entitled to receive or which is in the public interest.

This the 17th day of September, 2019.

JOSHUA H. STEIN
Attorney General

W. Swain Wood
General Counsel

Kevin Anderson
Senior Deputy Attorney General
Chief, Consumer Protection Division



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