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SUPERIOR COURT OF NEW JERSEY
CHANCERY DIVISION, ESSEX COUNTY
DOCKET NO. ESX-C- 115-19

GURBIR S. GREWAL, Attorney General of the
State of New Jersey, and PAUL R. RODRÍGUEZ,
Acting Director of the New Jersey Division of
Consumer Affairs,

Plaintiffs,

v.

RICHARD S. SACKLER, JONATHAN D.
SACKLER, ILENE SACKLER LEFCOURT,
KATHE SACKLER, BEVERLY SACKLER,
MORTIMER D.A. SACKLER, THERESA
SACKLER, and DAVID A. SACKLER,

Defendants.

Civil Action

**COMPLAINT FOR VIOLATION
OF THE NEW JERSEY
CONSUMER FRAUD ACT,
N.J.S.A. 56:8-1, ET SEQ., AS WELL
AS OTHER CLAIMS**

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Plaintiffs Gurbir S. Grewal, Attorney General of the State of New Jersey (the “Attorney General”), and Paul R. Rodríguez, Acting Director of the New Jersey Division of Consumer Affairs (the “Director,” and together with the Attorney General, “Plaintiffs”), with offices located at 124 Halsey Street, Newark, New Jersey, by way of Complaint state:

I. PRELIMINARY STATEMENT

1. The State of New Jersey (“New Jersey” or “State”) is in the grips of a long-building, now catastrophic public health crisis regarding the use of prescription opioid pain medications. Rampant opioid addiction, and the overdoses that are its consequence, are devastating New Jersey families and communities and straining the State’s resources. At the root of this epidemic is the widespread overprescribing of opioids long-term to treat chronic pain conditions. Prescribing opioids for chronic pain is dangerous and, in many cases, improper, but it became mainstream medical practice due to the fraudulent marketing efforts of pharmaceutical companies seeking an expanded market for their drugs. Chief among these is Purdue Pharma L.P. (“Purdue”),¹ a privately held company that mounted a hugely successful campaign based on downplaying the addictive potential of opioids and overstating their efficacy at treating chronic pain. Purdue executed this scheme at the direction of the family that owns the company and, through 2018, controlled the company’s Board of Directors.

2. Purdue manufactures, markets, and sells prescription opioid medications, including the brand-name drugs OxyContin, Butrans, and Hysingla ER. Although other brand-name opioids are available—along with widely prescribed generics like oxycodone and hydrocodone—Purdue

¹ Technically, Purdue is a group of three related companies: Purdue Pharma L.P., Purdue Pharma Inc., and The Purdue Frederick Company.

for 20 years has been the leading force in the prescription opioid market, both nationwide and in New Jersey.

3. Eight people in a single family made many of the choices that caused much of the opioid epidemic: Richard Sackler, Jonathan D. Sackler, Ilene Sackler Lefcourt, Kathe Sackler, Beverly Sackler, Mortimer D.A. Sackler, Theresa Sackler, and David Sackler (collectively, “the Sacklers”). The Sacklers’ ambition was to become unimaginably rich from the sale of opioids. To that end, they masterminded a strategy, carried out by Purdue, that changed the way the medical profession viewed opioid prescribing. Purdue exploited newly emerging concerns in the profession that pain was an undertreated priority. Purdue helped to institutionalize this patient-centric shift, and then capitalized on the platform it had created to push its message that health care providers should prescribe more opioids to treat this undertreated chronic pain. Purdue designed an array of deceptive messages that reduced concerns about opioids generally, and that promoted Purdue’s opioids specifically as safe, effective, and appropriate for long-term use and for moderate pain conditions. Purdue’s massive marketing scheme, which occurred alongside similar efforts of other industry players, was profoundly successful at shifting the medical and public consensus regarding the use of opioids.

4. Defendants controlled Purdue’s misconduct. Each of them took a seat on the Board of Directors of Purdue Pharma Inc. Together, they always held the controlling majority of the Board, which gave them full power over the Purdue entities, including Purdue Pharma L.P. They directed deceptive sales and marketing practices deep within Purdue.

5. The Sacklers well understood the addictive and dangerous qualities of the drugs they manufactured, but the risks presented by their drugs to individual consumers or public health did not constrain their marketing and promotional plans. The Sacklers set sales objectives and

shaped the marketing campaigns that Purdue carried out to meet them. The Sacklers directed and approved the hiring of hundreds of workers to carry out their wishes and blanketed the country with disinformation about opioids. The Sacklers directed Purdue employees to get more patients on opioids, at higher doses, for longer periods of time, and the company did exactly these things. And over the years, the Sacklers distributed billions of dollars earned from the sale of Purdue opioids to themselves and other family members.

6. The Sacklers' callousness is apparent on the face of internal planning documents. As reports of overdoses and deaths flowed into the company, the Sacklers sought to protect their profits by blaming addicts and doubling down on Purdue's aggressive marketing tactics. Once the opioid epidemic had undeniably materialized and opioid prescribing began to decline, the Sacklers planned to replace lost revenue by moving into new product ventures: drugs to treat opioid overdose and opioid addiction. This expansion was characterized as the logical coverage of a "spectrum" in which Purdue could be the "end-to-end pain provider."

7. The Sacklers were, in the words of one long-time company executive, the "de facto CEO" of Purdue. As set forth below, Defendants are personally liable for Purdue's misconduct in New Jersey because (a) they personally directed, approved, or participated in certain of the misconduct and (b) they knew about and sanctioned other misconduct, including by failing to stop it. Defendants made the decisions to break the law; they controlled the unfair and deceptive conduct; and they personally collected hundreds of millions of dollars from the deception.

8. The State, through its Attorney General and the Director, brings this suit to hold the Sacklers accountable for their key role in the opioid epidemic and demand their contribution to the expensive solutions, including addiction treatment and prescriber education, that are necessary to abate the crisis.

II. SUMMARY OF ALLEGATIONS

9. Prescription opioids are narcotics. They are derived from and possess properties similar to opium and heroin, which is why they are regulated as controlled substances. Opioids can create a euphoric high, which makes them addictive and, at higher doses, they cause respiratory depression that can be fatal. Patients who use opioids continuously grow tolerant to the drugs' analgesic effects, requiring progressively higher doses to obtain the same levels of pain relief, and increasing the risks of withdrawal, addiction, and overdose.

10. Historically, these risks were well-recognized. Before the 1990s, opioids typically were used only to treat short-term acute pain (e.g., trauma and post-surgical pain) or for palliative (end-of-life) care because they were considered too addictive and debilitating for long-term use. This prevailing medical and popular understanding operated as a constraint on the market for prescription opioids.

11. As described in Section V.A, beginning in the late 1990s, Purdue aggressively set out to change the perception of opioids to permit and encourage the use of these drugs not just for acute and palliative care, but also long-term, for chronic conditions like back pain, migraines, and arthritis. Purdue developed and then exploited the contentions that pain was undertreated and pain treatment should be a higher priority of health care providers, which paved the way for increased prescribing of opioids for chronic pain. (As used in this Complaint, "chronic pain" means non-cancer pain lasting three months or longer.) Purdue then piggybacked on these initiatives to promote opioids generally, and its opioids in particular, as safe, effective, and appropriate for even long-term use to treat routine pain conditions without disclosing the significant risks of doing so.

12. Purdue spent hundreds of millions of dollars on an array of promotional activities and materials that falsely denied or minimized the risk of addiction and overstated the benefits of opioids. These activities included (a) directly marketing Purdue opioids to prescribers;

(b) generating a biased and methodologically defective body of scientific research supporting opioid use; and (c) indirectly marketing opioids to doctors and consumers through unbranded websites as well as Purdue-funded pain advocacy groups, professional societies, and individual physicians whose talks and publications gave the appearance of being independent and therefore credible but were, due to Purdue's influence, flawed and misleading.

13. Purdue's massive marketing scheme proved to be resoundingly successful at shifting the medical consensus regarding the use of opioids. By 2006, opioids were widely prescribed for chronic pain conditions.

14. In the mid-2000s, federal and state law enforcement began investigating Purdue for deceptively marketing and misbranding OxyContin. During the time period covered by the investigation, at least three Sackler board members were among the highest executives inside the company: Richard Sackler was Chief Executive Officer, and Jonathan and Kathe Sackler were Vice Presidents. As explained below, they and their family members were intimately involved in the launch of OxyContin and the marketing campaigns that led to the explosion of over-prescribing.

15. As set forth in Section V.B, the investigations culminated in a series of settlements in 2007 under which Purdue and three of its now-former executives (but none of the Sackler family members) pleaded guilty to federal criminal charges for certain deceptive conduct in the sale and marketing of opioids. Purdue paid more than \$650 million in fines, forfeitures, and settlement of civil claims. The Sacklers decided which executives would offer guilty pleas, approved the settlement agreements, and then drew back from their roles as employees of the company to serve exclusively on the Board of Directors. As described below, in the years that followed the Sacklers approved several large payments—in the millions of dollars—to the executives who pled guilty.

At the same time, the Sacklers continued to manage the company's core business activities—marketing, sales, and product development.

16. As set forth in Section V.C, from 2007 into 2018, the Sacklers charted a new—but equally crooked—course for Purdue. The Sacklers directed and approved the hiring of a large sales force. They were deeply involved in guiding the strategy behind the marketing plans that directed these representatives into New Jersey on a frequent basis. The Sacklers met regularly as members of the Board of Directors and received detailed briefings from the staff not just on the company's finances, but on the size, distribution, daily activities, tactics, and compensation of the sales force. The Sacklers approved routine increases in the number of sales representatives and increases to their compensation, all while receiving detailed briefings on the contents of representatives' sales pitches and delivering unequivocal orders to meet the family's strategic imperatives: visit prescribers more frequently, and convince them to write more opioid prescriptions, over longer periods of therapy, at increasingly high doses.

17. In pursuit of the objectives set by the Sacklers, Purdue's sales representatives called on New Jersey prescribers more than [REDACTED] times between mid-2007 and mid-2017. They consistently misrepresented and otherwise minimized the risk of addiction to OxyContin and Purdue's other opioids, including by claiming that signs of addiction merely reflect undertreated pain and overstating doctors' ability to avoid drug abuse through screening tools and abuse-deterrent formulations. They also falsely claimed that OxyContin was effective for 12 hours, a marketing tactic that left users with end-of-dose cravings that fueled higher doses and addiction.

18. Purdue's sales representatives in New Jersey carried out several additional unconscionable schemes devised by the Sacklers to fortify the family's revenue stream. First, they set out to capture new initiates: the elderly and the "opioid naïve" (those who have not previously

used these powerful drugs). Second, they promoted the routine and speedy escalation of doses—under the guise of “individualized dosing”—to increase sales of Purdue’s more expensive products. And third, they encouraged long-term use—i.e., a steady stream of returning customers. They did so by [REDACTED] [REDACTED] despite the evidence— [REDACTED] [REDACTED]—that serial prescriptions were more likely to induce dependence and addiction.

19. The Sacklers are now poised to profit from the public health crisis that they created. Richard Sackler was awarded a patent in January 2018 for a new formulation of buprenorphine—one of the most effective drugs used to treat opioid addiction. In his patent application, Dr. Richard Sackler described the background of his new invention:

Over the last decades, prejudices in the medical community as to the use of strong opioids for treating chronic pain in patients has significantly decreased. Many of these prejudices were due to some of the characteristics being inherent to opioids. While opioids have always been known to be useful in pain treatment, they also display an addictive potential in view of their euphorogenic activity. Thus, if opioids are taken by healthy human subjects with a drug seeking behavior, they may lead to psychological as well as physical dependence.

The application goes on to link addiction to crime before presenting his invention—in an echo of OxyContin marketing—as less prone to diversion and abuse than other treatment drugs. Buprenorphine sales in the United States topped \$2.6 billion in 2017, and are expected to rise as the infrastructure and funding for addiction treatment expands to meet current and projected needs.

20. As described in Section V.E, Purdue’s deceptive marketing has reaped massive revenues for the company, and massive wealth for the Sacklers, but has imposed catastrophic harms on the State and its citizens. By exaggerating the benefits of chronic opioid therapy and downplaying its very serious risks, the Sacklers and Purdue maintained the market that they largely created. Purdue is far and away the market leader in sales of branded opioids nationwide, and

likewise sells the overwhelming majority of the branded opioids prescribed in New Jersey. According to the State's analysis, through 2016, Purdue opioids accounted for 63% of the brand-name opioid prescriptions reimbursed through the State's Medicaid program, employee and retiree health plans, and workers' compensation programs. As recently as 2015, Purdue reaped an estimated \$3 billion annually in revenue nationwide, virtually all of it from the sale of opioids.

21. As a direct result of Purdue's dangerous marketing tactics, all carried out at the behest of or sanctioned by the Sacklers, New Jersey and the nation are now swept up in what the CDC has called a "national epidemic." The increased volume of prescribing for chronic pain correlates directly to skyrocketing addiction, overdose, and death; booming secondary markets for diverted prescription opioids as well as heroin, to which many addicts cross over when prescription opioids prove too expensive or unavailable; and the devastating social and economic consequences of each of these problems. In October 2017, the federal government declared the opioid crisis a national public health emergency—the first such declaration under the Public Health Service Act not involving a natural disaster or infectious disease.

22. Sales of prescription opioids in the United States quadrupled between 1999 and 2015, and correspondingly, opioid-related overdoses (including prescription opioids, heroin, and fentanyl) quadrupled as well. Nationwide, 91 people die each day from an opioid-related overdose, and more than 1,000 patients are treated in emergency departments for misusing prescription opioids. And far more Americans than those who die or are hospitalized are swept into battles with addiction and abuse that they will fight their entire lives. As many as one in four patients who receive prescription opioids long-term for chronic pain in primary care settings struggle with addiction.

23. The opioid epidemic likewise has been catastrophic in New Jersey. In 2017, the last year for which fully confirmed data are available, 2,353 people died of an opioid-related overdose. Opioid-related trips to emergency departments in New Jersey doubled between 2005 and 2014, and as of 2017 the State met little more than half of demand for substance abuse treatment—with opioids as the leading reason for treatment admissions. New Jersey also has seen a dramatic surge in neonatal abstinence syndrome—babies born into opioid addiction. And the rise in opioid addiction has led to a growing number of robberies, assaults, and thefts in New Jersey, which, in turn, have required law enforcement to devote increasing resources to this epidemic.

24. The health care costs associated with opioid overprescribing, addiction, and abuse are crushing. The State estimates that its Medicaid vendors paid in excess of \$150 million for opioids between 2008 and 2016. The State directly paid another \$6 million under its Workers' Compensation Program since 2008, and \$136 million under its employee and retiree health plans since 2012. Since 2008, New Jersey consumers—individuals, employers and private insurers—easily have paid hundreds of millions for opioid prescriptions. In addition to these costs, the State and private consumers have paid millions of dollars to treat addiction, overdose, and other injuries associated with opioid overprescribing and misuse.

25. While opioids are diverted through illicit prescribing and sales, it is the routine prescribing of opioids for medical use that fueled the opioid and heroin epidemic. Four out of every five heroin addicts used prescription opioids before crossing over to heroin.

26. Accordingly, New Jersey has undertaken an array of efforts to curb overprescribing and limit its effects. These include:

- (a) establishing, and then mandating use of, a Prescription Monitoring Program to help providers determine what other opioids a patient has been prescribed;

- (b) making prescription pads more difficult to counterfeit;
- (c) publishing best practices for pharmacists for secure handling and dispensing of prescription drugs to reduce diversion;
- (d) providing immunity from arrest and prosecution for a use or possession charge when a person seeks medical assistance for overdose;
- (e) presenting the 2016 CDC Guideline to the State's Medicaid vendors and referring prescribers to the Guideline;
- (f) setting a new, five-day limit on initial prescriptions of opioids for acute pain;
- (g) providing funding and authority for health care providers to prescribe, and first responders to administer, overdose antidotes;
- (h) mandating continuing education on opioids for prescribers; and
- (i) requiring insurers to cover 180 days of addiction treatment.

27. Yet much more remains to be done. The cost and effort of remediating the opioid crisis require tremendous resources. Plaintiffs have brought this lawsuit in part because the burden of those costs should be shared by the Sacklers, who cultivated the demand for opioids and profited from their overprescribing, misuse, and abuse.

28. Even today, at the height of the opioid epidemic, the Sacklers seek to obscure their culpability for this crisis, as set forth in Section V.F. The Sacklers have tried to distance themselves from their company, and have directed Purdue to distance itself from its past misconduct. The Sacklers approved corporate messaging intended to portray Purdue as a responsible corporate citizen by depicting the opioid epidemic as principally a problem of illicit drug diversion and abuse, not overprescribing and addiction; falsely promoting the safety of Purdue's abuse-deterrent formulations; and touting Purdue's efforts to rein in diversion, even as the company failed to meaningfully investigate or report suspicious prescribing. The Sacklers received regular updates on just how many reports of suspicious prescribing—"Reports of Concern"—were coming into the company, but stood by as Purdue failed to report nearly all of

these to authorities. And the Sacklers hid behind the perception that they were a normal board, one that was not steeped in the details of Purdue's marketing but merely approved budgets and broad strategies.

29. In reality, the Sacklers were the architects and drivers of Purdue's promotional efforts. The Sacklers' communications were not limited to quarterly Board meetings. They were in touch with Purdue marketing employees throughout the year, at some points daily and on weekends—to the point that Purdue executives and staff felt harassed. The Sacklers' personal involvement in the running of the company was so long- and well-established that an implausible effort, in 2017, to issue a press statement denying the family's involvement in the company's affairs was abandoned. The initial draft statement—"Sackler family members hold no leadership roles in the companies owned by the family trust"—was watered down to "Sackler family members hold no management positions."

30. The Sacklers knowingly and intentionally sent sales representatives to promote opioids to New Jersey prescribers hundreds of thousands of times. The Sacklers knew and intended that the sales representatives in New Jersey would deceptively and misleadingly promote opioid sales, including by overstating the benefits and understating the risks. The Sacklers knew and intended that prescribers, pharmacists, and patients in New Jersey would rely on Purdue's deceptive sales campaign to prescribe, dispense, and take Purdue opioids; securing that reliance was the purpose of the sales campaign. And the Sacklers knowingly and intentionally took money from Purdue's deceptive business in New Jersey, distributing billions of dollars in Purdue profits to themselves and other family members over the years.

31. The Sacklers' specific deceptive and unconscionable conduct, which fomented and perpetuates the opioid crisis, violated the New Jersey Consumer Fraud Act, N.J.S.A. 56:8-1 et seq. ("CFA") and the New Jersey False Claims Act, N.J.S.A. 2A:32C-1 et seq. ("FCA").

32. To redress the Sacklers' misconduct and hold them accountable for it, Plaintiffs seek an order requiring the Sacklers to desist in the unlawful promotion of opioids and correct the misrepresentations previously made. Plaintiffs further seek a judgment requiring the Sacklers to pay damages and civil penalties; to disgorge payments received from Purdue; and to reimburse Plaintiffs' fees and costs.

III. PARTIES

A. Plaintiffs.

33. The Attorney General is charged with the responsibility of enforcing the CFA and all regulations promulgated thereunder, as well as the FCA. The Director is charged with the responsibility of administering the CFA on behalf of the Attorney General.

34. Under the CFA, the Attorney General may bring an action for injunctive relief, and the Court may order restitution, disgorgement, civil penalties, and fees and costs where, as here, it "appear[s] to the Attorney General that a person has engaged in, is engaging in, or is about to engage in any practice declared to be unlawful by this act." N.J.S.A. 56:8-8, 8-11, 8-13 and 8-19.

35. Under the FCA, the Attorney General may bring a civil action for treble damages, civil penalties, and costs where, as here, a person has caused false or fraudulent claims to be presented to the State or any agent or contractor working for the State. N.J.S.A. 2A-32C-1 through C-8.

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

B. Defendants.

37. Defendant Richard S. Sackler became a member of the Purdue Board in 1990 and became its co-chair in 2003, a position that he held until he left the board in 2018. He was also Purdue's head of research and development from at least 1990 through 1999, and its Chief Executive Officer and President from 1999 through 2003. He resides in New York, Florida, and Texas. At all times material to this Complaint, acting alone or in concert with others, Richard Sackler formulated, directed, controlled, had the authority to control, or participated in the deceptive and unconscionable acts and practices set forth in this Complaint. As a member of Purdue's Board, he approved and oversaw deceptive and unconscionable conduct that was purposely directed at New Jersey and gave rise to the State's claims as alleged in this Complaint.

38. Defendant Jonathan D. Sackler was a Senior Vice President of Purdue Pharma until May 2007 and a member of Purdue's Board from 1990 through 2018. He resides in Connecticut. At all times material to this Complaint, acting alone or in concert with others, Jonathan Sackler formulated, directed, controlled, had the authority to control, or participated in the deceptive and unconscionable acts and practices set forth in this Complaint. As a member of Purdue's Board, he approved and oversaw deceptive and unconscionable conduct that was purposely directed at New Jersey and gave rise to the State's claims as alleged in this Complaint.

39. Defendant Ilene Sackler Lefcourt was a member of Purdue's Board between 1990 and 2018. She resides in New York. At all times material to this Complaint, acting alone or in concert with others, Ilene Sackler Lefcourt formulated, directed, controlled, had the authority to control, or participated in the deceptive and unconscionable acts and practices set forth in this Complaint. As a member of Purdue's Board, she approved and oversaw deceptive and unconscionable conduct that was purposely directed at New Jersey and gave rise to the State's claims as alleged in this Complaint.

40. Defendant Kathe A. Sackler was a Senior Vice President of Purdue Pharma until May 2007 and a member of Purdue's Board from 1990 through 2018. She resides in New York and Connecticut. At all times material to this Complaint, acting alone or in concert with others, Kathe Sackler formulated, directed, controlled, had the authority to control, or participated in the deceptive and unconscionable acts and practices set forth in this Complaint. As a member of Purdue's Board, she approved and oversaw deceptive and unconscionable conduct that was purposely directed at New Jersey and gave rise to the State's claims as alleged in this Complaint.

41. Defendant Mortimer D.A. Sackler was a Vice President of Purdue Pharma until May 2007 and member of Purdue's Board from 1993 through 2018. He resides in New York. At all times material to this Complaint, acting alone or in concert with others, Mortimer Sackler formulated, directed, controlled, had the authority to control, or participated in the deceptive and unconscionable acts and practices set forth in this Complaint. As a member of Purdue's Board, he approved and oversaw deceptive and unconscionable conduct that was purposely directed at New Jersey and gave rise to the State's claims as alleged in this Complaint.

42. Defendant Beverly Sackler was a member of Purdue's Board from 1993 through 2017. She resides in Connecticut. At all times material to this Complaint, acting alone or in concert with others, Beverly Sackler formulated, directed, controlled, had the authority to control, or participated in the deceptive and unconscionable acts and practices set forth in this Complaint. As a member of Purdue's Board, she approved and oversaw deceptive and unconscionable conduct that was purposely directed at New Jersey and gave rise to the State's claims as alleged in this Complaint.

43. Defendant Theresa Sackler was a member of Purdue's Board from 1993 through 2018. She resides in New York and the United Kingdom. At all times material to this Complaint,

acting alone or in concert with others, Theresa Sackler formulated, directed, controlled, had the authority to control, or participated in the deceptive and unconscionable acts and practices set forth in this Complaint. As a member of Purdue's Board, she approved and oversaw deceptive and unconscionable conduct that was purposely directed at New Jersey and gave rise to the State's claims as alleged in this Complaint.

44. Defendant David A. Sackler was a member of Purdue's Board from 2012 through 2018. He resides in New York. At all times material to this Complaint, acting alone or in concert with others, David Sackler formulated, directed, controlled, had the authority to control, or participated in the deceptive and unconscionable acts and practices set forth in this Complaint. As a member of Purdue's Board, he approved and oversaw deceptive and unconscionable conduct that was purposely directed at New Jersey and gave rise to the State's claims as alleged in this Complaint.

IV. JURISDICTION AND VENUE

45. The Court has personal jurisdiction over Defendants because: (1) Defendants' deceptive and unconscionable activities alleged in this Complaint were purposely directed at New Jersey; (2) Plaintiffs' claims alleged in this Complaint arise out of or relate to those specific activities; and (3) jurisdiction in New Jersey is reasonable and otherwise comports with fair play and substantial justice.

46. As members of Purdue's Board, Defendants approved and oversaw a deceptive marketing scheme that was purposely directed at New Jersey prescribers, patients, and the State itself. Specifically, Defendants approved and oversaw: (1) the wide dissemination of deceptive marketing materials (Purdue-branded and unbranded) pertaining to opioids throughout New Jersey; and (2) the hiring and compensation of at least 107 Purdue sales representatives and sales managers active in New Jersey for the purpose of deceptively marketing and selling opioids in

New Jersey between mid-2007 and mid-2017. During that period, Purdue sales representatives made more than [REDACTED] sales visits regarding OxyContin and other Purdue opioids to New Jersey health care providers who were on Purdue's target lists. Defendants' deceptive marketing campaign in New Jersey generated hundreds of millions of dollars of revenue derived through sales of Purdue opioids to New Jersey consumers.

47. Venue in this Court is proper, pursuant to Rule 4:3-2, because Plaintiffs' claims arose, in part, in Essex County and Defendants directed business into Essex County. Among other things, Purdue has made thousands of sales visits regarding opioids to health care providers in Essex County. In addition, the New Jersey Division of Consumer Affairs has its principal office in Essex County.

V. GENERAL ALLEGATIONS COMMON TO ALL COUNTS

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

48. Beginning in 1996, Purdue presented OxyContin—and later its other opioids—as the solution to the problem of chronic pain. Through marketing that was as pervasive as it was deceptive, Purdue convinced health care providers both that the risks of long-term opioid use were overblown and that the benefits, in reduced pain and improved function and quality of life, were proven—even though Purdue had no evidence to support these assertions.

49. By the mid-2000s, Purdue had succeeded in drastically changing medical and public opinion about opioids. Purdue's marketing convinced prescribers, academics, and patients that opioids were appropriate for long-term use and also that they were a suitable first-line treatment for routine chronic pain conditions.

50. During this entire period, the Sackler Defendants held a majority of the seats on the Purdue Board of Directors. Three Sackler Defendants—Kathe, Jonathan, and Mortimer D.A.

Sackler—were high-ranking Vice-Presidents in the company until May 2007. Richard Sackler was not only the Chief Executive Officer and President of the company between 1999 and 2003; he had also served as the head of research and development from 1990 to 1999. The other Sacklers were less visible, but no less culpable. As described below, as members of the Board they shaped the company’s deceptive marketing strategies, received detailed reports on the implementation of those strategies, and continued to sanction this conduct, month after month and year after year. From these positions—Board members and high-ranking executive employees of Purdue—the Sacklers were personally aware of, engaged in, and responsible for the deceptive and unfair marketing activities described below.

51. To spread its false and misleading messages supporting chronic opioid therapy, Purdue marketed its opioids directly to health care providers and patients nationwide and in New Jersey. It did so principally through its sales force—sales representatives, also known as “detailers,” who made in-person sales calls to prescribers in which they misleadingly portrayed opioids as safe, effective, and appropriate for the treatment of chronic pain.

52. This misinformation included, most prominently, deceptive statements about the risk of addiction. For example, as the United States Department of Justice (“USDOJ”) found in settling criminal charges against Purdue in 2007, sales representatives had “falsely told some health care providers that OxyContin had less euphoric effect, and less abuse potential than short-acting opioids.” Among the tactics Purdue used, according to USDOJ, was training sales personnel to promote the false information that OxyContin—the first extended-release or long-acting (“ER/LA”) opioid—had fewer “peak and trough” effects than short-acting opioids, also known as immediate release (“IR”) opioids.

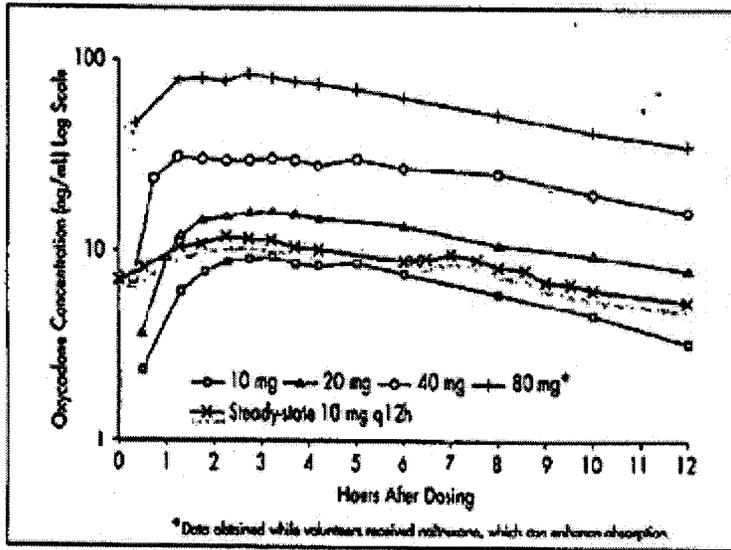
53. In addition to making deceptive claims through its sales force, Purdue also widely advertised OxyContin, including in print ads in medical journals and in videos distributed directly to physicians. These ad campaigns, too, deceptively portrayed both the risks and benefits of chronic opioid therapy. For example, in 1998 and 2000, Purdue distributed to doctors thousands of copies of videos, titled “I Got My Life Back,” which made the unsubstantiated claim that opioid addiction occurred in less than 1% of patients. And a 2005 ad that ran in pain journals misleadingly implied long-term improvement in patients’ pain, function, and quality of life, touting OxyContin as an “around-the-clock analgesic . . . for an extended period of time” and featuring a man and a boy fishing under the tagline “There Can Be Life With Relief.”

54. Purdue also falsely promoted OxyContin as effective for a full 12 hours and providing “steady state” relief, which purportedly made OxyContin less likely than other opioids to create a cycle of crash and cravings that increases the risk of addiction. As noted in Section V.D.2, promoting OxyContin as a 12-hour drug was critical to establish the drug’s market advantage over its 4- to 6-hour IR competitors and justify OxyContin’s higher price. Purdue’s advertising included the claim that OxyContin provides “Consistent Plasma Levels Over 12 Hours.” That claim was accompanied by a chart, shown below, that depicted plasma levels on a logarithmic scale:

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

Consistent Plasma Levels Over 12 Hours

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



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

Steady state achieved within 24 to 36 hours

55. This presentation obscured the steep decline in OxyContin's efficacy over 12 hours by depicting 10 milligrams in such a way that it appeared to be half of 100 milligrams in the table's y-axis, making the absorption rate appear more steady or consistent over 12 hours. In fact, OxyContin works by releasing a greater proportion of oxycodone (about 40%) into the body upon administration, followed by a steep decline over those hours.

56. Purdue's claims regarding chronic opioid therapy were not supported by substantial scientific evidence, so the company set out to create the illusion that such support existed. Purdue buttressed its direct promotion of its opioids with an array of marketing approaches that bolstered the same deceptive messages by filtering them through seemingly independent and objective sources. Purdue recruited and paid physician speakers to present talks on opioids to their peers at lunch and dinner events. It funded biased research and sponsored CME courses that misleadingly

portrayed the risks and benefits of chronic opioid therapy. It collaborated with professional associations and pain advocacy organizations, such as the American Pain Foundation, to develop and disseminate pro-opioid educational materials and guidelines for prescribing opioids. And it created “unbranded” websites and materials, copyrighted by Purdue but implied to be the work of separate organizations with names like Partners Against Pain, which echoed Purdue’s branded marketing.

57. Among these tactics, all of which originated in the late 1990s and early 2000s, three stand out for their lasting influence on opioid prescribing nationwide and in New Jersey: (1) Purdue’s capture, for its own ends, of physicians’ increased focus on pain treatment; (2) Purdue’s efforts to seed the scientific literature on chronic opioid therapy; and (3) Purdue’s corrupting influence on authoritative treatment guidelines issued by professional associations.

58. As described in more detail in Sections V.B and V.C, the Sacklers were personally aware of, engaged in, and responsible for Purdue’s decisions to invest in unbranded promotion through third parties. They approved budgets for grants to the professional associations and advocacy groups and received reports on the relationships and effectiveness of the communications that the associations and groups undertook. [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

1. Purdue Used the Medical Community's Increased Focus on Pain as a Springboard for Its Deceptive Marketing.

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

60. Purdue had already laid the groundwork for this strategy by financially supporting a cadre of researchers who spoke glowingly of the prospects for expanded use of opioids. Chief among these was Dr. Russell Portenoy, once dubbed the “King of Pain.” While receiving Purdue funding and serving as a Purdue consultant, he wrote a seminal 1986 paper supporting chronic opioid therapy. Dr. Portenoy concluded—based on a retrospective review of just 38 patients—that “opioid maintenance therapy can be a safe, salutary and more humane alternative” to not treating patients with chronic pain.

61. Beginning in 1995, the American Pain Society (“APS”), of which Dr. Portenoy later would become president, launched a national campaign to make pain a “vital sign”—an indicator doctors should monitor alongside blood pressure, temperature, heartbeat, and breathing. Purdue provided substantial funding to APS. The Veterans Health Administration adopted this concept in its facilities nationwide in 1999, and “Pain as the 5th Vital Sign” spread from there to the private sector.

62. In 2001, the Joint Commission on the Accreditation of Healthcare Organizations (“JCAHO”) issued pain treatment standards requiring the assessment of pain in all patients and in each physician-patient interaction, and made hospital accreditation decisions contingent on adherence to those standards. Purdue worked closely with JCAHO to promote the pain standards,

and JCAHO licensed Purdue—exclusively—to distribute educational videos about how to comply with the new pain management standards. Purdue also sponsored various guides for implementing the JCAHO pain standards, such as “Pain Assessment and Management: An Organizational Approach.” This book promoted the use of opioids, claiming that “[s]ome clinicians have inaccurate and exaggerated concerns about addiction, tolerance, respiratory depression, and other opioid side effects . . . despite the fact there is no evidence that addiction is a significant issue when persons are given opioids for pain control.” (Emphasis added.) JCAHO distributed the book to hospital officials and physicians nationwide at a series of Purdue-sponsored “leadership summits” on pain management.

63. Both the APS “Pain as the 5th Vital Sign” campaign and the JCAHO pain standards were widely integrated into medical practice. Numerous New Jersey health care providers interviewed by the State—including many who were unaware of Purdue’s involvement—credit these initiatives for “swinging the pendulum” toward overprescribing of opioids.

2. Purdue Corrupted the Science Regarding Opioids with Flawed and Biased Research.

64. Rather than rigorously test the safety and efficacy of opioids for long-term use, Purdue created scientific support for its marketing claims by sponsoring studies that were methodologically flawed, biased, and drew inappropriate conclusions from prior evidence. Purdue selectively published studies with favorable outcomes and suppressed the problematic ones. The result was an incomplete, inaccurate, and deceptive body of literature that was then cited by other researchers.

65. Some of these methodologically flawed studies made unsubstantiated claims that a patient’s risk of developing psychological dependence or addiction to opioids is low absent a history of substance abuse. One such study, published in the journal Pain in 2003 and widely

referenced since (with 625 citations in Google Scholar), ignored previous Purdue-commissioned research showing addiction rates between 8% and 13%—far higher than Purdue acknowledged was possible in its mainstream marketing. Instead, the 2003 study relied heavily on a 1980 letter to the editor—not a peer-reviewed article, but a letter—in the New England Journal of Medicine. That letter, J. Porter & H. Jick, “Addiction Rare in Patients Treated with Narcotics,” 302(2) New England Journal of Medicine 123 (1980) (“Porter-Jick Letter”), is reproduced in full below:

**ADDICTION RARE IN PATIENTS TREATED
WITH NARCOTICS**

To the Editor: Recently, we examined our current files to determine the incidence of narcotic addiction in 39,946 hospitalized medical patients¹ who were monitored consecutively. Although there were 11,882 patients who received at least one narcotic preparation, there were only four cases of reasonably well documented addiction in patients who had no history of addiction. The addiction was considered major in only one instance. The drugs implicated were meperidine in two patients,² Percodan in one, and hydromorphone in one. We conclude that despite widespread use of narcotic drugs in hospitals, the development of addiction is rare in medical patients with no history of addiction.

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

66. The Porter-Jick Letter does not reflect any study, but simply describes a review of the charts of hospitalized patients who had received opioids. One of the authors of the letter and the *New England Journal of Medicine* have since repudiated the misuse of Porter-Jick Letter, yet it has become a mainstay in scientific literature, in large part due to Purdue’s efforts, with more than 1,100 citations in Google Scholar.

3. Purdue Worked with Professional Associations to Create Treatment Guidelines that Overstated the Benefits and Understated the Risks of Opioids.

67. Treatment guidelines directly inform doctors' prescribing practices, are cited throughout the scientific literature, and are referenced by third-party payors in determining whether they should cover prescriptions. Purdue financed and collaborated with three groups, in particular, on guidelines that have been, and continue to be, broadly influential in New Jersey and nationwide.

a. AAPM/APS Guidelines

68. The American Academy of Pain Medicine ("AAPM") and APS each received substantial funding from Purdue. From 2009 to 2012, Purdue gave APS nearly \$500,000 and AAPM more than \$400,000. An internal Purdue request to its CEO for approval of "2009 funds for AAPM and APS proposals" described each group as "one of our top tiered organizations." Purdue gave APS another \$500,000 and AAPM more than \$700,000 between 2012 and 2017.

69. In 1997, AAPM and APS issued a consensus statement, "The Use of Opioids for the Treatment of Chronic Pain," that endorsed using opioids to treat chronic pain and claimed that the risk that patients would become addicted to opioids was low. The co-author of the statement, Dr. David Haddox, was at the time a paid speaker for Purdue, and shortly thereafter became a senior executive for the company. (Dr. Portenoy was a consultant on the project.) The consensus statement remained on AAPM's website until 2011.

70. AAPM and APS also issued a 2001 set of recommendations, titled "Definitions Related to the Use of Opioids for the Treatment of Pain," that advanced the unsubstantiated concept of "pseudoaddiction." The term, coined by Dr. Haddox in a 1989 journal article, reflects the idea that signs of addiction may actually be the manifestation of undertreated pain and will resolve once the pain is effectively treated—i.e., with more or higher doses of opioids. The 2001

AAPM/APS recommendations claimed “clock-watch[ing],” “drug seeking,” and “[e]ven such behaviors as illicit drug use and deception can occur in the patient’s efforts to obtain [pain] relief.” The lack of evidentiary support for this definition has been since exposed and the treatment approach discredited.

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

72. The 2009 AAPM/APS Guidelines were reprinted in the Journal of Pain, were distributed by Purdue sales representatives to New Jersey prescribers, and have been relied upon by New Jersey prescribers in their practices.

b. FSMB Guidelines

73. The Federation of State Medical Boards (“FSMB”) is an association of the various state medical boards in the United States, each of which, including New Jersey’s, has the power to license doctors, investigate complaints, and discipline physicians. The FSMB has financed opioid- and pain-specific programs through grants from pharmaceutical manufacturers, including more than \$800,000 from Purdue between 2001 and 2008.

74. In 1998, the FSMB developed its Model Guidelines for the Use of Controlled Substances for the Treatment of Pain (“FSMB Guidelines”), which the FSMB acknowledged were produced “in collaboration with” pharmaceutical companies and allied groups such as the APS.

The FSMB Guidelines described opioids as “essential” for treatment of chronic pain, including as a first-line option; failed to mention risks of respiratory depression and overdose; addressed addiction only to define the term as separate from physical dependence; and stated that an “inadequate understanding” of addiction can lead to “inadequate pain control.” Purdue sales representatives distributed the FSMB Guidelines to health care providers in New Jersey.

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

76. Responsible Opioid Prescribing was sponsored by Purdue, among other opioid manufacturers, and Purdue had editorial input into its contents. In particular, Dr. Haddox, by then employed directly by Purdue, edited the book to ensure that pseudoaddiction was presented as an accepted medical concept. Dr. Scott Fishman, however, is listed as the book’s sole author.

Purdue’s relationship with Fishman was such [REDACTED]
[REDACTED]
[REDACTED]
[REDACTED]

77. In all, more than 163,000 copies of Responsible Opioid Prescribing were distributed nationwide through state medical boards and non-profit organizations. The New Jersey Academy of Family Physicians purchased copies of the book and, on information and belief, distributed them to practitioners in the State. New Jersey prescribers interviewed by the State recalled receiving and reviewing the book.

B. The Sacklers Drove the Misconduct that Led to the 2007 Convictions and Settlements.

78. The misconduct of Richard, Beverly, Ilene, Jonathan, Kathe, Mortimer, and Theresa Sackler was particularly deceptive, unconscionable, and unlawful because they already had been given a second chance. From the 1990s until 2007, they directed misconduct that led to settlements, criminal convictions and commitments that Purdue would not deceive doctors and patients again. That background confirms that their misconduct since 2007 was knowing and intentional.

79. The Sackler family's first drug company was the Purdue Frederick Company, which they bought in 1952. In 1990, they formed Purdue Pharma Inc. and Purdue Pharma L.P. Richard, Beverly, Ilene, Jonathan, Kathe, Mortimer, and Theresa Sackler took seats on the Board. For events before July 2012, this Complaint uses "the Sacklers" to refer to them. David Sackler joined the Board in July 2012. From that time forward, "the Sacklers" includes him as well.

80. The Sacklers always insisted that their family control Purdue. From 1990 until today, their family always held the majority of seats on the Board. In 1994, Jonathan Sackler issued a memorandum to Purdue staff requiring that the Sacklers "should receive all Quarterly Reports and any other reports directed to the Board."

81. After Purdue launched OxyContin in 1996, it became one of the deadliest drugs of all time. The FDA scientist who evaluated OxyContin wrote in his original review: "Care should be taken to limit competitive promotion." The Sacklers did not agree. From the beginning, the Sacklers viewed limits on opioids as an obstacle to greater profits. To make more money, the Sacklers considered whether they could sell OxyContin in some countries as an uncontrolled drug. Staff informed Richard Sackler that selling OxyContin as "non-narcotic," without the safeguards that protect patients from addictive drugs, would provide "a vast increase of the market potential."

The inventor of OxyContin, Robert Kaiko, wrote to Richard Sackler that he was “very concerned” about the danger of selling OxyContin without strict controls. Kaiko warned: “I don’t believe we have a sufficiently strong case to argue that OxyContin has minimal/or no abuse liability.” To the contrary, Kaiko wrote, “oxycodone containing products are still among the most abused opioids in the U.S.” Kaiko predicted, [REDACTED]: “If OxyContin is uncontrolled . . . it is highly likely that it will eventually be abused.” Richard Sackler responded: “How substantially would it improve your sales?”

82. At the OxyContin launch party, Richard Sackler spoke as the Senior Vice President responsible for sales. He asked the audience to imagine a series of natural disasters: an earthquake, a volcanic eruption, a hurricane, and a blizzard. [REDACTED], he said: “the launch of OxyContin Tablets will be followed by a blizzard of prescriptions that will bury the competition. The prescription blizzard will be so deep, dense and white....”

83. From the beginning, the Sacklers were behind Purdue’s decision to deceive doctors and patients. In 1997, Richard Sackler and other Purdue executives determined that doctors had the crucial misconception that OxyContin was weaker than morphine, which led them to prescribe OxyContin much more often. In fact, OxyContin is more potent than morphine. Richard Sackler recognized that the truth could reduce OxyContin sales [REDACTED]

84. From the start, the Sacklers were also the driving force behind Purdue’s strategy to push opioids with the false promise that they create an enhanced “lifestyle.” In 1998, Richard Sackler told Purdue’s executives that OxyContin tablets provide more than merely “therapeutic” value and instead “enhance personal performance.”

85. Most of all, the Sacklers cared about money. Millions of dollars were not enough.

They wanted billions. They cared more about money than about patients, or their employees, or the truth. In 1999, when CEO Michael Friedman reported to Richard Sackler that Purdue was making more than \$20 million per week, Richard replied immediately, at midnight, that the sales were “not so great.” “After all, if we are to do 900M this year, we should be running at 75M/month. So it looks like this month could be 80 or 90M. Blah, humbug. Yawn. Where was I?”

86. In 1999, Richard Sackler became the President and CEO of Purdue. Jonathan, Kathe, and Mortimer Sackler were Vice Presidents. The company hired hundreds of sales representatives and taught them false claims to use to sell drugs. Purdue managers tested the sales representatives on key messages during training at company headquarters. On the crucial issue of addiction, which would damage so many lives, Purdue trained its sales representatives to deceive doctors that the risk of addiction was “less than one percent.” [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED] Purdue mailed thousands of doctors promotional videos with that same false claim:

There’s no question that our best, strongest pain medicines are the opioids. But these are the same drugs that have a reputation for causing addiction and other terrible things. Now, in fact, the rate of addiction amongst pain patients who are treated by doctors is much less than one percent. They don’t wear out, they go on working, they do not have serious medical side effects.

A sales representative told a reporter: “We were directed to lie. Why mince words about it? Greed took hold and overruled everything. They saw that potential for billions of dollars and just went after it.”

87. In addition to using the sales force to deceptively promote Purdue’s opioids, the Sacklers approved and oversaw [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED] The Sacklers approved and oversaw [REDACTED]

[REDACTED]

88. In 2000, the Sacklers were warned that a reporter was “sniffing about the OxyContin abuse story.” The Sacklers put the threat on the agenda for the next Board meeting and began covering their tracks. They planned a response that “deflects attention away from the company owners.”

89. In January 2001, staff forwarded to Richard Sackler a plea for help from a Purdue sales representative. The sales representative described a community meeting at a local high school, organized by mothers whose children overdosed on OxyContin and died: “Statements were made that OxyContin sales were at the expense of dead children and the only difference between heroin and OxyContin is that you can get OxyContin from a doctor.”

90. The next month, a New York Times article reported on OxyContin abuse, citing a federal prosecutor who reported 59 deaths from OxyContin in a single state. Richard Sackler wrote to Purdue executives: “This is not too bad. It could have been far worse.”

91. That same month, Richard Sackler wrote down his solution to the overwhelming evidence of overdose and death: blame and stigmatize people who become addicted to opioids. In a confidential email, he wrote: “[W]e have to hammer on the abusers in every way possible. They are the culprits and the problem. They are reckless criminals.”

92. Richard Sackler consistently took this position. [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

93. In his time as President and CEO, Richard Sackler's view became the company's view as well. That is evident in the narrative the company advanced then, and still advances today, that criminal abusers—not the company that deceptively peddles the drugs—are to blame for the opioid crisis.

94. Not long after the New York Times report on OxyContin abuse, the Sacklers achieved a long-sought goal: the front page of the Times reported that "OxyContin's sales have hit \$1 billion, more than even Viagra's." The same article noted that "OxyContin has been a factor in the deaths of at least 120 people, and medical examiners are still counting."

95. When Time magazine published an article about OxyContin deaths, Purdue employees expressed concern. Richard Sackler responded with a message to his staff. He wrote that Time's coverage of people who lost their lives to OxyContin was not "balanced." Richard Sackler added: "[W]e intend to stay the course and speak out for people in pain—who far outnumber the drug addicts abusing our product. . . . [REDACTED]

[REDACTED]

96. That spring, Purdue executives met with the U.S. Drug Enforcement Agency

(“DEA”). A senior DEA official sat across from Richard Sackler. Before the meeting ended, she leaned over the table and told Richard Sackler: “People are dying. Do you understand that?”

97. The Sacklers and Purdue remained indifferent to the impact of their deceptive sales practices. In 2002, [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

98. As Purdue kept pushing opioids and people kept dying, the company was engulfed in a wave of investigations by state attorneys general, the DEA, and the USDOJ. In 2003, Richard Sackler left his position as President of Purdue. After a few more years of investigation, Jonathan, Kathe, and Mortimer Sackler resigned from their positions as Vice Presidents. But those moves were for show. The Sacklers kept active control of the company. Their family owned Purdue. They controlled the Board. They paid themselves the profits. And, as alleged in detail below, they continued to direct Purdue’s deceptive marketing campaign.

99. By 2006, prosecutors found damning evidence that Purdue intentionally deceived doctors and patients about its opioids. The Sacklers voted that their first drug company, the Purdue Frederick Company, should plead guilty to a felony for misbranding OxyContin as less addictive, less subject to abuse and diversion, and less likely to cause adverse events and side effects than other pain medications. The Sacklers also voted that three Purdue executives (Michael Friedman, Paul Goldenheim, and Howard Udell)—but no member of the Sackler family—should plead guilty as individuals.

100. In May 2007, the Sacklers voted again to have the Purdue Frederick Company plead guilty and enter a series of agreements that Purdue Pharma L.P. and its related and associated

entities would never deceive doctors and patients about opioids again. The Purdue Frederick Company confessed to a felony and effectively went out of business. The Sacklers continued their opioid business in two other companies: Purdue Pharma Inc. and Purdue Pharma L.P.

101. The Sacklers voted to admit in an Agreed Statement Of Facts that, for more than six years, supervisors and employees intentionally deceived doctors about OxyContin: “Beginning on or about December 12, 1995, and continuing until on or about June 30, 2001, certain PURDUE 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”

102. To remove any doubt, the Sacklers voted to enter into a plea agreement that stated: “PURDUE is pleading guilty as described above because PURDUE is in fact guilty” Those intentional violations of the law happened while Richard Sackler was CEO; Jonathan, Kathe, and Mortimer Sackler were Vice Presidents; and Richard, Jonathan, Kathe, Mortimer, Ilene, Beverly, and Theresa Sackler were all on the Board.

103. The Sacklers also voted for Purdue to enter a Corporate Integrity Agreement with the U.S. government. The agreement required the Sacklers to ensure that Purdue did not deceive doctors and patients again. The Sacklers promised to comply with rules that prohibit deception about Purdue opioids. They were required to complete hours of training to ensure that they understood the rules. They were required to report any deception. Richard, Beverly, Ilene, Jonathan, Kathe, Mortimer, and Theresa Sackler each certified in writing to the government that he or she had read and understood the rules and would obey them.

C. After the 2007 Settlements, The Sacklers Devised New Unconscionable Practices and Directed the Purdue Sales Force to Carry Them Out.

104. Following the 2007 convictions and settlements, the Sacklers could have fundamentally reformed the company. Instead, they devised and sanctioned new deceptive and unconscionable practices designed to maximize prescriptions, profits, and their own distributions.

105. Continuing their pattern of deep involvement in Purdue's operations, the Sacklers directed the company to hire hundreds more sales representatives to visit doctors thousands more times. They insisted that sales representatives repeatedly visit the most prolific prescribers. They directed representatives to encourage doctors to prescribe more of the highest doses of opioids. They studied tactics to keep patients on opioids longer and then ordered staff to use them. [REDACTED]

[REDACTED] They asked for detailed reports about doctors suspected of misconduct, how much money Purdue made from them, and how few of them Purdue had reported to the authorities. They sometimes demanded more detail than anyone else in the entire company, so staff had to create special reports just for them. Richard Sackler even went into the field to promote opioids to doctors and supervise representatives face to face.

106. The Sacklers' micromanagement was so intrusive that staff asked Purdue executives to intervene. The Vice President of Sales and Marketing wrote to the CEO:

Anything you can do to reduce the direct contact of Richard into the organization is appreciated.

107. The Sacklers' directions moved straight through the company. When the Sacklers berated sales managers, the managers turned around and fired straight at representatives in the field. When Richard Sackler wrote to managers, "This is bad," to criticize the sales of Purdue's Butrans opioid, the managers in turn drafted a warning for employees:

Just today, Dr. Richard sent another email, 'This is bad,' referring to current Butrans trends. I am quite sure that Dr. Richard would not be sympathetic to the plight of the Boston District.

The manager then threatened to fire every sales representative in the Boston district:

I am much closer to dismissing the entire district than agreeing that they deserve a pass for poor market conditions.

On information and belief, Richard Sackler's displeasure over Butrans sales was communicated to New Jersey sales representatives as well.

108. The Sacklers' main motivation was money. From 2007 to 2018, they voted to direct Purdue to pay their family billions of dollars, including tens of millions of dollars from opioids sold in New Jersey. These payments show the total control that the Sacklers exercised over Purdue. The payments were the motivation for the Sacklers' misconduct, and the payments were deliberate decisions to benefit from deception in New Jersey, at great cost to patients and families.

109. As detailed below, the Sacklers' misconduct continued from the 2007 convictions into 2018.

❖ ❖ ❖ 2007 ❖ ❖ ❖

110. In February 2007, staff told [REDACTED]

[REDACTED]

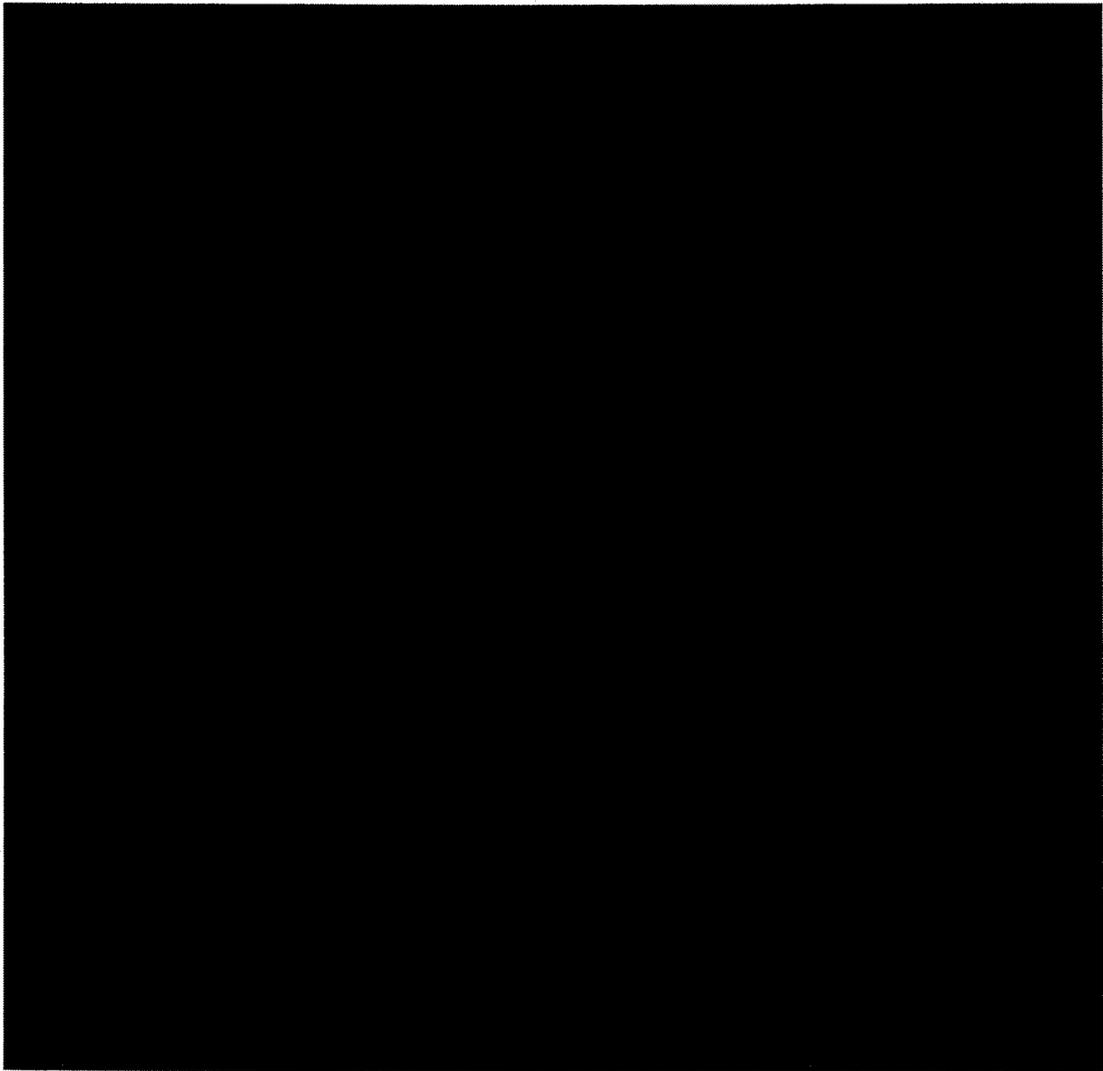
111. In April— [REDACTED]

[REDACTED]

[REDACTED]

112. Later that month, [REDACTED]

[REDACTED]



OAG graphic based on Purdue documents

113. The impact of Purdue's sales representatives in New Jersey was direct and profound. From the 2007 felony conviction through mid-2017, Purdue sales representatives visited New Jersey prescribers and pharmacists more than [REDACTED] times.

114. In May, while still in the midst of the criminal proceedings, [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

115. In July, staff told the Sacklers that more than 5,000 cases of adverse events had been reported to Purdue in just the first three months of 2007. Staff also told the Sacklers that Purdue received 572 Reports of Concern about abuse and diversion of Purdue opioids during Q2 2007—including several reports [REDACTED]. Staff reported to the Sacklers that they completed only 21 field inquiries in response. Staff also told the Sacklers that they received 101 calls to Purdue's compliance hotline during the quarter, which was a "significant quarterly increase," but Purdue did not report any of the hotline calls or Reports of Concern to the FDA, DEA, Department of Justice, or state authorities. Quarter after quarter, over the ensuing decade, Purdue and the Sacklers would not deviate from this pattern: Staff would tell the Board that there had been hundreds of Reports of Concern; staff would further note that only a handful had been investigated, with none reported to authorities; and, on information and belief, the Board accepted this inaction.

116. Purdue's self-interested failure to report abuse and diversion continued even though the 2007 Judgment required Purdue to report "potential abuse or diversion to appropriate medical, regulatory or law enforcement authorities." Instead of reporting dangerous prescribers, or even

directing sales representatives to stop visiting them, the Sacklers chose to keep pushing opioids to whoever prescribed the most. [REDACTED]

[REDACTED]

117. By July of 2007, [REDACTED]

[REDACTED]

118. Also in July, staff reported to the Sacklers that they continued to mail out thousands of deceptive marketing materials, including 12,528 publications in the first half of 2007. The single most-distributed material was volume #1 of Purdue's Focused and Customized Education Topic Selections in Pain Management (FACETS). In FACETS, Purdue falsely instructed doctors and patients that physical dependence on opioids is not dangerous and instead improves patients' "quality of life"—just as Richard Sackler had been saying since the 1990s. In the same material, Purdue also falsely told doctors and patients that signs of addiction are actually "pseudoaddiction," and that doctors should respond by prescribing more opioids. Staff reported to the Sacklers that another of the publications they had sent most often to doctors was Complexities in Caring for

People in Pain. In it, Purdue repeated again its false claim that warning signs of addiction are really “pseudoaddiction” that should be treated with more opioids.

119. Purdue sent both of those misleading publications to doctors [REDACTED]

120. At the same time, staff also reported to the Sacklers that Purdue was making more money than expected. A few months earlier, they had projected a profit of \$407,000,000; now they expected more than \$600,000,000.

121. Staff reported to the Sacklers that “[REDACTED]” and “[REDACTED] sales effort [REDACTED]” were key reasons that profits were high. Staff also reported to the Sacklers that Purdue employed 301 sales representatives to promote opioids and that sales representatives were the largest group of Purdue employees by far. By comparison, Purdue employed only 34 people in drug discovery.

122. **In August**, Mr. Udell was still serving as Purdue’s top lawyer, even after his criminal conviction. He wrote to Richard, Ilene, Jonathan, Kathe, Mortimer, and Theresa Sackler: “Over the last week there have been numerous news stories across the nation reporting on the Associated Press’s analysis of DEA data showing very large increases in the use of opioids analgesics (particularly OxyContin) between the years 1997 and 2005. Many of these articles have suggested that this increase is a negative development suggesting overpromotion and increasing abuse and diversion of these products.”

123. **In October**, staff told the Sacklers that Purdue received 284 Reports of Concern about abuse and diversion of Purdue’s opioids in Q3 2007, and they conducted only 46 field inquiries in response. Staff reported to the Sacklers that they received 39 tips to Purdue’s compliance hotline during the quarter, but Purdue did not report any of them to the authorities.

124. [REDACTED]

[REDACTED]

125. Staff told the Sacklers that Purdue had hired more sales representatives and now employed 304. They also reported to the Sacklers that Purdue was succeeding at promoting its highest doses of opioids: “OxyContin 80mg is at Rx levels not seen in over 2 years.” From 2007 to 2018, encouraging prescriptions of the highest doses of opioids—which were the most lucrative to Purdue and the Sacklers—was a primary focus of the sales force, including in New Jersey, as discussed in Section V.D.4.

126. In preparation for an upcoming Board meeting, Richard Sackler instructed staff to give him the spreadsheets underlying their sales analysis, so that he could do his own calculations. The spreadsheets showed that, in 2007, Purdue expected to collect more than half its total revenue from sales of 80mg OxyContin—its most powerful, most profitable, and most dangerous pill.

127. In November, the Sacklers voted to spend \$86,900,000 to employ sales representatives in 2008. The Sacklers also voted for a resolution regarding salary increases and bonus targets for the representatives. Every time the Sacklers voted to spend tens of millions of

dollars on sales representatives, they knew and intended that they were sending representatives to promote opioids in New Jersey.

❖ ❖ ❖ 2008 ❖ ❖ ❖

128. Staff told the Sacklers that Purdue still employed 304 sales representatives and they were succeeding at the goal of promoting higher doses of opioids: “OxyContin 80mg continues to grow.” Staff told the Sacklers that, in 2007, Purdue’s net sales were just over \$1 billion, almost “DOUBLE” what the company had planned. OxyContin accounted for more than 90% of those sales.

129. **In January**, staff also told the Sacklers that Purdue received 689 Reports of Concern about abuse and diversion of Purdue’s opioids in Q4 2007, and they conducted only 21 field inquiries in response. Staff also reported to the Sacklers that they received 83 tips to Purdue’s compliance hotline during the quarter, but Purdue did not report any of them to the authorities.

130. The Sacklers wanted more details on tactics for pushing sales. Richard Sackler wrote to Russell Gasdia, Vice President of Sales and Marketing (hereinafter “Sales VP”), demanding information about Purdue’s opioid savings cards. Richard Sackler asked Gasdia how long the opioid savings cards lasted, how much savings they offered a patient, and whether there had been any changes since he had last been briefed on the opioid savings cards. Richard Sackler sent Gasdia [REDACTED] a detailed hypothetical scenario to make sure he understood the sales tactic down to the smallest details. [REDACTED] staff followed up with a presentation about opioid savings cards to the Sacklers. From 2007 to 2018, savings cards were a key element of the strategy to promote long-term use of opioids, including in New Jersey, as discussed in Section V.D.5.

131. Meanwhile, when staff proposed a plan to get pharmacies to increase their

inventory of OxyContin from 2 bottles to 3 bottles, Richard Sackler questioned why they could not get up to 4 bottles or more.

132. The Sacklers were not just involved in the details of Purdue's marketing. They also made the fundamental decision to hire a sales force, and then to expand it. At Purdue, hiring more sales representatives was not a matter for middle management. Selling opioids through in-person visits to doctor's offices and hospitals was the core business of the company. The Sacklers themselves made the decisions about how big the sales force would be and what it would do.

133. In February, the Sacklers used their power on the Board of Directors to "begin expanding [Purdue's] sales force by an additional 100 sales representatives beginning effective as of April 1, 2008."

PURDUE PHARMA INC.

**Minutes of a Meeting
of the Board of Directors**

February 8, 2008

RESOLVED that the Partnership be and it hereby is authorized and directed to begin expanding the sales force by an additional 100 sales representatives beginning effective as of April 1, 2008 at an additional cost in 2008 of \$12.5 million, and in connection with the addition of such 100 sales representatives, to add 12 District Managers, 2 Regional Managers, 2 regional administrators, 2 trainers and 1 marketing/convention manager starting July 1, 2008; and further

134. The Sacklers knew and intended that, because of their orders, more sales representatives would promote opioids to prescribers in New Jersey, and that those sales representatives would pursue the objectives set by the Sacklers using the tactics on which the Sacklers had been briefed. In preparation for the Sacklers' vote, staff told them that adding 100

sales representatives would allow Purdue to make 12,000 more sales visits to prescribers every month.

135. From 2008 to mid-2017, sales representatives hired in the 2008 expansion promoted Purdue opioids [REDACTED]

136. The Sacklers also knew and intended that the sales representatives would push higher doses of Purdue's opioids. That same month, Richard Sackler directed Purdue management to "measure our performance by Rx's by strength, giving higher measures to higher strengths." He copied Jonathan and Mortimer Sackler on the instruction. The Sacklers knew higher doses put

patients at higher risk. As far back as the 1990s, Jonathan and Kathe Sackler knew that patients frequently suffer harm when “high doses of an opioid are used for long periods of time.”

137. On Valentine’s Day, the Sacklers voted to pay former CEO and criminal convict Michael Friedman \$3 million. It was one of several multi-million-dollar payments to the convicted executives.

138. Also in February, [REDACTED]

[REDACTED] Mortimer Sackler wrote to Richard Sackler [REDACTED]: “Purdue should be leading the charge on this type of research and should be generating the research to support our formulation. Why are we playing catch up ...? Shouldn’t we have studies like this ...?”

139. [REDACTED]

[REDACTED] Later that month, Stewart wrote to Richard Sackler that reformulating OxyContin “will not stop patients from the simple act of taking too many pills.” As discussed in Section V.D.1.c, Purdue and the Sacklers deployed as a marketing tool the abuse-deterrent formulation ultimately developed by the company, despite the fact that its efficacy in reducing abuse was unproven. Further, as discussed in Section V.F, Purdue—at the Sacklers’ direction—used its abuse-deterrent technology to deflect blame for the opioid crisis.

140. Meanwhile, on February 26, 2008, staff gave Jonathan, Kathe, Mortimer, and Richard Sackler projections indicating that OxyContin sales could plateau. Mortimer Sackler demanded answers to a series of questions about why sales would not grow. Richard Sackler

chimed in at 8:30 p.m. to instruct the staff to find answers “before tomorrow.” Staff emailed among themselves about how the Sacklers’ demands were unrealistic and harmful and then decided it was safer to discuss the problem by phone.

141. **In March**, Richard Sackler dug into Purdue’s strategy for selling more OxyContin. He directed sales and marketing staff to turn over thousands of pieces of data about sales trends, including data to distinguish the kilograms of active drug from the number of prescriptions, so he could analyze sales of higher doses. Staff delivered the data early Sunday morning; Richard Sackler responded with detailed instructions for new data that he wanted that same day. An employee sent Richard Sackler the additional data only a few hours later and pleaded with him: “I have done as much as I can.” The employee explained that he needed to attend to family visiting from out of town. Richard Sackler responded by calling him at home, insisting that the sales forecast was too low, and threatening that he would have the Board reject it. On Monday, staff emailed among themselves to prepare for meeting with Richard Sackler, indicating that the results he was looking for [REDACTED] more sales representatives. Meanwhile, Richard Sackler met with Acting President John Stewart to discuss his analysis of the weekend’s data and new graphs Richard Sackler had made.

142. Sales VP Russell Gasdia was struggling to handle the pressure. When Richard Sackler sent Gasdia a list of seven sales questions to answer on Saturday, March 8, 2008 (and copied Ilene, Jonathan, Kathe, Mortimer, and Theresa Sackler), Gasdia wrote to Acting President John Stewart:

John, I know it is tricky, but Dr Richard has to back off somewhat. He is pulling people in all directions, creating a lot of extra work and increasing pressure and stress. I will draft a response but he is not realistic in his expectations and it is very difficult to get him to understand.

143. Richard Sackler did not back off. Instead, he pushed staff to sell more of the highest doses of opioids and increase the pills in each prescription. That same Saturday night, Richard Sackler sent Gasdia yet another set of instructions, directing him to [REDACTED] [REDACTED] “exceeding 2007 Rx numbers on an adjusted basis (adjusted for strength and average number of tablets per Rx).” The very next day, Gasdia explained to him that [REDACTED] [REDACTED], such as adding sales representatives, promoting Purdue’s existing opioid savings cards, and promoting more intermediate doses of OxyContin.

144. Richard Sackler followed through on his weekend threat that he would have the Board reject the sales plan. Two days later, Richard Sackler circulated his own sales analysis to the Board, ordered the Secretary to “put this high in the Board agenda,” and proposed that he and Mortimer Sackler oversee a re-do of the annual plan as well as the 5-year plan for Purdue’s opioids.

145. At the same time, Jonathan, Kathe, and Mortimer Sackler were also pushing staff to grow sales. Staff told those three Sacklers that they would use opioid savings cards to meet the challenge of keeping OxyContin scripts at the same level in 2008 as in 2007, “in spite of all the pressures.” Kathe Sackler demanded that staff identify the “pressures” and provide “quantification of their negative impact on projected sales.” In New Jersey in 2008, Purdue’s sales representatives [REDACTED] [REDACTED]

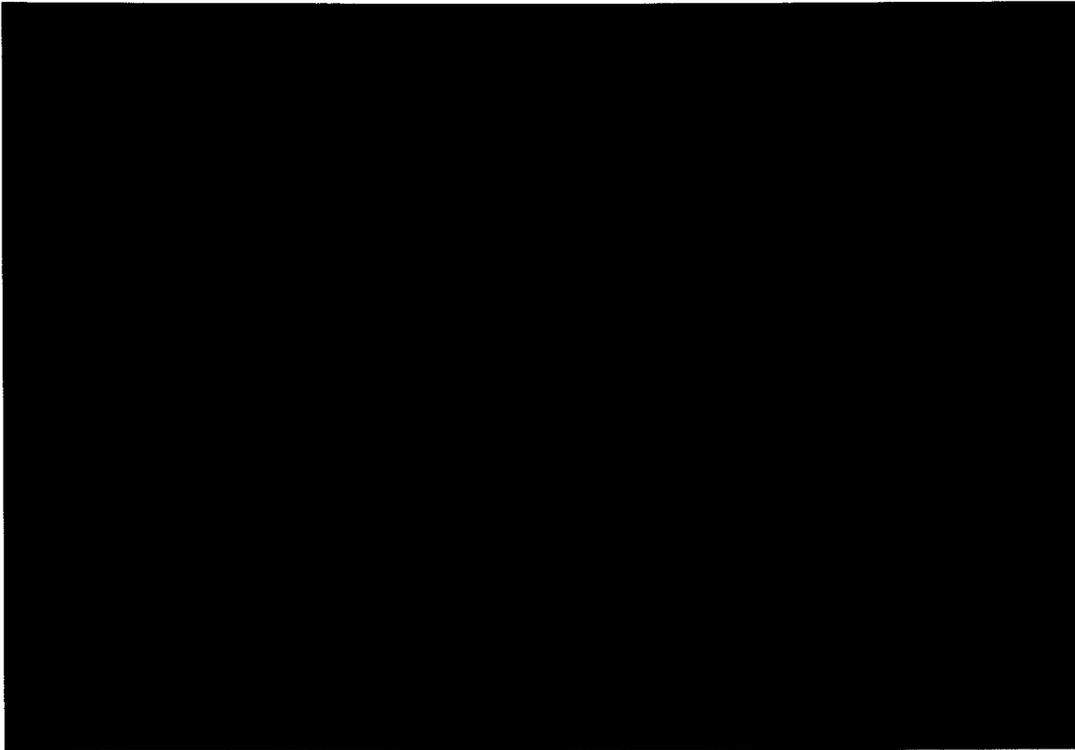
146. In April, staff reported to the Sacklers that Purdue employed 304 sales representatives. Staff also reported to the Sacklers that Purdue received 853 Reports of Concern about abuse and diversion of Purdue opioids in Q1 2008, and that they had conducted only 17 field inquiries in response. The same report also informed the Sacklers that Purdue received 83 tips to

its compliance hotline during the quarter, but did not report any of them to the authorities.

147. On April 18, Richard Sackler sent Kathe, Ilene, David, Jonathan, and Mortimer Sackler a secret memo about maintaining their profits. Richard Sackler wrote that Purdue's business posed a "dangerous concentration of risk," [REDACTED]

[REDACTED] After the criminal investigations that almost reached the Sacklers, Richard Sackler wrote that it was crucial to install a CEO 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." Richard Sackler recommended John Stewart for CEO because of his loyalty. Richard Sackler also proposed that the family should either sell Purdue in 2008 or, if they could not find a buyer, milk the profits out of the business and "distribute more free cash flow" to themselves.

148. That month, the Sacklers voted to have Purdue pay their family \$50,000,000. From the 2007 convictions until 2018, the Sacklers voted dozens of times to pay out Purdue's opioid profits to their family—in total more than four billion dollars.



OAG graphic based on Purdue's internal Board documents

149. When the Sacklers directed Purdue to pay their family, they knew and intended that they were paying themselves from opioid sales in New Jersey. Purdue and the Sacklers tracked revenue from [REDACTED]. For example, when the U.S. Centers for Disease Control warned that high doses of opioids endanger patients, staff reported to the Sacklers that [REDACTED]

[REDACTED] Similarly, prescription data on more than 500,000 individual prescribers that Purdue tracked from 2007 to 2017 confirm that [REDACTED] of Purdue sales. On information and belief, since May 15, 2007, the Sacklers paid their family many tens of million dollars out of revenues from New Jersey sales.

150. On April 18, the Sacklers voted to increase the 2008 Purdue budget for Sales and Promotion to \$155,802,000. Then, Richard Sackler sent Sales VP Russell Gasdia a series of

questions about Purdue's efforts to get patients to take higher doses and stay on opioids for longer times. Richard Sackler [REDACTED]

[REDACTED] He requested that sales staff be assigned to answer his questions "by tomorrow morning." When the sales staff asked for more time to collect the data, Richard Sackler agreed to give them until the end of the day.

151. Meanwhile, Purdue was in the process of seeking FDA approval for the abuse-deterrent reformulation of OxyContin. [REDACTED]

152. Also in April, Purdue's executives considered more ideas about ways to promote Purdue's opioids. The proposal matched the Sacklers' own plan, which Richard Sackler had concocted as CEO: deflect blame from Purdue's addictive drugs by stigmatizing people who become addicted. The proposal identified "KEY MESSAGES THAT WORK" including this dangerous lie: "It's not addiction, it's abuse[.] It's about personal responsibility[.]" On information and belief, staff sent the proposal to the Sacklers.

153. This narrative became the underpinning for Purdue's various deceptive messages designed to minimize the risk of addiction, as described in Section V.D.1. It also was the spark for Purdue's public relations strategy to obscure its misconduct by emphasizing all it was doing to combat the straw man of illicit abuse, even as it ignored the fundamental problem of overprescribing, as discussed in Section V.F.

154. Also in May, Purdue received pushback from an FDA advisory panel convened to

consider the company's application for approval of an abuse-deterrent formulation of OxyContin. The FDA's experts opined that they were unconvinced that the new formulation would be effective in the real world, and that indicating the tablets were somehow tamper-resistant might give doctors and patients the false impression that the drugs were not abusable or did not carry risks of addiction or overdose. [REDACTED]

155. In June, the Sacklers voted to appoint John Stewart as President and CEO of Purdue Pharma Inc. and Purdue Pharma LP. The appointment followed through on Richard Sackler's suggestion in his secret memo that the Sacklers should put a premium on loyalty to the family. On the same day, the Sacklers voted to pay their family \$250,000,000. The payment followed Richard Sackler's suggestion in the memo to "distribute more free cash flow" to themselves.

156. Meanwhile, Richard Sackler asked sales staff for information about a [REDACTED] opioid savings card program. Staff explained to Richard, Jonathan, Kathe, and Mortimer Sackler that [REDACTED], 67,951 unique opioid savings cards had been used in Purdue's current program, and that the cards provided a discount on a patient's first five prescriptions.

157. After five prescriptions, many patients would face significant withdrawal symptoms if they tried to stop taking opioids. Staff informed Richard, Jonathan, Kathe, and Mortimer Sackler that 27% of the savings cards had been used for all five prescriptions.

158. Also in June, [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED] As discussed in Section V.D.3, Purdue promoted its lowest-dose pills (10 and 15mg) for use by the elderly and opioid-naïve, even though it had no proof those doses were effective.

159. In July, Purdue's Fleet Department reported to the Sacklers that Purdue had bought one hundred new Pontiac Vibes for the expanded sales force. Staff also reported to the Sacklers that Purdue received 890 Reports of Concern regarding abuse and diversion of Purdue's opioids in Q2 2008 and had conducted only 25 field inquiries in response. Staff reported to the Sacklers that they received 93 tips to Purdue's compliance hotline during the quarter, but did not report any of them to the authorities.

160. Staff also told the Sacklers that they promoted Purdue opioids in presentations at Tufts University titled The Assessment and Management of Chronic Pain with an Emphasis on the Appropriate Use of Opioid Analgesics on April 25, and The Role of Urine Drug and other Biofluid Assays in Pain Management on June 26 and 27. Convincing prescribers that Purdue opioids could be used safely in conjunction with screening tools was a component of Purdue's deceptive messaging from 2007 to 2018, as discussed in Section V.D.1.b.

161. In September, the Sacklers voted to pay their family \$199,012,182.

162. In October, staff reported to the Sacklers that surveillance data monitored by Purdue indicated a "wide geographic dispersion" of abuse and diversion of OxyContin "throughout the United States." Staff reported to the Sacklers that "availability of the product" and "prescribing practices" were key factors driving abuse and diversion of OxyContin." The same report informed

the Sacklers that Purdue had begun a new “Toppers Club sales contest” for sales representatives to win bonuses, based on how much a representative increased OxyContin use in his or her territory. It also reported to the Sacklers that Purdue had received 163 tips to its compliance hotline during Q3 2008, but did not report any of them to the authorities.

163. Staff also told the Sacklers that the Board-ordered sales force expansion had been implemented and Purdue now employed 414 sales representatives. The Sacklers’ decision to expand the sales force caused the effect they intended in New Jersey. During Q3 2008, the number of sales visits to [REDACTED]

164. **In November**, the Sacklers turned to expanding the sales force again. Purdue’s 2009 budget identified expanding the sales force as the #1 sales and marketing objective. The Sacklers voted to spend [REDACTED]

[REDACTED] Staff reported to the Sacklers that an average sales representative’s salary would be \$89,708 with an average bonus of \$43,470, and the sales representatives would visit prescribers more than 518,000 times.

165. That same month, the Sacklers voted to pay their family \$325,000,000. They also voted to pay \$5,000,000 to Howard Udell—Purdue’s lawyer and a convicted criminal.

❖ ❖ ❖ 2009 ❖ ❖ ❖

166. **In February 2009**, Kathe Sackler instructed staff to report on Purdue’s grants and donations. Staff reported that [REDACTED]

[REDACTED]

167. **In March**, the Sacklers voted to pay Purdue sales representatives and sales managers bonuses of 103% of Purdue’s target because they sold so many opioids in 2008. The

Sacklers also voted to increase the base pay of sales staff for 2009. On the same day, the Sacklers voted to pay their family \$200,000,000.

168. In April, staff reported to the Sacklers that Purdue employed 412 sales representatives and had made dramatic progress promoting higher doses. [REDACTED]

[REDACTED] "For the first time since January 2008, OxyContin ® 80mg strength tablets exceeded the 40mg strength." [REDACTED] a detailed conversation with Sales VP Russell Gasdia about the staffing of the sales force, how many sales representatives the company should employ, and how many prescribers each representative would visit each year. The Sacklers authorized sales executives to hire a new staff member who would contact prescribers electronically and would promote Purdue opioids through the deceptive website Partners Against Pain.

169. Staff reported to the Sacklers that they received 122 tips to Purdue's compliance hotline during Q1 2009, and revealed one of them to an outside monitor. The report also informed the Sacklers that the compliance problems included improper use of OxyContin marketing materials and opioid savings cards.

170. [REDACTED]
[REDACTED]
[REDACTED]

171. In May, staff reported to the Sacklers that Purdue had violated its Corporate Integrity Agreement with the U.S. government by failing to supervise its sales representatives. Because sales representatives lobbying doctors poses a high risk of misconduct (no witnesses, and the representative is paid to increase opioid sales), the United States required that Purdue managers supervise sales representatives in person at least 5 days each year. Purdue management, however,

did not even set up a system to track the obligation. Even though Purdue executives had failed to monitor compliance with the requirement, they responded to the violation by firing three [REDACTED] employees in the field and letting all the executives [REDACTED] keep their jobs.

172. In June, Richard Sackler asked sales staff how a competing drug company had increased sales: “What is happening???” Staff replied that it was all about sales representatives:

They have 500 reps actively promoting to top decile MDs Their messaging is “we are not OxyContin”, alluding to not having the “baggage” that comes with OxyContin.

Interestingly, their share is highest with MDs we have not called on due to our downsizing [before 2008] and up until last year, having half as many reps. Where we are competing head to head, we decrease their share by about 50%.

173. A few days later, staff reported to the Sacklers that Purdue had expanded its sales force at the Board’s direction: “As approved in the 2009 Budget, 50 New Sales Territories have been created” Staff told the Sacklers the expansion was focused on the most prolific opioid prescribers, because “there are a significant number of the top prescribers” that Purdue had not been able to visit with its smaller force of sales representatives. Later that month, the Sacklers voted to pay their family \$162,000,000.

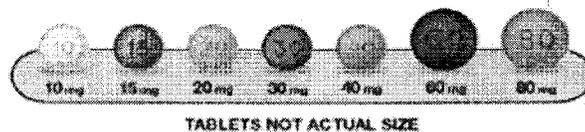
174. In July, staff reported to the Sacklers that Purdue employed 429 sales representatives. Richard Sackler wrote [REDACTED] that he was not satisfied with OxyContin sales and requested a plan to “boost” them. He asked for the topic to be added to the agenda for the Board.

175. In August, Richard Sackler convened a meeting of Board members and staff about “all the efforts Sales and Marketing is doing and planning to do to reverse the decline in OxyContin tablets market.” He emphasized that \$200,000,000 in profit was at stake. At the meeting, staff

told the Sacklers that the 80mg OxyContin pill was far-and-away Purdue's best-performing drug. Purdue sold many more kilograms of active ingredient in the 80mg dose than any other dose (almost 1,000 kilograms per month: literally a ton of oxycodone).

176. [REDACTED] informing the Sacklers about Purdue's newest OxyContin sales campaign, titled: Options. The Options campaign set the pattern that Purdue would follow for years: pushing doctors to "titrate" patients up to higher doses. To make it easy for sales representatives to promote higher doses, the campaign materials emphasized the "range of tablet strengths," provided a picture of each dose, and said: "You can adjust your patient's dose every 1 to 2 days." Staff told the Sacklers that they would advertise the Options campaign in medical journals reaching 245,000 doctors.

OPTIONS



**Through a wide range of tablet strengths,
OxyContin® provides options to meet the individual
therapeutic needs of your appropriate patient**

- Q12h dosing with as few as 2 tablets per day
- When converting from other opioids, the 7 OxyContin® Tablet strengths enable you to closely approximate the calculated conversion dose
- OxyContin® is a single-entity opioid
- You can adjust your patient's dose every 1 to 2 days, if needed, because steady-state plasma concentrations are approximated within 24 to 36 hours

Purdue's 2009 marketing campaign 'Options'

177. Staff also reported to the Sacklers that more than 160,000 patients had used Purdue's opioid savings cards, more than doubling the result reported to the Sacklers the summer before. Staff also told the Sacklers that they would advertise OxyContin using a special television network: thousands of doctors would be given free digital video recorders for their home televisions, in exchange for watching advertisements for drugs.

178. Immediately after meeting with sales staff, Richard Sackler asked for the raw data underlying their presentation. When staff had not responded within five minutes, he asked again.

179. **In September**, the Sacklers voted to pay their family \$173,000,000. But Mortimer Sackler demanded to know why staff predicted a decline in OxyContin sales when he believed the market should grow.

180. Also in September, [REDACTED]

[REDACTED]
[REDACTED]
[REDACTED]
[REDACTED] Purdue's public position on abuse-deterrent formulations furthered the Sackler-created narrative that abusers, not overprescribing, are the root of the opioid crisis, as discussed in Sections V.D.1.c and V.D.F.

181. **In October**, staff told the Sacklers that Purdue had expanded its sales force by an additional 50 territories and now employed 475 sales representatives. Richard Sackler directed staff to send him weekly reports on OxyContin sales. No one in the company received reports that often, so staff were not sure how to reply. Staff considered telling Richard Sackler that there were no weekly reports, but they decided to make a new report just for him instead. The CEO also instructed the Sales Department to report to the Board of Directors with more explanation about

its activities.

182. In November, the Sacklers voted to spend \$121,628,000 to employ sales representatives in 2010. Kathe and Richard Sackler were designated to review the sales projections. They also voted to pay disgraced former employee Howard Udell up to another \$1,000,000, and to pay \$2,700,000 to settle personal injury claims by people harmed by Purdue's opioids.

183. At the Board meeting that month, Kathe and Richard Sackler 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 provide a copy of a report from McKinsey, a business consulting firm hired by Purdue, on tactics to increase OxyContin sales and market share. The McKinsey report instructed sales representatives to maximize profits by "emphasizing [the] broad range of doses"—which, on information and belief, was a sales technique intended to sell more of the doses that were highest and most profitable.

184. At the same meeting, the Sacklers also asked staff, "What are OxyContin's clinical advantages vs. Opana ER, MS Contin, Kadian, Exalgo, Avinza, Nucynta and Duragesic? How are these differences communicated?" In response, staff reported to the Sacklers 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. These were all improper and deceptive claims.

185. The Sacklers also asked staff why Purdue's operating margin in 2010 was less than in 2009. Staff responded to the Sacklers that one of the biggest reasons was the cost of the expanded sales force—which the Sacklers had ordered.

186. **In December**, Kathe and Richard Sackler met with sales staff to review plans for 2010. Staff warned the two Sacklers that, although OxyContin sales were at record-breaking levels (nearly \$3 billion per year), the decade-long rise in the total kilograms of oxycodone ER prescribed in the United States was beginning to flatten—[REDACTED]. Higher doses contain more of that active ingredient and are more profitable to Purdue.

❖ ❖ ❖ 2010 ❖ ❖ ❖

187. **In January 2010**, Richard Sackler started the year by asking sales staff for new customized reports. Staff complained to each other until Sales VP Russell Gasdia asked CEO John Stewart to intervene: "Can you help with this? It seems like every week we get one off requests from Dr. Richard." Stewart [REDACTED]

[REDACTED] Days later, Richard was writing to the sales employee on Saturday morning, ordering that [REDACTED] and saying it was "urgent" and should be provided "this weekend."

188. That same month, [REDACTED]
[REDACTED]
[REDACTED]
[REDACTED]
[REDACTED]

189. Also in January, [REDACTED]
[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

190. **In February**, Purdue's Sales and Marketing Department told the Sacklers that a key objective for 2010 would be to "Meet or exceed total prescriber call targets of 545,000" visits to prescribers to promote Purdue opioids. For the next four years or more, a key objective for the sales employees was to meet a quota of sales visits, and the Sacklers tracked their performance. The target rose from 545,000 prescriber visits in 2010, to 712,000 visits in 2011, 752,417 visits in 2012, and 744,777 visits in 2013.

191. Staff also told the Sacklers that McKinsey estimated that new tactics by Purdue sales representatives would generate \$200,000,000 to \$400,000,000 more sales of OxyContin [REDACTED], and that sales representatives had been practicing the new tactics in front of management. McKinsey had reported to Purdue on opportunities to increase prescriptions by convincing doctors that opioids provide "freedom" and "peace of mind" and give patients "the best possible chance to live a full and active life." McKinsey also suggested sales "drivers" based on the ideas that opioids reduce stress and make patients more optimistic and less isolated. In fact, becoming addicted to opioids makes patients more stressed, more isolated, and less likely to survive. On information and belief, the Sacklers approved these new tactics.

192. The Sacklers voted to spend \$226,000,000 on Sales and Promotion in 2010, and to pay their family \$236,650,000.

193. **In March**, Richard Sackler instructed sales staff to send him monthly reports on sales of OxyContin and its competitors. They complied within ten minutes. The report showed

that sales of Purdue's 80mg OxyContin (the highest dose) [REDACTED]

194. Staff also told the Sacklers that a key selling point for OxyContin compared to a competitor's product was that OxyContin could be used by patients who had not taken opioids before. Deceptively promoting opioids for patients who had not taken them before, also referred to as opioid-naïve patients, was one of the ways Purdue put patients at risk, as discussed in V.D.3.

195. In April, the Sacklers voted to pay their family another \$141,000,000.

196. Meanwhile, staff told the Sacklers that Purdue was pushing back against the "threat" of public health rules that would limit high doses of opioids. They told the Sacklers [REDACTED]

[REDACTED]

197. [REDACTED]

[REDACTED]

198. [REDACTED] Purdue was pushing high doses with great success. [REDACTED]

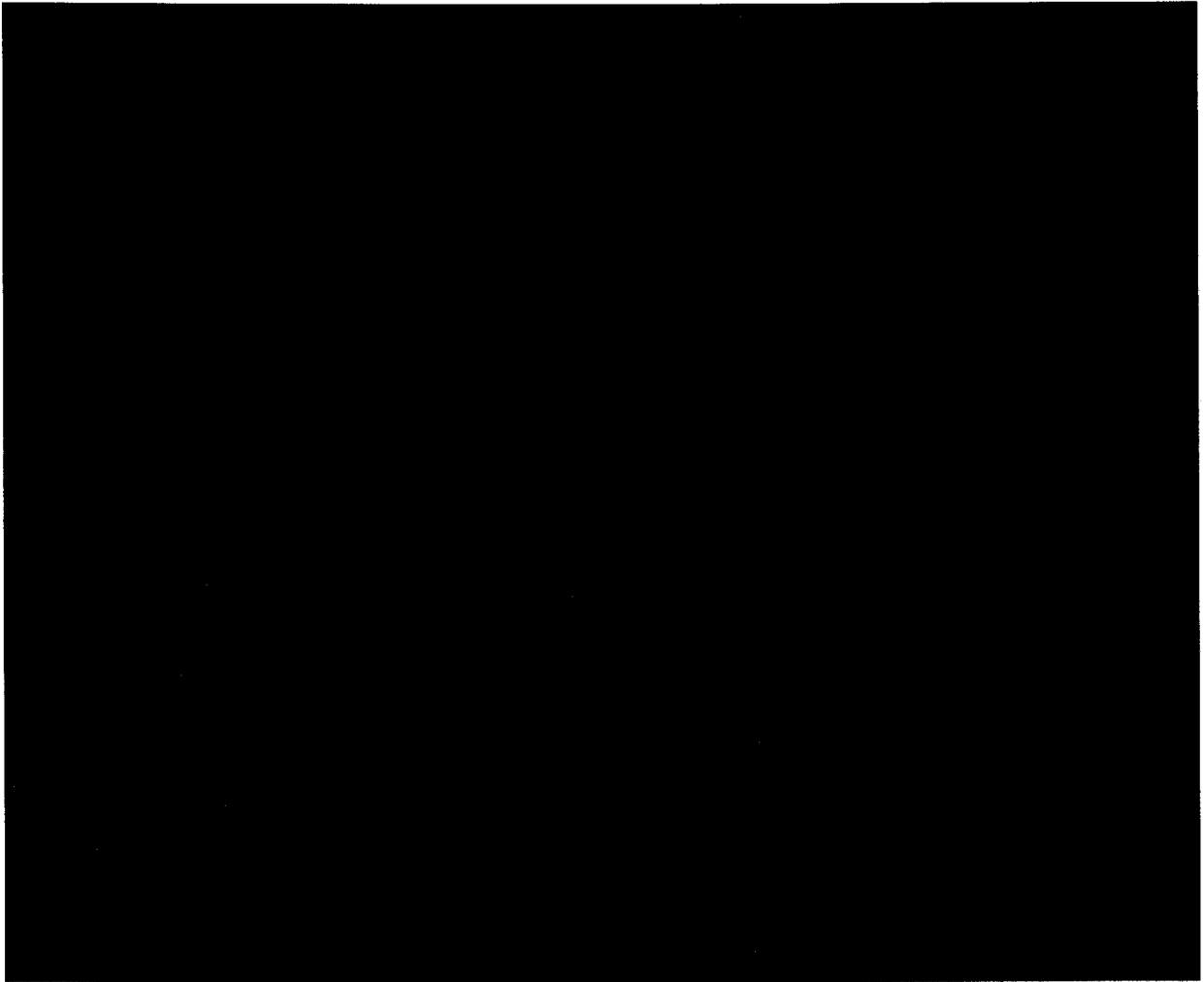
[REDACTED]

❖ ❖ ❖ The Sacklers' Control of Sales Visits ❖ ❖ ❖

199. That same month (April 2010), staff gave the Sacklers one of many detailed reports on sales representatives' visits to prescribers. As with every reference to "the Sacklers" before July 2012, that includes Beverly, Ilene, Jonathan, Kathe, Mortimer, Richard, and Theresa Sackler.

200. Acting on the Sacklers' repeated insistence on increasing sales projections, Purdue required each sales representative to visit an average of 7.5 prescribers per day. In April 2010, staff reported that they were falling short. During Q1 2010, representatives had averaged only 7.0 visits per day. Staff promised to try harder. Purdue continued to set a target for daily sales visits for every sales representative, and the Sacklers tracked the results, quarter by quarter, for at least the next four years in marketing plans and updates provided to the Board. The results were always close to 7 visits per day.

201. Purdue also set targets for the total number of sales visits by the entire sales force per quarter—huge numbers that were always more than a hundred thousand visits. Meeting those targets was a top priority for the entire company. For Q1 2010, the target was to visit prescribers 127,376 times. Staff told the Sacklers that Purdue employed 489 sales representatives and that, during Q1 2010, they achieved the goal.



OAG graphic based on Purdue's internal Board documents

202. During every quarter, sales representatives [REDACTED]

[REDACTED]

[REDACTED]

203. The Sacklers also tracked the cost of the sales visits. In April 2010, staff reported to the Sacklers that each visit to a prescriber cost Purdue \$219, and they were working to lower the cost to a target of \$201.

❖ ❖ ❖

204. In June 2010, Purdue staff completed an updated 10-year plan for growing

Purdue's opioid sales. On information and belief, based on distribution of other 10-year plans, this plan was presented to the Sacklers. According to the plan, the Sacklers were to receive at least \$700,000,000 each year from 2010 through 2020. Beginning on page one, staff emphasized that selling this volume of opioids "will require significant salesforce support." The plan detailed the "optimization" of sales visits and the number of representatives they would require. Sales VP Gasdia wrote that they planned for each representative to visit prescribers 1,540 times per year, so that 500 representatives could make 770,000 visits at a cost of \$212 per visit. He proposed to grow the sales force to 1,050 sales representatives by 2015. To reach the Sacklers' expectations, the plan projected that Purdue would convince doctors to switch patients from short-acting opioids and opioid-combination drugs (drugs that combined an opioid with acetaminophen or ibuprofen) to Purdue's soon-to-be-released Butrans opioid, and that Butrans would become a billion-dollar drug.

205. In July, Richard Sackler emailed staff just before the July 4th holiday weekend to demand more details about sales and marketing. Richard Sackler directed them to send to the Board plans for "the marketing program" and "the sales program," with instructions to "█ get this out before the weekend." A staff member wrote to the CEO: "Are you expecting us to provide the marketing plan by tomorrow?" █

█ Staff promised to provide full details about sales and marketing at the July Board meeting. Kathe Sackler then asked staff to circulate the materials before the meeting.

206. At a Board meeting in Bermuda, the Sacklers focused on sales tactics again. Staff presented plans for selling Purdue's new Butrans opioid. Staff told the Sacklers that they had

identified [REDACTED] prescribers to target with the Butrans sales campaign. Staff reported that they planned to add 125 sales representatives and increase the number of prescriber visits by more than 30%.

207. The Board (the Sacklers, and at that point, three other directors) responded with numerous questions and orders about the sales campaign. The Board asked staff to determine whether sales would increase if they gave doctors free samples of opioids, even though Purdue had expressly agreed in the 2007 Settlements to stop distributing samples of OxyContin. The Board requested details about tactics Purdue sales staff used to influence doctors that Purdue viewed as "key opinion leaders," who could influence other doctors to prescribe more opioids: "Provide the Board with more information on the strategy/tactics with respect to KOL's, 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."

208. In New Jersey, [REDACTED]
[REDACTED]
[REDACTED]

209. [REDACTED]
[REDACTED]
[REDACTED]
[REDACTED]

210. The Board pushed staff on whether they were describing the benefits of opioids aggressively enough. Purdue was not legally allowed to claim that Butrans was effective for 7 days because the evidence did not support that claim. Nevertheless, the Board wanted to know

why Purdue did not claim 7 days of effectiveness in its marketing.

211. Purdue was not legally allowed to claim that Butrans was effective for osteoarthritis (“OA”) because the clinical trials testing Butrans for patients with OA had failed. Despite this, the Board wanted to know if sales representatives could remain silent about the failed trial: “What can be said in response to a prescriber who asks directly or indirectly, ‘can this product be prescribed for my patient with OA?’ In responding are we required to specifically mention the failed trials in OA, [REDACTED]”

❖ ❖ ❖ Region Zero ❖ ❖ ❖

212. At the July 2010 Board meeting in Bermuda, the Sacklers and other Board members asked staff about opioid sales generated by doctors who were suspected of diversion and abuse, which Purdue had collected on a list code-named Region Zero. Staff assured the Board that Purdue tracked prescriptions by Region Zero doctors, including the exact prescriptions, units, and dollars from each prescriber. Staff told the Board that Purdue had identified [REDACTED] as likely involved in diversion and abuse. Staff gave the Board a list of the specific problem prescribers by name, address, and specialty, along with the exact number of prescriptions and dollars of revenue each provided to Purdue.

213. For example, staff reported to the Board that Purdue [REDACTED]
[REDACTED] Staff reported to the Board that, [REDACTED]
[REDACTED]

214. Staff also reported to the Board that Purdue [REDACTED]
[REDACTED] Staff reported to the Board that, [REDACTED]

[REDACTED]

215. [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]



216. At that same Board meeting in Bermuda, the Sacklers voted to pay \$10,000,000 to settle lawsuits by people injured by OxyContin.

217. Later that month, staff told the Sacklers that Purdue employed 491 sales representatives and that, during Q2 2010, they visited prescribers 135,824 times. [REDACTED]

[REDACTED] Meanwhile, staff told the Sacklers that Purdue had paid their family \$389,200,000 in the first six months of 2010.

218. **In August**, the Sacklers continued to focus on the sales force. That month, Purdue decided not to acquire a new insomnia drug because of the risk that promoting it could distract sales representatives from selling Purdue's opioids. Richard Sackler concluded that "loss of focus" in sales representatives' meetings with prescribers was too great a risk, and Purdue decided not to go through with the deal.

219. A few days later, the Sacklers received information regarding the abuse of OxyContin. Staff told them that the most common way of abusing oxycodone, by far, was swallowing it—which a crush-proof coating on OxyContin did not affect. Staff also reported to the Sacklers that data from one state's prescription monitoring program showed far higher rates of

“doctor-shopping” for OxyContin prescriptions than for other long-acting opioids. The prescription monitoring program identified “doctor-shopping” when a patient gets opioids from multiple prescribers—an indication that the patient is at risk of addiction, overdose, and death.

220. **In September**, staff discussed the Board’s July 2010 decision to hire more sales representatives. Staff said they were working to implement the decision, adding 125 sales territories. Staff also reported that 82% of prescriptions for OxyContin were to patients who were already on the drug—a key part of Purdue and the Sacklers’ plans to keep patients on opioids longer. The same month, the Sacklers voted to pay their family \$240,000,000.

221. **In October**, staff told the Sacklers that Purdue employed 506 sales representatives and, during Q3 2010, they visited prescribers 141,116 times. [REDACTED]

222. Meanwhile, staff told the Sacklers that Purdue had paid their family \$629,000,000 in the first nine months of 2010. The Sacklers voted to pay another \$12,000,000 to settle claims of more patients injured by OxyContin.

223. At the September Board meeting, [REDACTED]

[REDACTED] In October, [REDACTED]

224. [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

225. In November, staff warned the Sacklers that doctors were not prescribing Purdue's highest dose and most profitable opioids as much as the company had expected, so it might be necessary to cut the family's quarter-end payout from \$320,000,000 to \$260,000,000 and distribute it in two parts: one in early December and one closer to the end of the month. Mortimer Sackler objected to the decrease and the division into two payments, and he demanded answers from staff: "Why are you BOTH reducing the amount of the distribution and delaying it and splitting it in two?" "Just a few weeks ago you agreed to distribute the full 320 [million dollars] in November."

226. Staff also reported that the expansion of the sales force that the Sacklers had ordered was being implemented. The Sacklers voted to spend \$158,086,000 to employ sales representatives in 2011.

227. Staff also reported to the Sacklers that drug company leaders can be punished for breaking the law and "owners, officers, and managers will especially face even more serious scrutiny in the future."

228. In December, the Sacklers voted to pay their family \$260,000,000.

❖ ❖ ❖ 2011 ❖ ❖ ❖

229. In 2011, the Sacklers continued to direct Purdue's deceptive sales tactics and give themselves multi-million-dollar payouts. In January, the Sacklers voted to pay the legal expenses of specific individuals if they were defendants or witnesses in investigations of Purdue, including several sales executives and John Crowley, Executive Director of Controlled Substances Act

Compliance. The Sacklers knew these employees were aware of misconduct because they had directed it. In September 2009, a Purdue sales manager had emailed Crowley that Purdue was promoting opioids to an illegal pill mill. In his email to Crowley, the sales manager wrote: "I feel very certain this is an organized drug ring," and asked, "Shouldn't the DEA be contacted about this?" Purdue sat on the information and did not report it to the authorities for more than two years, until after the pill mill doctor had already been arrested and the Sacklers had arranged for lawyers in case Crowley was questioned.

230. In January 2011, staff reported to the Sacklers that a key initiative in Q4 2010 had been the expansion of the sales force. Staff told the Sacklers that Purdue employed 590 sales representatives and, during Q4 2010, they visited prescribers 125,712 times. [REDACTED]

231. Staff told the Sacklers that Purdue paid their family \$889,000,000 in 2010. But staff reported that Purdue's revenue was still hundreds of millions of dollars less than expected because doctors were prescribing less of Purdue's highest dose opioids. Staff told the Sacklers that sales of the highest doses continued to fall below expectations, and the gap had cost the company \$120,000,000 in the month of December 2010 alone. The Sacklers faced the prospect of shrinking payouts if doctors did not prescribe more of the highest doses.

232. Also in January 2011, Richard Sackler met with sales representatives for several days at the Butrans Launch Meeting and discussed how they would promote Purdue's newest opioid. Richard Sackler quickly followed up with sales management to demand a briefing on how the sales visits were going in the field:

I'd like 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?

233. Richard Sackler's interventions into sales tactics made employees nervous. When Richard followed up to ask for information "tomorrow," CEO John Stewart tried to slow things down, warning staff that such requests would be "never-ending."

234. Two hours after sending his request, Richard Sackler asked Sales VP Russell Gasdia to call him, on a Sunday morning, on his cell phone. He wanted to discuss "the resistance" to Butrans and how Purdue's sales representatives were "overcoming" it right away.

235. Richard Sackler kept pushing for more sales. After one week of prescriptions doubled Purdue's forecast, Richard Sackler wrote to Gasdia: "I had hoped for better results." In a follow-up message, Richard Sackler asked staff to tell him the ratio of prescriptions per sales representative visit to a prescriber, divided out by the prescribers' specialties. He asked for a Board discussion of the barriers that sales representatives were encountering during promotion. After trying to answer Richard Sackler's questions and getting another dissatisfied response, [REDACTED] wrote to the CEO, asking him to intervene. In a later message, Richard Sackler wrote to the staff again: "What do I have to do to get a weekly report on Butrans sales without having to ask for it?" One staff member asked [REDACTED] to respond. The CEO announced that, from then on, staff would send a sales report to the Sacklers every week. When staff sent the first weekly report, Richard Sackler responded immediately: "What else more can we do to energize the sales and grow at a faster rate?"

236. Mortimer Sackler also pressed staff for more information about sales. When two days passed without an answer to Richard and Mortimer Sackler's inquiry, Mortimer inquired: "Any answer to this yet?" Staff rushed to prepare answers to share with all the Sacklers.

237. The people who worked for the Sacklers knew their appetite for sales was extreme.

Although the launch of Purdue's Butrans opioid was on track to beat every drug in its class, Richard Sackler asked the CEO and Sales VP: "Do you share my disappointment [regarding the trajectory of Butrans prescriptions]?" Gasdia replied privately to the CEO: "as far as his disappointment, I do not share that."

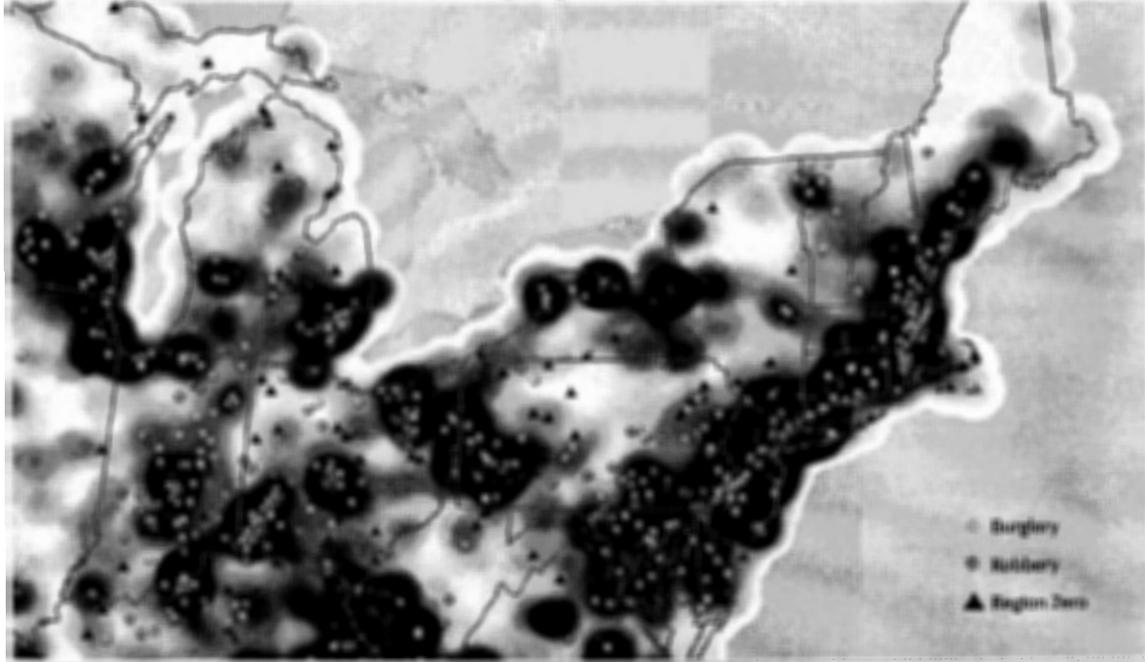
238. In February, staff reported to the Sacklers that law enforcement was increasingly concerned about lawbreaking by drug companies and the resulting "danger to public safety." Staff also told the Sacklers that Purdue was receiving a rising volume of hotline calls and other compliance matters, reaching an all-time high during Q4 2010. Staff informed the Sacklers that sales representatives had engaged in improper promotion of Purdue opioids, but the company had decided not to report the violations to the government. Staff also reported to the Sacklers about the risks of OxyContin, including that 83% of patients in substance abuse treatment centers began abusing opioids by swallowing pills, and that it took, on average, 20 months for a patient to get treatment. Staff reported to the Sacklers that Purdue tracked at the level of individual zip codes the correlation between poison control calls for OxyContin overdose, pharmacy thefts, and Region Zero prescribers Purdue suspected of abuse and diversion.

239. Staff even gave the Sacklers a map correlating dangerous prescribers in New Jersey with reports of oxycodone poisonings, burglaries, and robberies.

We are examining the spatial relationship between different aspects of the abuse environment

ILLUSTRATIVE

Poison Control oxycodone exposure call density, Region Zero prescribers, and pharmacy theft



SOURCE: AAPCC, PPLP, RxPatrol

13

Map presented to the Purdue Board in 2011

240. **In March**, staff reported to the Sacklers on OxyContin sales and again focused on revenue from doctors in Region Zero—prescribers that Purdue suspected of improper prescribing but that Purdue had not reported to the authorities. Staff told the Sacklers that if Region Zero doctors stopped prescribing opioids, Purdue would lose almost 10% of its sales.

241. **In April**, the Sacklers met with Sales VP Russell Gasdia to talk about sales. He told them that OxyContin was the best-selling painkiller in America, with more than three billion dollars in annual sales—almost double the second-place drug. The Sacklers voted to pay their family \$189,700,000.

242. **In May**, in response to the Sacklers' repeated requests, staff sent Richard, Jonathan, Kathe, Mortimer, and Theresa Sackler a report on the sales tactics representatives were using to

push Butrans. The first tactic reported to these Sacklers was focusing on a select “core” of physicians that Purdue calculated would be most susceptible to sales representatives lobbying to prescribe more opioids. [REDACTED]

243. The second tactic staff reported to Richard, Jonathan, Kathe, Mortimer, and Theresa Sackler in the May 25, 2011 email was “positioning of Butrans for specific patient types.” [REDACTED]

[REDACTED] promotion for “specific patient types” often meant pushing opioids for elderly patients. [REDACTED]

[REDACTED] From 2007 to 2018, expanding Purdue’s captive customer base by promoting opioids for the elderly was a key tactic of the sales force, including in New Jersey, as discussed in Section V.D.3.

244. A third tactic reported to these five Sacklers was getting prescribers to commit to put specific patients on opioids. [REDACTED]

[REDACTED]

make sales visits every week. [REDACTED]

249. The Sacklers immediately pushed to find ways to increase sales. Richard Sackler asked Sales VP Russell Gasdia to include him in a meeting with District Managers who were the day-to-day supervisors of the sales representatives. Then, having missed the meeting, he engaged Gasdia again by email, [REDACTED]

[REDACTED] Gasdia told Richard Sackler that Purdue had hired 147 new sales representatives at the Board's direction. Gasdia also told him that Purdue instructed the sales representatives to focus on converting patients who had never been on opioids or patients taking "low dose Vicodin, Percocet, or tramadol"—all patients for whom Purdue's opioids posed an increase in risk.

250. [REDACTED]

251. In an email message, Gasdia told Richard Sackler (again) that Purdue instructed sales representatives to focus on the few highest-prescribing doctors in their territory and visit them over and over. Gasdia also told Richard Sackler that staff had initiated performance enhancement plans for sales representatives who were not generating enough opioid prescriptions.

252. In response to Gasdia's message about the sales representatives, Richard Sackler wrote back six minutes later and asked to meet with Gasdia without delay. Gasdia scheduled a meeting about sales tactics with Richard for first thing the next morning. Richard Sackler would not wait until the morning and instructed Gasdia to call him that same day.

253. Richard Sackler continued the correspondence that day, criticizing Purdue's managers for allowing sales representatives to target "non-high potential prescribers." "How can

our managers have allowed this to happen?" Richard insisted that sales representatives push the doctors who prescribed the most drugs.

254. To make sure his orders were followed, Richard Sackler demanded to be sent into the field with the sales representatives. He wanted a week shadowing Purdue sales representatives, two representatives per day. Gasdia appealed to Purdue's Chief Compliance Officer, warning that Richard Sackler promoting opioids was "a potential compliance risk." Compliance replied: "LOL." Staff instructed: "Richard needs to be mum and be anonymous." Excerpts from the staff emails regarding Richard Sackler's request to shadow sales representatives in the field appear below.

To: Gasdia, Russell[Russell.Gasdia@pharma.com]
From: Weinstein, Bert
Sent: Thur 6/16/2011 7:47:14 PM
Subject: Re: Feedback from District Manager Advisory Council - FYI

LOL - I told him you raised concerns with me. We agreed Richard needs to be mum and be anonymous

From: Gasdia, Russell
To: Weinstein, Bert
Sent: Thu Jun 16 17:08:15 2011
Subject: Fw: Feedback from District Manager Advisory Council - FYI

I spoke to John and he said Stuart cleared Dr Richard observing calls with reps. I told him I spoke with you and you have concerns...he said he'd speak with you.

From: Sackler, Dr Richard
To: Gasdia, Russell
Cc: JHS (US)
Sent: Thu Jun 16 16:45:56 2011
Subject: Re: Feedback from District Manager Advisory Council - FYI

Russ,
One more thing. Who have you chosen for me to go to the field with the week after the budget meetings? Where are they? Can we conveniently do two reps each day especially if I travel to get to the right place as I probably should do.

Purdue internal emails

255. Several Purdue executives, including the CEO, got involved in planning Richard Sackler's sales visits. All of them were worried. One wrote:

About 5 last night, John [Stewart, the CEO] was walking by my office—I yelled out to stop him—and said that you had mentioned to me that Richard wanted to go into the field, and that you had raised concerns with me. John seemed angry, and asked if I had concerns. I told him could be issues and Richard could be out on a limb if he spoke about product at all or got into conversations with HCPs [health care providers], or identified himself, especially with FDA Bad Ad possibilities. John agreed Richard would have to be mum throughout, and not identify himself other than as a home office person.

256. Richard Sackler indeed went into the field to promote opioids to doctors alongside a sales representative. In a conversation about his field contact, Richard Sackler argued to the VP of Sales that a legally required warning about Purdue's opioids was not needed. He asserted that the warning "implies a danger of untoward reactions and hazards that simply aren't there." He insisted there should be "less threatening" ways to describe Purdue opioids.

257. Meanwhile, the Sacklers voted to pay their family \$200,000,000.

258. A few days later, sales and marketing staff again rushed to prepare responses to questions from the Sacklers. Mortimer Sackler asked about launching a generic version of OxyContin to "capture more cost sensitive patients." Kathe Sackler recommended looking at the characteristics of patients who had switched to OxyContin to see if Purdue could identify more patients to convert. Jonathan Sackler wanted to study changes in market share for opioids, focusing on dose strength.

259. At the same time, sales staff were organizing more ways for Richard Sackler to oversee their work in the field. Gasdia proposed to Richard Sackler:

In addition to field contacts with representatives, you may want to consider attending one of the upcoming conventions where we will be attending. At each of the ones listed below, we will have a

promotional booth for OxyContin & Butrans. In addition, we are sponsoring educational programs for Butrans and OxyContin in the form of a 'Product Theater.'

This would provide you the opportunity to be on the convention floor, observing numerous presentations being provided by our representatives and see a wide range of interactions over the course of a day. In addition, we can arrange for one-on-one meetings with key opinion leaders who are attending, many of them are approved consultants/advisors for us and you can have some open conversations regarding the market, perceptions around Butrans and OxyContin. Finally, you could observe the Product Theaters we are implementing.

260. **In August**, staff told the Sacklers that Purdue employed 640 sales representatives and, during Q2 2011, they visited prescribers 189,650 times. [REDACTED]

261. Meanwhile, staff reported to the Sacklers that, in the first seven months of 2011, Purdue paid the family \$211,000,000.

262. **In September**, Richard Sackler directed staff to study a savings card program for a widely used cholesterol medication (not an addictive narcotic) to learn how Purdue could use it for opioids. That same month, the Sacklers voted to pay their family \$140,800,000 more.

263. **In November**, staff told the Sacklers that Purdue still employed 640 sales representatives and, during Q3 2011, they visited prescribers 189,698 times. [REDACTED]

[REDACTED] Looking ahead, the Sacklers voted to spend \$162,682,000 to employ sales representatives in 2012.

264. [REDACTED]

[REDACTED] This and other Purdue publications advanced the false public relations narrative—first conceived by Richard Sackler—that illicit drug abuse, not overprescribing, was the root of the opioid crisis, as discussed in

Section V.F.

265. Meanwhile, staff told the Sacklers that, in the first nine months of 2011, Purdue paid their family \$551,000,000.

266. In December, [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

❖ ❖ ❖ 2012 ❖ ❖ ❖

267. In January 2012, Jonathan Sackler started the year pressing Sales VP Russell Gasdia for weekly updates on sales. A few days later, Richard Sackler raised concerns to staff about Purdue's online advertising. He noticed that online ads appeared indiscriminately on webpages with content associated with the ad—regardless of whether the association was positive or negative. Staff assured Richard Sackler that, when Purdue bought online advertising for opioids, it specified that the ads appear only on pages expressing positive views toward opioids, and would not appear with articles “about how useless or damaging or dangerous is our product that we are trying to promote.”

268. That same month, staff told the Sacklers that Purdue employed 632 sales representatives and, during Q4 2011, they visited prescribers 165,994 times. [REDACTED]

[REDACTED]

269. The Sacklers were not satisfied with the sales effort. In February, staff reported to the Sacklers that prescriptions had dropped, and that a decrease in sales representative visits to

prescribers was a major driver of the decline. Staff asked the Sacklers to be patient, because representatives had missed work for December holidays and the company's mandatory National Sales Meeting in January. Mortimer Sackler was not pleased. He suggested that "in future years we should not plan the national sales meeting so close following the winter break as it extends the period of time since the doctor last saw our rep." Mortimer Sackler further wrote: "Wouldn't it be better to have the reps get back to work for January and back in front of doctors." Mortimer Sackler was agitated by the thought of doctors going too many days without a sales representative visiting to promote Purdue opioids. If Purdue rescheduled its meeting, "[a]t least then the doctors will have gotten at least one reminder visit from our reps in the last month whereas now they might go two months without seeing one of our reps??" Staff replied to Mortimer Sackler, arguing for "balance." Richard Sackler replied within minutes that, since the National Sales Meeting prevented sales representatives from visiting doctors, "Maybe the thing to have done was not have the meeting at all." Purdue's compliance officer forwarded the exchange to his staff, commenting: "Oh dear."

270. Meanwhile, Richard Sackler interrupted sales multiple times daily, often in a hurry: "I had hoped you would have updated this," "Will I have it by noon?" "[G]et to this ASAP." Staff advised each other: "avoid as much e mail with dr. r as you can." Sales VP Gasdia wrote to the CEO: "I'm not sure what we can do about Dr. Richard."

271. Also in February, staff sent the Sacklers [REDACTED]

[REDACTED]

[REDACTED]

272. Throughout the spring, the Sacklers pressed staff to promote Purdue's opioids more aggressively. In February, Gasdia wrote to sales staff that the Board of Directors ("BOD") was

not satisfied with the money coming in: "Things are not good at the BOD level." When sales dropped for one week on account of the Presidents' Day holiday, Richard Sackler wrote to sales management: "This is bad." Gasdia forwarded Richard's message to his colleagues, asking how they could "create a greater sense of urgency at the regional management and district management level."

273. Meanwhile, Gasdia urged the CEO to defend him [REDACTED] against Richard Sackler's micromanagement of sales: "Anything you can do to reduce the direct contact of Richard into the organization is appreciated." A week later, Richard wrote to sales management again to criticize them for U.S. sales being "among the worst" in the world.

274. In March, staff sent the Sacklers a revised 2012 budget that cut the proposed payout to their family from \$472,500,000 to \$418,200,000.

275. On one Saturday morning, Richard Sackler wrote to marketing staff, demanding monthly data for all extended release pain medications for the past twelve years and an immediate meeting that Monday night. Gasdia [REDACTED]

[REDACTED] Do let us know how this goes." Later that month, staff created for Richard Sackler a historical summary of key events determining OxyContin sales. Eleven of the key events in sales history were changes in the size of the Purdue sales force—all known to Richard Sackler because the Sacklers had ordered them.

276. A few days later, staff sent Richard Sackler an assessment of recently improved opioid sales. Staff told Richard that the increase in prescriptions was caused by tactics that Purdue taught sales representatives: pushing opioids for elderly patients ("proper patient selection") and encouraging doctors to use higher doses of opioids ("quick titration"). In the coming months, Purdue would study, document, and expand the use of higher doses to increase sales.

277. Richard Sackler wrote that he was not satisfied with a report on sales and instructed Gasdia to discuss it with him within a day. Then Richard Sackler raised the stakes and asked Gasdia to address both Butrans sales tactics and a decline in OxyContin sales and propose corrective actions. John Stewart suggested that Richard Sackler's frustrations could be linked to dosing. He encouraged Gasdia to tell Richard Sackler that patients on lower doses seemed to stop taking opioids sooner, and that much of the profit that Purdue had lost had been from doctors backing off the highest dose of OxyContin (80mg).

278. Richard Sackler was not satisfied. Days later, after sales did not increase, staff told him that they were starting quantitative research to determine why patients stay on opioids, so they could find ways to sell more opioids at higher doses for longer.

279. In April, staff told the Sacklers that Purdue employed 630 sales representatives and, during Q1 2012, they visited prescribers 179,554 times. [REDACTED]

280. Meanwhile, Richard Sackler kept pushing the staff to increase sales. When the mandatory weekly report to the Sacklers showed that sales representatives achieved 9,021 [REDACTED] prescriptions in a week, Richard Sackler asked Sales VP Russell Gasdia for a commitment that the representatives would get weekly prescriptions to 10,000: "Are you committed to breaking 10K/wk Rx's this month?" A colleague replied to Gasdia: "Is there any question of your commitment?"

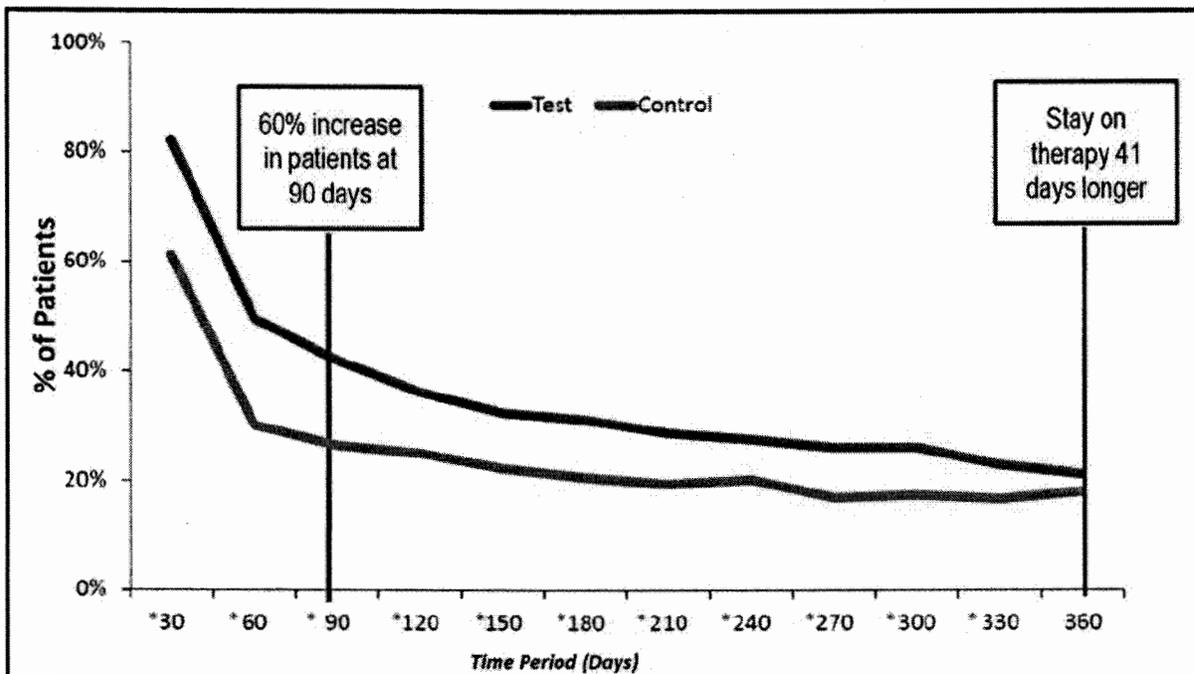
281. Gasdia tried to assure Richard Sackler that Purdue was selling opioids aggressively: "Windell and the sales force, as well as Mike and the marketing team (initiatives being implemented) are focused and committed to accelerating the growth trend . . . everyone in the commercial organization is focused on exceeding the annual forecast." Richard Sackler wanted

more. He wanted to know what tactics sales staff would use to get more prescriptions, and he wanted to talk about it right away. First he wrote: “give me the table of weekly Rx plan and the actual. Then show how you plan to make up the current shortfall.” Then he asked for a meeting within 24 hours. Then Richard Sackler did not want to wait that long: “Can we meet in person today?”

282. **In May**, executives emphasized to the managers overseeing sales representatives, [REDACTED] that the Sacklers were tracking their efforts, and that Richard Sackler required weekly reports. Staff gave the only reply that was acceptable at Purdue: “All our efforts are focused on attaining the objective” of increased opioid prescriptions that the Sacklers set.

283. **In June**, the Sacklers discussed sales and marketing again. Staff reported to the Sacklers that they had added 120,000 sales visits to drive sales of OxyContin.

284. Staff also told the Sacklers that they expanded the use of opioid savings cards, because Purdue’s latest data showed opioid savings cards led to 60% more patients remaining on OxyContin longer than 90 days. The Sacklers reviewed the results of Purdue’s confidential studies showing that opioid savings cards kept more patients on opioids for 90 days, 120 days, 150 days, 180 days, 210 days, 240 days—even an entire year.



Purdue internal analysis about keeping patients on opioids longer

Keeping patients on opioids for these lengths of time was especially dangerous for the patients and especially profitable for Purdue.

285. Staff also told the Sacklers (as they had in 2009) that they were again targeting prescribers for OxyContin promotion through a special television network, the “Physicians Television Network.” [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

286. In July, David Sackler (Richard Sackler’s son) took a seat on the Board. For events after July 2012, this Complaint includes David in “the Sacklers.”

287. Staff also told the Sacklers that Purdue employed 633 sales representatives and, during Q2 2012, they visited prescribers 183,636 times. [REDACTED]

[REDACTED]

288. In August, the Sacklers voted to direct Purdue to recruit an additional marketing executive and make candidates available to meet with members of the Board.

289. In November, staff told the Sacklers the results of [REDACTED] study of 57,000 patients that Purdue performed explicitly to determine how opioid dose “influences patient length of therapy.” The results showed that patients on the highest doses “are the most persistent.” The “Recommended Actions” presented to the Sacklers included “additional workshops for the sales force” and “specific direction” to the sales representatives about using higher doses to keep patients on drugs longer. Staff told the Sacklers that encouraging higher doses “is a focal point of our promotion,” and that sales representatives would “emphasize the importance” of increasing patients’ opioid doses, as soon as three days after starting treatment.

290. That same month, the Sacklers voted to set Purdue’s budget for Sales and Promotion for 2013 at \$312,563,000. Staff told the Sacklers that Purdue employed 622 sales representatives and, during Q3 2012, they visited prescribers 180,723 times. [REDACTED]
[REDACTED]

❖ ❖ ❖ 2013 ❖ ❖ ❖

291. In January 2013, in what was becoming a yearly ritual, Richard Sackler questioned staff about the drop in opioid prescriptions caused by Purdue sales representatives taking time off for the holidays: “Really don’t understand why this happens. What about refills last week? Was our share up or down?” Staff assured him that doctors were “sensitive” to sales representative visits and, as soon as the representatives resumed their schedules, they would “boost” opioid prescriptions again.

292. Staff told the Sacklers that they continued to reinforce the Individualize The Dose campaign, which the Sacklers knew and intended would promote higher doses. Staff also told the

Sacklers that sales representatives would place greater emphasis on the opioid savings cards, which the Sacklers knew and intended would keep patients on opioids longer. Staff reported to the Sacklers that Purdue had conducted a sensitivity analysis on the opioid savings cards to maximize their impact and, as a result, had increased the dollar value and set the program period to be 15 months long. Staff also reported to the Sacklers that Purdue had created promotional materials to support these tactics and had distributed them to the sales force. Staff also told the Sacklers that Purdue showed an opioid promotional video to 5,250 physicians on the Physician's Television Network. The video urged doctors to give patients Purdue's opioid savings cards.

293. Also in January, [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

294. That same month, staff told the Sacklers that Purdue employed 609 sales representatives and, during Q4 2012, they visited prescribers 153,890 times. [REDACTED]

[REDACTED]

295. **In February**, the Sacklers met with staff about tactics for promoting Purdue's opioids. They discussed research on what influences prescriptions, how doctors had responded to Purdue's increased promotion, and sales force promotion themes. On the same day, the Sacklers voted to award bonuses and salary increases to executives, including those involved in marketing Purdue's opioids.

296. **In March**, staff reported to the Sacklers on the devastation caused by prescription opioids. [REDACTED] staff told the Sacklers that drug overdose

deaths had more than tripled since 1990—the period during which Purdue had made OxyContin the best-selling painkiller. Staff told the Sacklers that tens of thousands of deaths were only the “tip of the iceberg.” Staff reported that, for every death, there were more than a hundred people suffering from prescription opioid dependence or abuse. For the Sacklers, however, the opioid epidemic was simply another opportunity to sell more opioids: [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

297. In April, [REDACTED]

[REDACTED]

[REDACTED]

298. In May, staff reported to the Sacklers again that they were successfully using opioid savings cards to get patients to “remain on therapy longer.” Staff told the Sacklers that they were using direct mail and email, as well as sales visits, to push the opioid savings cards.

299. Staff reported to the Sacklers that, despite these sales efforts, they were not achieving the goals of getting enough patients on higher doses of opioids and getting doctors to prescribe more pills in each prescription. Staff told them that “there is an unfavorable ‘mix’ of prescriptions across strengths,” and Purdue was losing tens of millions of dollars in revenue because sales of the highest doses (60mg and 80mg) were too low. Staff told the Sacklers that there was also a second problem: “lower average tablet counts per prescription.” Because doctors were not prescribing enough pills during each patient visit, Purdue was losing tens of millions of dollars in revenue. Staff promised the Sacklers: “A deeper analysis is underway to determine the cause of the decline in the 30mg, 60mg, and 80mg tablet strengths, as well as the lower than

budgeted average tablets per prescription. Once the analysis is complete, we will have a better sense of what tactics to implement to address both issues.”

300. The Sacklers met with Sales VP Russell Gasdia about the strategy for selling high doses. Gasdia told the Sacklers that “[t]itration up to higher strengths, especially the 40mg and 80mg strengths is declining.” He analyzed the “Causes of OxyContin’s Decline in Higher Strengths,” and how Purdue would reverse that decline. He told the Sacklers that Purdue’s #1 tactic to sell higher doses was sending sales representatives to visit prescribers. The #2 tactic was a marketing campaign designed to promote high doses—Purdue’s Individualize The Dose campaign. After that, Gasdia told the Sacklers, came opioid savings cards. After that came special focus on the most prolific opioid prescribers.

301. Gasdia told the Sacklers that the staff would develop even more tactics to sell higher doses. Purdue was using its data on thousands of doctors and patients to learn what made people willing to use high doses of opioids. They had started a study of physician characteristics and a “patient level analysis to determine what patient characteristics” were associated with “higher dose volume.”

302. That same month, staff told the Sacklers that Purdue employed 637 sales representatives and, during Q1 2013, they visited prescribers 155,354 times. [REDACTED]

[REDACTED]

303. **In July**, Purdue staff discussed “threats” to their business from data on long-term opioid use, as public health authorities reacted to the danger of keeping patients on opioids for longer periods of time. On information and belief, this issue was presented to the Sacklers at a Board meeting. Meanwhile, staff sent the Sacklers a “Flash Report” that OxyContin sales had dropped \$96,400,000 from the year before. Staff explained to the Sacklers that insufficient volume

of sales visits to prescribers was an important reason for the dropping sales. Staff told the Sacklers that they would increase the number of sales visits and had hired McKinsey to study how to get doctors to prescribe more OxyContin.

304. Staff also reported to the Sacklers that key priorities were to reverse “the decline in higher strengths” of Purdue opioids and the decline in “tablets per Rx,” which were reducing Purdue’s profit. They told the Sacklers that Purdue staff were studying ways to fight these trends, and McKinsey would analyze the data down to the level of individual physicians.

305. Mortimer Sackler asked for more detail on what was being done to increase sales. Staff told the Sacklers that McKinsey would analyze whether sales representatives were targeting the prescribers who were most susceptible to increasing opioid use. Staff told the Sacklers that McKinsey would study whether Purdue could use incentive compensation to push representatives to generate more prescriptions. Making the sales representatives’ income depend on increasing prescriptions could be a powerful lever. Staff told the Sacklers that McKinsey would study using “patient pushback” to get doctors to prescribe more opioids: when doctors hesitated to prescribe Purdue opioids, Purdue could get patients to lobby for the drugs. Staff told the Sacklers that McKinsey would also study techniques for keeping patients on opioids longer, including the need for sales representatives “to make a lot of calls on physicians with a high number of continuing patients.”

306. Staff also reported to the Sacklers that they had trained Purdue’s sales representatives to use new sales materials designed to get patients on higher doses of opioids for longer periods. Staff told the Sacklers that Purdue employed 634 sales representatives and, during Q2 2013, they visited prescribers 177,773 times. [REDACTED]

[REDACTED] Staff assured the Sacklers that they were trying to achieve even more sales visits by

monitoring the representatives.

307. [REDACTED]

308. Before the month ended, the Sacklers met to discuss a report on sales tactics that McKinsey had prepared for them: Identifying Granular Growth Opportunities for OxyContin: First Board Update. McKinsey confirmed that Purdue's sales visits generated opioid prescriptions. The consultants urged the Sacklers to demand more sales visits from sales representatives, by increasing each representative's annual quota from 1,400 towards 1,700. McKinsey also advised the Sacklers to control the sales representatives' target lists more strictly, to make representatives visit doctors who give the biggest payoff. Based on a review of data, McKinsey also suggested that the Sacklers should have staff emphasize opioid savings cards in neighborhoods with high concentration of Walgreens pharmacies. To allow even more targeted promotion of high doses, McKinsey asked Purdue to obtain "prescriber level milligram dosing data" so they could analyze the doses prescribed by individual doctors.

309. Days later, staff told the Sacklers that Purdue paid their family \$42,000,000.

310. **In August**, the Sacklers met to discuss an update to the McKinsey report on sales tactics: Identifying Granular Growth Opportunities for OxyContin: Addendum to July 18th and August 5th Updates. McKinsey recommended that the Sacklers immediately order a series of actions to increase sales. First, McKinsey urged the Sacklers to direct sales representatives to visit the most prolific opioid prescribers. The consultants told the Sacklers that prescribers in the more prolific group write "25 times as many OxyContin scripts" as less prolific prescribers. McKinsey

also reported to the Sacklers that sales representative visits to these prolific prescribers cause them to prescribe even more opioids: if Purdue ordered representatives to focus on the most prolific prescribers, it could increase sales.

311. Second, McKinsey recommended that the Sacklers fight back against steps that the DEA, the USDOJ, and others were taking to stop illegal drug sales. Two months earlier, the Walgreens pharmacy company had admitted that it broke the law by filling illegitimate prescriptions, and it agreed to new safeguards to stop illegal prescribing. McKinsey told the Sacklers that “deep examination of Purdue’s available pharmacy purchasing data shows that Walgreens has reduced its units by 18%.” Even worse for the Sacklers, the new safeguards were hurting sales of the highest doses: “the Walgreens data also shows a significant impact on higher OxyContin dosages”—specifically the 80mg dose. McKinsey urged the Sacklers to lobby Walgreens’ leaders to loosen up. For the longer term, McKinsey advised the Sacklers to develop a “direct-to-patient mail order” business for Purdue opioids, so they could sell the high doses without pharmacies getting in the way.

312. Third, McKinsey advised the Sacklers that they should use their power on the Board to insist on increasing sales, with monthly accountability: “Establish a revenue growth goal (e.g., \$150M incremental stretch goal by July 2014) and set monthly progress reviews with CEO and Board.” McKinsey knew what the Sacklers were looking for, reporting that “the value at stake is significant—hundreds of millions, not tens of millions.” The consultants urged the Sacklers to make “a clear go-no go decision to ‘Turbocharge the Sales Engine.’”

313. **In October**, the Sacklers met again to discuss implementation of the sales tactics McKinsey had recommended. The Sacklers discussed DEA efforts to stop illegal dispensing of

opioids at CVS and Walgreens and how Purdue could get around the new safeguards by shifting to mail-order and specialty pharmacies and by distributing opioids to patients directly.

314. Meanwhile, McKinsey kept reporting to Purdue on tactics to get more patients on higher doses of opioids. McKinsey found that Purdue could drive opioid prescriptions higher by targeting the highest-prescribing doctors and sending sales representatives to visit each prolific prescriber dozens of times per year. McKinsey pointed to a “true physician example” who wrote 167 more OxyContin prescriptions after Purdue sales representatives visited him.

True physician example		
	Specialty : Anesthesiology Location : Wareham, Massachusetts Market Decile : 8	
	12 months ending March 2012	12 months ending March 2013
	0 P1 1 P2	18 P1 1 P2
OxyContin scripts written during 2nd half of year	177	344

Graphic from McKinsey presentation recommending targeting high prescribers

315. In October, Mortimer Sackler pressed for more information on dosing and “the breakdown of OxyContin market share by strength.” Staff told the Sacklers that “the high dose prescriptions are declining,” and “there are fewer patients titrating to the higher strengths from the lower ones.” In response to the Sacklers’ questions, staff also explained that sales of the highest doses were not keeping up with the Sacklers’ expectations because some pharmacies had implemented “good faith dispensing policies” to double-check prescriptions that looked illegal and

some prescribers were under pressure from the DEA. Staff proposed to increase the budget for promoting OxyContin by \$50,000,000, and promised to generate more prescriptions with a new initiative to be presented to the Sacklers the following week.

316. At the end of the month, the Sacklers met to discuss Purdue's budget for sales and marketing for 2014. Staff told the Sacklers (again) that Purdue's opioid savings cards kept patients on opioids longer. Looking ahead to 2014, staff reported to the Sacklers that doctors shifting away from high doses and towards fewer pills per prescription could cost Purdue hundreds of millions of dollars in lost sales. To fight against that threat, staff told the Sacklers that they would increase the sales visits by each representative to 7.3 visits per day and visit prescribers a total of 758,164 times.

317. [REDACTED]

318. In November, Richard Sackler complained that he was getting too much information about the dangers of Purdue opioids. He had set up a Google alert to send him news about OxyContin, and he objected to a Purdue Vice President: "Why are all the alerts about negatives and not one about the positives of OxyContin tablets?" Staff immediately offered to replace Richard Sackler's alert with a service that provided more flattering stories.

319. Staff reported to the Sacklers that a key initiative during Q3 2013 was for sales representatives to encourage doctors to prescribe OxyContin to elderly patients on Medicare. [REDACTED]

sales materials; and initial orders were double the company's forecasts. Staff reported to the Sacklers that marketing and sales activities generated 266,842 additional [REDACTED] prescriptions and highlighted that opioid savings cards generate especially "high returns" by keeping patients on opioids longer.

324. Staff reported to the Sacklers that Purdue had sent more than 880,000 emails to health care professionals to promote its Butrans opioid, and posted online advertising seen more than 5 million times for Butrans and nearly 4 million times for OxyContin. They told the Sacklers that hundreds of thousands of communications to prescribers nationwide presented the same "key selling messages" designed to get more patients on OxyContin at higher doses for longer periods of time, and specifically promoted Purdue's opioid savings cards. On information and belief, these communications were disseminated to New Jersey prescribers.

325. Staff reported to the Sacklers that they were working with McKinsey to study ways to sell even more OxyContin. Staff also reported that they had direct access to physician-level data to analyze prescriptions by individual doctors. Staff gave the Sacklers the latest results regarding how opioid savings cards led to patients staying on OxyContin longer.

326. Staff also told the Sacklers that they would begin reviews of sales representatives according to their sales ranking, with a focus on the bottom ten percent. Staff reported to the Sacklers that Purdue employed 637 sales representatives and, during Q3 2013, they visited prescribers 179,640 times. [REDACTED]

327. **In December**, staff told Richard Sackler that Butrans sales were increasing, and they suspected the increase was caused by Purdue's improved targeting, in which sales representatives visited the most prolific prescribers.

328. Meanwhile, staff contacted Richard Sackler because they were concerned that the

company's "internal documents" could cause problems if investigations of the opioid crisis expanded. Early the next year, staff told Jonathan Sackler about the same concern. Jonathan studied collections of news reports and asked staff to assure him that journalists covering the opioid epidemic were not focused on the Sacklers.

❖ ❖ ❖ 2014 ❖ ❖ ❖

329. In January 2014, staff reported to the Sacklers on how Purdue's program for complying with state and federal law compared to recent agreements between other drug companies and the government. Other companies had agreed that sales representatives should not be paid bonuses based on increasing doctors' prescriptions, but Purdue still paid representatives for generating sales. Other companies disclosed to the public the money they spent to influence continuing medical education, but Purdue did not. Other companies had adopted "claw-back" policies so that executives would forfeit bonuses they earned from misconduct, but Purdue had not. The boards of other companies passed resolutions each quarter certifying their oversight of the companies' compliance with the law, but the Sacklers did not.

330. In February, staff sent the Sacklers the final results from 2013. Staff told the Sacklers that net sales were hundreds of millions of dollars below budget because doctors were not prescribing enough of the highest doses of opioids, doctors were including too few pills with each prescription, and sales representatives were not visiting doctors enough. Sales VP Russell Gasdia wrote privately to a friend: "Our myopic focus on extended release opioids with abuse deterrent properties has not yielded the results people thought it would in the market. It's been hard to convince colleagues and the board that our success in this market is over."

331. To increase sales, staff told the Sacklers that they had tightened the requirements for sales representatives' pay: from now on, sales representatives would lose bonus pay if they did

not visit “high value” prescribers often enough. [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

332. A few days later, staff told the Sacklers that Purdue’s marketing had an immense effect in driving opioid prescriptions: according to Purdue’s analysis, its sales and marketing tactics generated an additional 560,036 prescriptions of OxyContin in 2012 and 2013. Nevertheless, staff reported to the Sacklers that net sales for 2013 had been \$377,000,000 less than budgeted. Staff again reported that Purdue was losing hundreds of millions of dollars in expected profits because prescribers were shifting away from higher doses of Purdue opioids and including fewer pills per prescription. Staff told the Sacklers that a “Key Initiative” was to get patients to “stay on therapy longer.”

333. Staff also told the Sacklers that key sales priorities were again to encourage doctors to prescribe Purdue opioids for elderly patients and patients who had not taken opioids before. Staff reported to the Sacklers again that sales representatives were continuing the Individualize The Dose campaign. As the Sacklers knew, Purdue designed that campaign to encourage higher doses. Staff also told the Sacklers that Purdue’s “eMarketing” campaign for OxyContin reached 84,250 health care providers during Q4 2013. Staff told the Sacklers that they found increasing compliance concerns with Purdue’s speaker programs, in which the company paid doctors to promote Purdue opioids to other doctors.

334. [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

335. Staff told the Sacklers that Purdue employed 632 sales representatives and, during Q4 2013, they visited prescribers 176,227 times. [REDACTED]

[REDACTED]

336. That February report was the last of its kind. After Q4 2013, Purdue abolished the detailed Quarterly Reports that had created a paper trail of targets for sales visits and had been emailed among the Board and staff. In 2013, the City of Chicago served Purdue with a subpoena seeking internal documents about Purdue's marketing of opioids. Purdue fought the subpoena, and it was withdrawn. For 2014, Purdue decided to limit many of its official Board reports to numbers and graphs, and relay other information orally. But the Sacklers continued to demand information about sales tactics, and their control of Purdue's deceptive marketing did not change.

337. **In March and April**, staff told the Sacklers that Purdue was achieving its goals of selling higher doses of OxyContin and more pills of OxyContin per prescription, but weekly prescriptions of Purdue's Butrans opioid were below expectations because of a reduced number of sales representative visits promoting that opioid. The Sacklers had assumed prescriptions would fall, but staff were concerned that the effect could be greater than anticipated.

338. That same month, Richard and Jonathan Sackler's father, Raymond Sackler, sent David, Jonathan, and Richard Sackler a confidential memo about Purdue's strategy [REDACTED]

[REDACTED] The memo recounted that some physicians had argued that patients should not be given high doses of Purdue opioids, or kept on Purdue opioids for long periods of time, but Purdue had defeated efforts to

impose a maximum dose or a maximum duration of use. Raymond Sackler asked David, Jonathan, and Richard Sackler to talk with him about the memo.

339. **In June**, the Sacklers removed Russell Gasdia as Vice President of Sales and Marketing and began pushing his replacement to sell more opioids faster. Gasdia warned his replacement that Richard Sackler managed the sales operation intensely—“there are times this becomes a tennis match with Dr. Richard.” Sure enough, Richard Sackler told Gasdia’s replacement that he would be given little time to show that he could increase opioid sales: “it is very late in the day to rescue the failed launch” of Butrans, which was not making as much money as Richard Sackler desired. CEO Mark Timney tried to caution Richard that it was “a little early” to be attacking the new sales leader, since he had been at Purdue only two weeks.

340. That same month, staff sent the Sacklers an “Update on L.A. Times mitigation effort” about tactics to discourage scrutiny of Purdue’s misconduct. Staff wrote to the Sacklers:

As you may recall, one of our efforts to mitigate the impact of a potential negative Los Angeles Times (LAT) story involved assisting a competing outlet in marginalizing the LAT’s unbalanced coverage by reporting the facts before the LAT story ran. The following Orange County Register story, developed in close coordination with Purdue, achieved this goal. This fact-based narrative robs the LAT account of its newsworthiness and contradicts many of the claims we expected that paper to make.

In 2012, the Los Angeles Times had studied coroner’s records and revealed that overdoses killed thousands of patients who were taking opioids prescribed by their doctors, refuting the Sacklers’ lie that patients who are prescribed opioids do not get addicted and die. The next year, the Los Angeles Times revealed that Purdue tracked suspicious prescribing of OxyContin with a secret list of 1,800 doctors code-named Region Zero, but did not report them to the authorities.

341. **In July**, Richard Sackler called staff to complain about studies that the FDA required for opioids and how they might undermine Purdue’s sales. He emphasized that Purdue

Board members felt the requirements to conduct studies were unfair. Staff tried to reassure Richard that the studies would take “several years to complete, thereby keeping our critics somewhat at bay during this time.”

342. In July and again in August, September, and October, staff warned the Sacklers that two of the greatest risks to Purdue’s business were “Continued pressure against higher doses of opioids,” and “Continued pressure against long term use of opioids.”

RISKS

- i. Continued pressure against higher doses of opioids,
- ii. Continued pressure against long term use of opioids,

Staff report to the Board on risks facing Purdue’s business

Staff told the Sacklers that Purdue’s #1 opportunity to resist that pressure was by sending sales representatives to visit prescribers; and specifically, by targeting the most susceptible doctors, who could be convinced to be prolific prescribers, and visiting them many times.

343. In August, [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

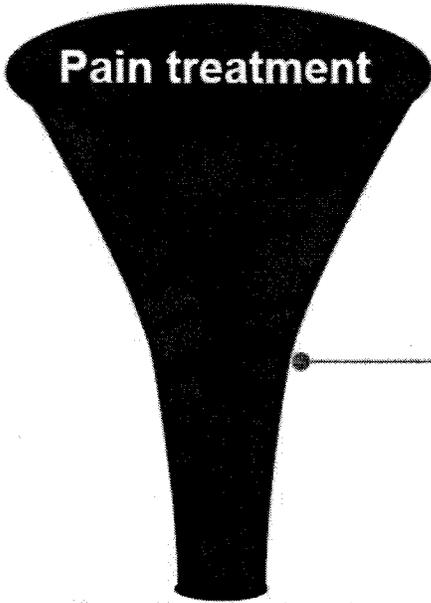
❖ ❖ ❖ Project Tango ❖ ❖ ❖

344. In September 2014, Kathe Sackler dialed in to a confidential call about Project Tango, which was a secret plan for Purdue to expand into the business of selling drugs to treat opioid addiction. In their internal documents, Purdue staff wrote down what Purdue had publicly denied for decades: that addictive opioids and opioid addiction are “naturally linked.” Staff proposed that Purdue should expand across “the pain and addiction spectrum,” to become “an end-to-end pain provider.” Purdue illustrated the end-to-end business model with a picture of a dark

hole labeled “Pain treatment” that a patient could fall into—and “[o]pioid addiction treatment” waiting at the bottom.

Purdue should consider expansion across the pain and addiction spectrum

Pain treatment and addiction are naturally linked



Pain treatment

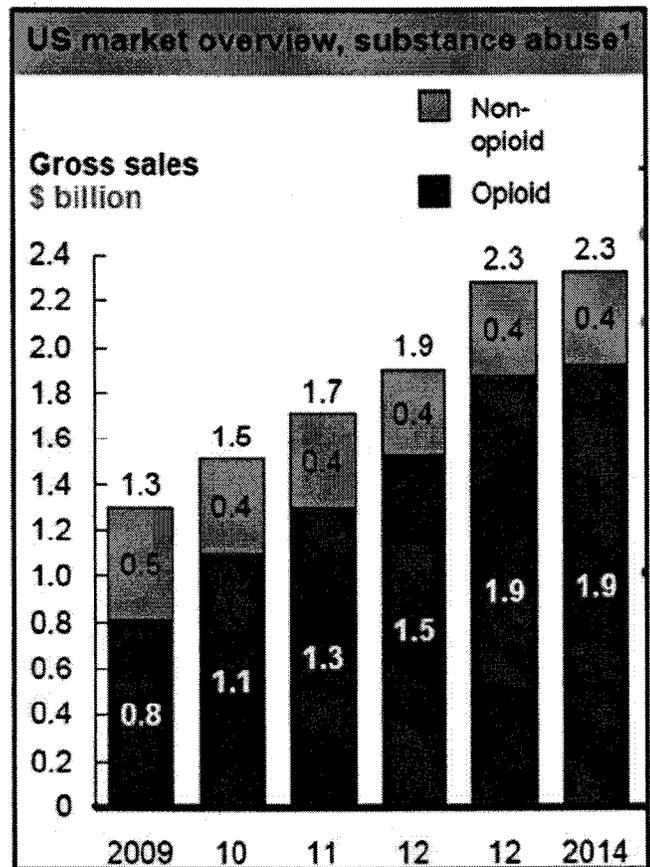
ADF reduces the likelihood of abuse of products

Opioid addiction treatment

There is an opportunity to expand our offering as an end-to-end pain provider

Purdue's secret Project Tango

345. Kathe Sackler and the Project Tango team reviewed findings that the “market” of people addicted to opioids, measured in billions of dollars, had doubled from 2009 to 2014.



Purdue's measure of the opioid addiction "market"

The presentation reviewed by Kathe Sackler and the staff showed that the addiction "market" provided an excellent compound annual growth rate ("CAGR"): "Opioid addiction (other than heroin) has grown by ~20% CAGR from 2000 to 2010."

346. The presentation made clear that Purdue's tactic of blaming addiction on untrustworthy patients was a lie. Instead, the truth is that opioid addiction can happen to anyone who is prescribed opioids:

▪ *"This can happen to any-one – from a 50 year old woman with chronic lower back pain to a 18 year old boy with a sports injury, from the very wealthy to the very poor"*

Purdue's Project Tango patient and clinical rationale

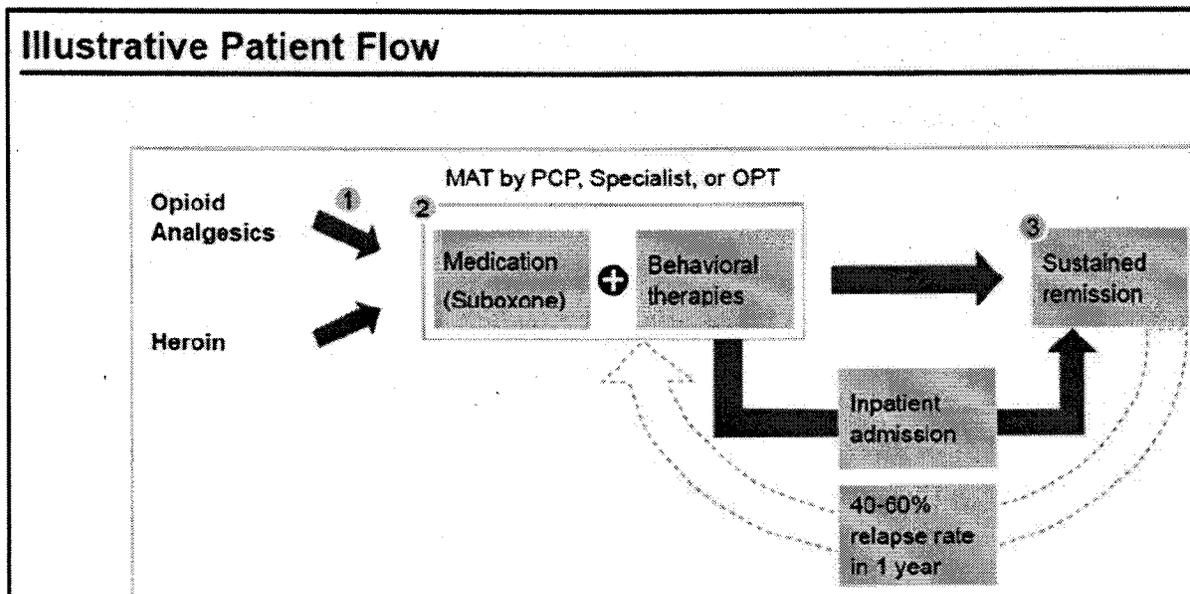
The presentation concluded that the millions of people who became addicted to opioids were the Sacklers' next business opportunity. Staff wrote: "It is an attractive market. Large unmet need for vulnerable, underserved and stigmatized patient population suffering from substance abuse, dependence and addiction." The team identified eight ways that Purdue's experience getting patients on opioids could now be used to sell treatment for opioid addiction.

347. Kathe Sackler instructed staff to look into reports of children requiring hospitalization after swallowing buprenorphine—the active ingredient in both Purdue's Butrans opioid and the opioid addiction treatment that the Sacklers considered selling, through Project Tango, in a film that dissolves in a patient's mouth. Staff assured Kathe Sackler that children were overdosing on pills, not films, "which is positive for Tango."

348. [REDACTED]

349. In February 2015, staff [REDACTED] presented Project Tango to the Board. The Tango team mapped how patients could get addicted to opioids through prescription opioid analgesics (such as Purdue's OxyContin) or heroin, and then become consumers of the new company's

Suboxone. The team noted the opportunity to capture repeat customers: even after patients were done buying Suboxone the first time, between 40-60% would relapse and need it again.



Purdue presentation explaining Project Tango patient flow

350. The next month, Project Tango came to an end. Kathe, David, Jonathan, and Mortimer Sackler discussed the discontinuation of the project at their Business Development Committee meeting. But the Sacklers' efforts to sell addictive opioids continued.



351. In October 2014, staff sent the Sacklers a Proposed Operating Plan and Budget to be approved by the Board for 2015. Staff told the Sacklers that a key tactic for 2015 would be to convert patients from short-acting opioids to OxyContin. Staff warned the Sacklers that prescribers were shifting away from the highest doses of Purdue's opioids, and toward fewer pills per prescription, and that those shifts would cost Purdue \$99,000,000 a year. Staff told the Sacklers that a key tactic to increase Butrans sales in 2015 would be for Purdue sales representatives to push doctors to "titrate up" to higher doses. Staff likewise told the Sacklers that visits to doctors by sales representatives would be a key tactic to launch Purdue's new Hysingla opioid: the company

would “[I]everage Purdue’s existing, experienced sales force to drive uptake with target HCPs” and “[a]dd additional contract sales force capacity at launch to drive uptake.” Staff proposed that Purdue employ 519 sales representatives, to be paid an average salary of \$81,300 plus a bonus of up to an additional \$124,600 based on sales.

352. Meanwhile, sales staff exchanged news reports of a lawsuit accusing Purdue of deceptive marketing in Kentucky. One report quoted Purdue’s own attorney and Chief Financial Officer stating that the company faced claims of more than a billion dollars that “would have a crippling effect on Purdue’s operations and jeopardize Purdue’s long-term viability.” Purdue’s Vice President of Corporate Affairs was delighted by the article, because it did not reveal the Sacklers’ role in the misconduct. “I’m quite pleased with where we ended up. There’s almost nothing on the Sacklers and what is there is minimal and buried in the back.” [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

353. In November, staff reported to the Sacklers that their sales tactics were working, and the shift away from higher doses of OxyContin had slowed.

354. In December, staff told the Sacklers that Purdue would pay their family \$163,000,000 in 2014 and projected \$350,000,000 in 2015.

355. On New Year’s Eve, Richard Sackler told staff that he was starting a confidential sales and marketing project on opioid prices and instructed them to meet with him about it on January 2.

❖ ❖ ❖ 2015 ❖ ❖ ❖

356. Early in the morning of **January 2**, staff began collecting sales data for Richard Sackler. They did not move quickly enough. Days later, Richard Sackler demanded a meeting with sales staff to go over plans for selling the highest doses. He asked for an exhaustive examination to be completed within 5 days, including:

unit projections by strength, mg by strength . . . pricing expectations by strength . . . individual strength's market totals and our share going back[w]ard to 2011 or 12 and then forward to 2019 or 2020 . . . the same information for Hysingla . . . [and] the history of OxyContin tablets from launch to the present.

The CEO stepped in to say the work would have to wait 3 weeks [REDACTED]

[REDACTED] Richard Sackler let him know that was not a great response—"That's longer than I had hoped for"—and directed marketing staff to start sending him materials immediately.

357. That same month, the Sacklers voted to evaluate employees' 2014 performance on a scorecard that assigned the greatest value to the volume of Purdue opioid sales. Employees were expected to generate more than one-and-a-half billion dollars. The Sacklers also voted to establish the company's scorecard for 2015: once again, the biggest factor determining employees' payouts would be the total amount of Purdue opioid sales.

358. **In April**, staff told the Sacklers that sales of Purdue's highest dose 80mg OxyContin were down 20% [REDACTED] and that the average prescription [REDACTED] [REDACTED] had declined by eight pills since 2011.

359. The Sacklers voted to expand the sales force by adding another 122 representatives. As with every reference to "the Sacklers" after July 2012, that includes Beverly, David, Ilene, Jonathan, Kathe, Mortimer, Richard, and Theresa Sackler.

360. Staff told the Sacklers the additional representatives would increase net sales of opioids by \$59,000,000.

361. The Sacklers knew and intended that, because of their vote, more sales representatives would promote opioids to prescribers in New Jersey. From 2015 to mid-2017, representatives hired in the 2015 expansion promoted Purdue opioids [REDACTED]

362. In June, after the City of Chicago sued Purdue Pharma for deceptive advertising,

[REDACTED]
[REDACTED]
[REDACTED]

[REDACTED]
[REDACTED]
[REDACTED], as discussed in Section V.D.5.

363. In October, Purdue executives identified avoiding investigations of Purdue's opioid marketing as a "Key Activity" in the company's Operational Plan.

364. In November, the Sacklers voted on Purdue's 2016 budget. Staff warned the Sacklers that public concern about opioids could get in the way of Purdue's plans and told them that some states were considering legislation that worried Purdue. Staff again told the Sacklers that two of the most significant challenges to Purdue's plans were doctors not prescribing enough of the highest strength opioids and including too few pills in each prescription. Staff told the Sacklers that declining prescriptions of the highest doses and fewer pills per prescription would cost Purdue \$77,000,000.

365. Staff proposed to the Sacklers that, for 2016, Purdue would plan for prescribers to average 60 pills of Purdue opioids per prescription. They told the Sacklers that they would aim to make enough of those pills be high doses that the average amount of oxycodone per pill would be 33 milligrams. That way, Purdue could hit its target for the total kilograms of oxycodone it wanted to sell.

366. To make sure Purdue hit the targets, staff told the Sacklers that sales representatives were visiting prescribers 21% more often than before. Staff told the Sacklers that they had aggressively reviewed and terminated representatives who failed to generate prescriptions. Staff reported to the Sacklers that, in 2015 alone, Purdue replaced 14% of its sales representatives and 20% of its district managers for failing to create enough opioid sales. [REDACTED]
[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

367. Looking ahead, staff told the Sacklers that “the 2016 investment strategy focuses on expanding the Sales Force.” They reported that the proposed budget for sales and promotion was \$11,600,000 higher than 2015, “primarily due to the Sales Force expansion.” The top priority for the sales representatives would be to visit the highest-prescribing doctors again and again. Staff proposed to the Sacklers that the #1 overall priority for 2016 would be to sell OxyContin through “disproportionate focus on key customers.” They told the Sacklers that sales representatives would also target prescribers with the lowest levels of training, physician’s assistants and nurse practitioners, because they were “the only growing segment” in the opioid market. Purdue executives expected that, each quarter, the sales representatives would visit prescribers more than 200,000 times and would get 40,000 new patients onto Purdue opioids.

368. **In December**, staff prepared to address wide-ranging concerns raised by the Sacklers. Kathe and Mortimer Sackler wanted staff to break out productivity data by indication versus prescriber specialty for each drug. Richard Sackler sought details on how staff were calculating 2016 mg/tablet trends. Jonathan Sackler sought a follow-up briefing on how public health efforts to prevent opioid addiction would affect OxyContin sales.

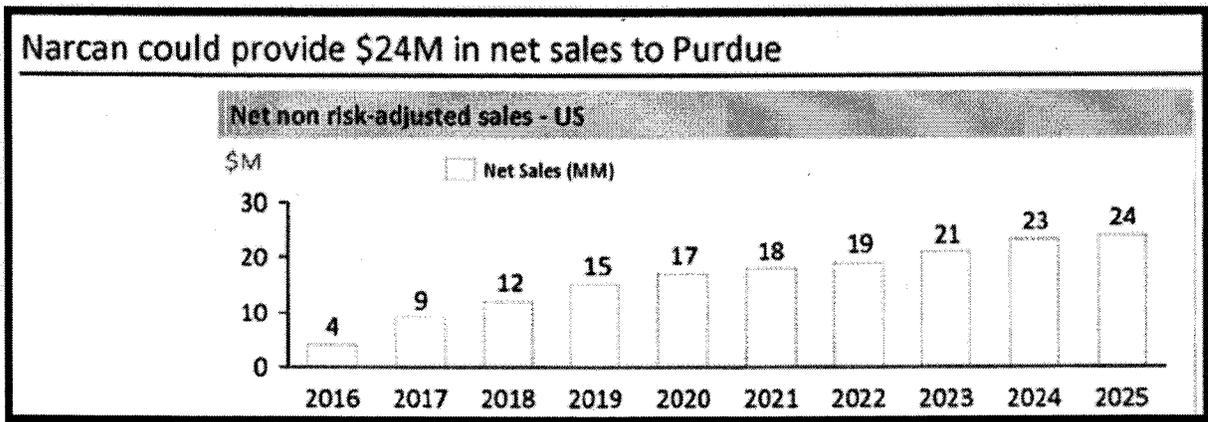
❖ ❖ ❖ 2016 ❖ ❖ ❖

369. **In 2016**, the Sacklers met with the rest of the Board in January, March, April, June, August, October, November, and December.

370. In April, the Sacklers considered exactly how much money was riding on their strategy of pushing higher doses of opioids. The month before, the U.S. Centers for Disease Control announced guidelines to try to slow 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 OxyContin strengths—40mg, 60mg, and 80mg. Staff studied how much money Purdue was making from its high dose strategy and told the Sacklers that [REDACTED] each year.

371. In May, Richard Sackler told staff to circulate a New York Times story reporting that opioid prescriptions were dropping for the first time since Purdue launched OxyContin twenty years earlier. The Times wrote: "Experts say the drop is an important early signal that the long-running prescription opioid epidemic may be peaking, that doctors have begun heeding a drumbeat of warnings about the highly addictive nature of the drugs." The only person quoted in favor of more opioid prescribing was a professor whose program at Tufts University was funded by the Sacklers.

372. In June, the Sacklers met to discuss a revised version of Project Tango—another try at profiting from the opioid crisis. This time, they considered a scheme to sell the overdose antidote NARCAN. The need for NARCAN to reverse overdoses was rising so fast that the Sacklers calculated it could provide a growing source of revenue, tripling from 2016 to 2018.



Board presentation showing potential sales from acquiring NARCAN

Like Tango, Purdue’s analysis of the market for NARCAN confirmed that Purdue saw the opioid epidemic as a money-making opportunity and that the Sacklers understood how Purdue’s opioids put patients at risk. Staff presented NARCAN to the Sacklers as a “strategic fit” because NARCAN is a “complementary” product to Purdue opioids. The presentation specifically identified patients on Purdue’s prescription opioids as the target market for NARCAN. The plan called for studying “long-term script users” to “better understand target end-patients” for NARCAN. Likewise, the plan identified the same doctors who prescribed the most Purdue opioids as the best market for selling the overdose antidote; Purdue planned to “leverage the current Purdue sales force” to “drive direct promotion to targeted opioid prescribers.” Finally, staff’s presentation to the Sacklers noted that Purdue could profit from government efforts to use NARCAN to save lives, including [REDACTED]

373. That same month, staff presented the 2016 Mid-Year Update. They warned the Sacklers that shifts in the national discussion of opioids threatened their plans. The deception that Purdue had used to conceal the risks of opioids was being exposed. Staff summarized the problems on a slide:

Critical Shifts in The National Discussion about Pain And Opioids

From	To
Undertreatment of Pain	Opioid Epidemic
Abuse	Addiction
Criminal	Victim
FDA	CDC
Benefits Outweigh Risks	Lack of Long-Term Evidence
ADFs as Part of Solution	ADF Value Unproven



CONFIDENTIAL 18

2016 mid-year Board update

374. First, to convince doctors to prescribe dangerous opioids, Purdue had promoted its drugs as the solution to “undertreatment of pain.” Richard Sackler had made sure that Purdue bought the internet address 5thvitalsign.com so it could promote pain as the “fifth vital sign” (along with temperature, blood pressure, pulse, and breathing rate) to expand the market for opioids. But now, staff reported to the Sacklers, doctors and patients were starting to worry more about the epidemic of opioid addiction.

375. Second, to conceal the danger of addiction, Purdue had falsely blamed the terrible consequences of opioids on drug abuse. One of Purdue’s key messages argued: “It’s not addiction, it’s abuse.” But now, staff reported to the Sacklers, doctors and patients were realizing that addiction was a true danger.

376. Third, to avoid responsibility for Purdue’s dangerous drugs, the Sacklers had chosen to stigmatize people who were hurt by opioids, calling them “junkies” and “criminals.”

Richard Sackler had written that Purdue should “hammer” them in every way possible. But now, staff reported to the Sacklers, Americans were seeing through the stigma and recognizing that millions of families were victims of addictive drugs. Staff told the Sacklers that nearly half of Americans reported that they knew someone who had been addicted to prescription opioids.

377. Fourth, the Sacklers had long sought to hide behind the approval of Purdue’s drugs by the FDA. But FDA approval could not protect the Sacklers when their deceptive marketing led thousands of patients to become addicted and die. The U.S. Centers for Disease Control (“CDC”) reported that opioids were, indeed, killing people. The CDC Director said: “We know of no other medication that’s routinely used for a nonfatal condition that kills patients so frequently.” The 2016 Mid-Year Update warned that the truth was threatening Purdue.

378. Fifth, the Sacklers and Purdue had seized on abuse-deterrent formulations [REDACTED]

[REDACTED]
[REDACTED]
[REDACTED]
[REDACTED]

[REDACTED] In fact, [REDACTED] abuse deterrent formulations led those addicted to opioids to seek other forms of the drug, leading to spikes in heroin and fentanyl overdoses and deaths.

379. **In November**, staff prepared statements to the press denying the Sacklers’ involvement in Purdue. Their draft claimed: “Sackler family members hold no leadership roles in the companies owned by the family trust.” That was a lie. Sackler family members held the controlling majority of seats on the Board and, in fact, controlled the company. A staff member

reviewing the draft commented: “Love the . . . statement.” Staff eventually told the press: “Sackler family members hold no management positions.”

380. Some employees worried about the deception. When journalists asked follow-up questions about the Sacklers, communications staff deliberated about whether to repeat the “no management positions” claim. They double-checked that Purdue’s top lawyers had ordered the statement. Then they arranged for one of the Sacklers’ foreign companies to issue it: “The statement will come out of Singapore.”

381. **In December**, Richard, Jonathan and Mortimer Sackler had a call with staff about another revised version of Project Tango. The new idea was to buy a company that treated opioid addiction with implantable drug pumps. The business was a “strategic fit,” because Purdue sold opioids and the new business treated the “strategically adjacent indication of opioid dependence.” The Sacklers kept searching for a way to expand their business by selling both addictive opioids and treatment for opioid addiction.

❖ ❖ ❖ 2017 ❖ ❖ ❖

382. **In April 2017**, [REDACTED]
[REDACTED]
[REDACTED]
[REDACTED]
[REDACTED]
[REDACTED]

383. **In May**, staff told the Sacklers that ICER’s final report had concluded that Purdue’s reformulation of OxyContin was not a cost-effective way to prevent opioid abuse. Theresa Sackler

asked staff what they were doing to fight back to convince doctors and patients to keep using the drug.

384. That same month, the Sacklers were looking for a new CEO. Long-time employee Craig Landau wanted the job and prepared a business plan titled "SACKLER PHARMA ENTERPRISE." Landau was careful to acknowledge their power: he recognized that Purdue operated with "the Board of Directors serving as the 'de facto' CEO." He proposed that Purdue should take advantage of other companies' concerns about the opioid epidemic through an "opioid consolidation strategy" and become an even more dominant opioid seller "as other companies abandon the space." The Sacklers made him CEO a few weeks later.

385. In June, staff told the Sacklers that getting doctors to prescribe high doses of opioids and many pills per prescription were still key "drivers" of Purdue's profit. Purdue's management was concerned that the CDC's efforts to save lives by reducing doses and pill counts would force the company "to adjust down our revenue expectations."

386. Staff told the Sacklers that Purdue's opioid sales were being hurt by cultural trends such as the HBO documentary, Warning: This Drug May Kill You. HBO's film showed actual footage from Purdue's misleading advertisements next to video of people who overdosed and died.

387. Staff felt the pressure of the opioid epidemic, even if the Sacklers did not. In one presentation, staff told the Sacklers: "Purdue Needs a New Approach." Their suggestion for a new direction was: "A New Narrative: Appropriate Use."



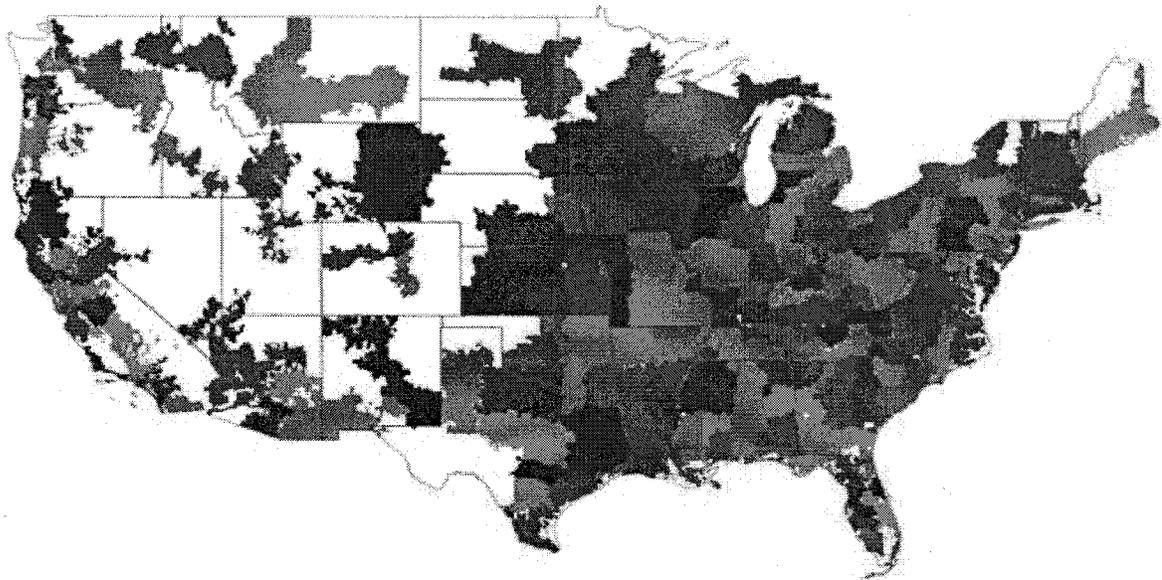
The Sacklers' unrelenting focus on opioid sales was so extreme that employees proposed "appropriate use" of drugs to reinvent the company. Staff also suggested that the Sacklers create a family foundation to help solve the opioid crisis.

388. The Sacklers did not redirect the company toward appropriate use or create the suggested family foundation. Instead, they approved a target of [REDACTED]

389. **In October**, Richard Sackler learned that insurance company Cigna had cut OxyContin from its list of covered drugs and replaced it with a drug from Purdue's competitor, Collegium. Richard read that Collegium had agreed to encourage doctors to prescribe lower doses of opioids, and Collegium's contract with Cigna was designed so Collegium would earn less money if doctors prescribed high doses. Cigna announced that opioid companies influence dosing: "While drug companies don't control prescriptions, they can help influence patient and doctor conversations by educating people about their medications." Richard Sackler's first thought was to counterpunch. He immediately suggested that Purdue drop Cigna as the insurance provider for the company health plan.

390. On October 17, Beverly Sackler served her last day on the Board. A week later, the New Yorker published an article entitled “The Family That Built an Empire of Pain.” The story quoted a former FDA Commissioner: “the goal should have been to sell the least dose of the drug to the smallest number of patients.” The reporter concluded: “Purdue set out to do exactly the opposite.”

391. In November, Jonathan Sackler suggested that Purdue launch yet another opioid. Staff promised to present a plan for additional opioids at the next meeting of the Board. At the Board meeting that month, the remaining Sackler Board members (Richard, David, Ilene, Jonathan, Kathe, Mortimer, and Theresa Sackler) voted to cut the sales force from 582 representatives to 302 representatives. They knew sales representatives would continue to promote opioids in New Jersey. Staff even gave Richard, David, Ilene, Jonathan, Kathe, Mortimer, and Theresa Sackler a map of where the remaining sales representatives worked, with New Jersey shaded to show that Purdue would keep visiting prescribers here.



Purdue internal map of planned sales representative territories for 2018

❖ ❖ ❖ 2018 ❖ ❖ ❖

392. In January 2018, Richard Sackler received a patent for a drug to treat opioid addiction—his own version of Project Tango. Richard had applied for the patent in 2007. He assigned it to a different company controlled by the Sackler family, instead of Purdue. Richard's patent application says opioids are addictive. The application calls the people who become addicted to opioids “junkies” and asks for a monopoly on a method of treating addiction.

393. [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED] Richard Sackler also met with Purdue staff about the sales force again. They discussed plans to cut the force to 275 representatives. In February, Richard, David, Ilene, Jonathan, Kathe, Mortimer, and Theresa Sackler decided to lay off 300 sales representatives.

394. By April, staff were scared. Richard Sackler was again asking questions about sales. Staff prepared a presentation for the Board of Directors (“BoD”). One employee suggested that they add more information about the company's problems. Another cautioned against that:

I think we need to find a balance between being clear about what reality looks like—which I certainly support in [this] situation—and just giving so much bad news about the future that it just makes things look hopeless. Let's not give the BoD a reason to just walk away.

395. On May 3 and again on June 6 and 8, all seven remaining Sacklers attended meetings of the Board: Richard, David, Ilene, Jonathan, Kathe, Mortimer, and Theresa Sackler. But shortly thereafter, the departures started. Richard Sackler was the first to go: he resigned from the Board in July 2018. By April 2019, the other six had left, too, leaving no Sackler family

members on the Board—for the first time in Purdue Pharma history.

D. In Carrying Out the Sacklers' Instructions from 2007 to 2018, Purdue's Sales Force Misrepresented the Risks of Opioids and Deployed Unconscionable Tactics to Maximize Profits.

396. In 2007, Purdue entered into consent decrees with the federal government and numerous states to resolve investigations into its marketing of OxyContin. As reported by USDOJ, those investigations centered on misrepresentations that OxyContin was less addictive and had less abuse potential than IR opioids, and that patients taking OxyContin could discontinue the drug without withdrawal symptoms. Prospectively, the decrees required Purdue more generally to discontinue all deceptive marketing, including any misrepresentations regarding OxyContin's potential for abuse, addiction, or physical dependence, and to provide a fair balance of risk and benefit information as required by FDA regulations.

397. As a part of Purdue's agreement with the United States, the Sacklers, as members of the Board of Directors, were required to undergo training to understand the terms of the corporate integrity agreement and to verify their agreement to comply with its terms. This training was to include "the proper methods of promoting, marketing, selling, and disseminating information about Purdue's products in accordance with . . . FDA requirements."

398. Rather than correct its misrepresentations and truly reform its conduct, Purdue—directed by the Sacklers—instead built upon the deceptive messaging that had established chronic opioid therapy as commonplace and reaped Purdue massive revenues. Since that time, and up to 2018, Purdue both echoed the deceptions for which it was cited in 2007 and compounded those deceptions with additional misconduct. Purdue has continued to omit discussion of the serious risks of opioids and lack of evidence supporting long-term opioid use and to affirmatively misrepresent the risks and benefits of opioids for the treatment of chronic pain. Purdue has also pursued new, unconscionable marketing tactics to expand and preserve its customer base.

399. Purdue did so under orders from the Sacklers to implement several specific campaigns and under intense pressure to increase sales and revenues. The Sacklers outlined particular objectives—to build a market of new initiates to opioid therapy, to boost the length of opioid prescriptions, and to boost the dosages of opioids prescribed. The Sacklers approved or sanctioned marketing messages that Purdue sales representatives were trained to convey: that pain was undertreated, that opioids were preferable to over-the-counter and milder combination drugs, that the benefits of opioids greatly outweighed the risks, and that the risks of addiction and death were minimal and attached to very particular types of undesirable persons and behaviors.

400. Purdue accomplished much of this through its New Jersey sales force, including the messages they verbally conveyed to prescribers and the materials they showed or distributed to prescribers. From the launch of OxyContin forward, Purdue relied heavily on its sales representatives to market its opioids. For example, of the \$167 million Purdue spent on promoting opioids nationwide in 2016, \$156 million was spent on detailing. By establishing personal relationships with doctors, Purdue's sales representatives were able to disseminate their misrepresentations in targeted, one-on-one settings.

401. As described in Section V.C, the Sacklers constantly directed Purdue to be more aggressive with its sales force. Between 2007 and 2016, the Sacklers directed significant expansions of the sales force, with the express purpose of increasing revenues. The Sacklers also pushed Purdue to increase the intensity of detailers' activities—requiring more visits per day and more visits to higher volume prescribers. Between 2008 and 2017, Purdue's Board, including the Sacklers on the Board, repeatedly approved increases in the number of sale representatives and the budget for marketing. At the same time, the Sacklers were setting and approving sales goals—in terms of dollars, prescriptions written, and milligrams purchased.

402. The Sacklers were obsessed with results, down to the most granular details. As directors, they did not simply approve budgets and top-line sales goals. As described in Section V.C, they regularly sought and received a host of data, including quarterly and yearly sales representative visits; sales trends—at times, on a weekly basis—and projections by product, pill strength, and number of prescriptions; prescriptions of competitor pain medications; new patient starts and existing patient retentions; pharmacy inventory; the relationships between sales representative visits and prescribing, patient dose and length of therapy, and various marketing tactics and sales; and more.

403. At least 107 different Purdue sales representatives (excluding supervisors) operated in New Jersey since 2007. Each of those representatives was expected to make at least seven in-person sales calls to prescribers per day—a target the Sacklers set and tracked, quarter by quarter, as described in Section V.C. Purdue’s own records indicate that its representatives detailed at least 5,800 New Jersey prescribers between 2007 and 2016. Most of these prescribers were visited repeatedly—often monthly or even more frequently. Indeed, from 2007 through 2017, Purdue sales representatives made in excess of [REDACTED] unique sales visits in New Jersey—more than 20,000 per year.

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

approved, and supplied by the company.

405. As set forth below, through its sales force and deceptive promotional materials, Purdue misrepresented the serious risk of addiction posed by its opioids and misleadingly promoted OxyContin as effective for 12 hours—a claim that heightened the risk of addiction. Purdue also unconscionably promoted its opioids in new ways and to new groups, by (a) targeting the elderly and those who had never used opioids with false claims about the safety and efficacy of low doses; (b) pushing physicians to prescribe the highest strengths of Purdue’s opioids, without disclosing the risks attendant to higher dosing; and (c) scheming to keep patients on opioids for longer periods, including offering innocuous-seeming savings cards, even though Purdue knew both that there was no good science supporting the efficacy of long-term opioid therapy and that the serious risks of addiction, overdose, and death increased with duration of use. The Sacklers oversaw, approved or sanctioned all of this conduct, both by (a) ordering certain strategies purposely directed to and deployed in New Jersey and (b) being fully apprised of others, then directing Purdue to implement those strategies in New Jersey with more sales representatives making more visits to more prescribers throughout New Jersey.

1. At the Direction and Under the Supervision of the Sacklers, Purdue Falsely Minimized or Failed to Disclose the Known, Serious Risk of Addiction.

406. To convince New Jersey prescribers and patients that opioids are safe, Purdue deceptively minimized and failed to disclose the risks of long-term opioid use, particularly the risk of addiction. Purdue sales representatives were trained to deflect questions about addiction into discussions of abuse, and to draw technical distinctions between dependence and addiction to allay prescribers’ concerns about addiction risks. Purdue’s misrepresentations and omissions, which are described below, reinforced each other to create the dangerously misleading impressions that: (a) Purdue’s ER/LA opioids present a reduced risk of addiction, and even patients who seem

addicted may simply be physically dependent on the drug or have undertreated pain that requires more opioids; (b) patients at greatest risk of addiction can be identified, allowing doctors to confidently prescribe opioids to all other patients and even prescribe to high-risk patients, provided they are closely managed; and (c) the abuse-deterrent formulations of Purdue's opioids both prevent abuse and are inherently less addictive. Each of these misrepresentations has been debunked by the FDA and the CDC.

407. These core messages on addiction risk flowed directly from the strategy approved and overseen by the Sacklers and devised personally by Richard Sackler, who directed Purdue to characterize the growing opioid problem as one of "abuse" rather than "addiction." Thus, in Purdue's false telling, doctors had no reason to fear that legitimate pain patients would become addicted, and screening tools and abuse-deterrent formulations could keep the abusers at bay. As described in Section V.C, in 2016, when the tide of public opinion regarding opioids had turned, the staff reported to the Sacklers that the concepts of undertreatment and abuse—which had long been successful parts of Purdue's marketing—were no longer accepted as plausible explanations for an epidemic of addiction linked tightly to overprescribing.

a. Omitting, trivializing, and mischaracterizing addiction risk

408. In furtherance of the strategic narrative set by the Sacklers—to deny addiction risk or deflect addiction concerns—Purdue's sales representatives regularly omitted from their sales conversations any discussion of the risk of addiction from long-term use of opioids. Of the 239,742 call notes that were generated by Purdue sales representative visits to New Jersey doctors over nearly a decade, there are only 433 instances of the words "addict" or "addiction" in the text box where the representative is required to describe "pertinent information" from the visit.

409. These omissions, which were false and misleading in their own right, rendered even seemingly truthful statements about opioids false and misleading, especially in light of Purdue's

prior misrepresentations regarding the risk of addiction.

410. When Purdue's sales representatives raised the topic of addiction, they emphasized to New Jersey prescribers that Purdue's ER/LA opioids (OxyContin, Butrans, and Hysingla) provide a slow-onset, stable dose without "peaks and valleys"—encouraging prescribers to infer that these opioids are safer because they do not produce the euphoric high that fosters addiction. In a 2011 sales training document, Purdue acknowledged that the "fewer peaks and valleys" message seen in a review of sales representative call notes was "problematic"—confirming both that the statements were made and that they were false.

411. Purdue sales representatives also explained to New Jersey prescribers—including with visual aids—that signs of addiction may actually reflect undertreated pain that should be treated with higher doses. This message reflected the same unsubstantiated and misleading concept of "pseudoaddiction" that Purdue advanced in its earlier marketing. Purdue consistently used this concept to suggest to prescribers that they should actually prescribe more or higher doses of opioids when presented with patients who exhibit drug-seeking behaviors. Similarly, sales representatives were trained to assuage prescribers' worry about addiction by distinguishing it from opioid dependence, which they describe as a normal, benign consequence of extended opioid use. As described by one former sales manager, an addict is a patient who uses the drug despite harm, but a patient who simply needs the drug to function in normal daily life is dependent.

412. Promotional materials and other publications Purdue disseminated or made available in New Jersey included similar, mutually reinforcing messages minimizing the risk of addiction.

413. In 2011, for example, Purdue published a pamphlet for prescribers and law enforcement that misleadingly depicted the signs of addiction. The pamphlet Providing Relief,

Preventing Abuse showed graphic pictures of the stigmata of injecting or snorting opioids—skin popping, track marks, and perforated nasal septa. In fact, opioid addicts who resort to these extremes are uncommon; the far more typical reality is patients becoming addicted through oral use. These depictions deceptively reassured doctors that, as long as they do not observe those signs of misuse, they need not worry that their patients are abusing or addicted to opioids. The pamphlet also promoted the concept of pseudoaddiction. Purdue sales representatives distributed Providing Relief, Preventing Abuse to New Jersey prescribers.

414. Purdue relied, in particular, on unbranded marketing—“educational” materials for prescribers that discussed pain or opioids generally, and not particular Purdue products—to disseminate misleading messages about the risk of addiction. These efforts included, most prominently, a campaign under the banner Partners Against Pain.

415. Partners Against Pain was a Purdue marketing imprint consisting of both medical education resources, distributed to prescribers by the sales force, and a now-defunct website that, before Purdue shut it down in 2016, was styled as an “advocacy community” for better pain care. As described in Section V.C, [REDACTED] Partners Against Pain program, which had existed since at least the early 2000s and was a vehicle for Purdue to downplay the risks of addiction from long-term opioid use. One early pamphlet, for example, answered concerns about OxyContin’s addictiveness by claiming: “Drug addiction means using a drug to get ‘high’ rather than to relieve pain. You are taking opioid pain medication for medical purposes. The medical purposes are clear and the effects are beneficial, not harmful.” Purdue sales representatives widely showed and disseminated Partners Against Pain materials to New Jersey prescribers and encouraged prescribers to use the Partners Against Pain website as a resource.

416. Through at least 2013, the Partners Against Pain website relied on and directed users to the 2001 guideline from AAPM and APS, which endorsed the concept of pseudoaddiction and claimed that patients who engage in drug-seeking behaviors may not be addicted but simply have undertreated pain.

417. Purdue sales representatives in New Jersey also distributed a Partners Against Pain document titled “Key Terms in Pain Management,” which made similar claims about drug-seeking behaviors. The document claimed that “[p]seudoaddiction can be distinguished from true addiction in that the behaviors resolve when the pain is effectively treated,” again suggesting that the solution to the behavior was to prescribe more opioids. Purdue included this document as part of a Partners Against Pain pamphlet, “Clinical Issues in Opioid Prescribing,” which the company also made available to prescribers.

418. A Partners Against Pain “Pain Management Kit” that debuted in 2009 likewise advocated the pseudoaddiction concept, referring prescribers to the 2001 AAPM/APS “Definitions Related to the Use of Opioids for the Treatment of Pain.” The kit also introduced another resource—a set of drug abuse screening tools, discussed in Section V.D.1.b—by stating that “[b]ehaviors that are suggestive of drug abuse exist on a continuum, and pain-relief seeking behavior can be mistaken for drug-seeking behavior.” A 2010 Purdue pamphlet billed as “A Training Guide for Healthcare Providers” made the same claim.

419. Purdue also worked closely with allies, such as the American Pain Foundation (“APF”), to disseminate misleading, unbranded messages about the risks of opioids.

420. Purdue had a particularly close relationship with APF, which was highly dependent on pharmaceutical company funding and produced numerous publications touting the use of opioids to treat chronic pain. Purdue was APF’s second-biggest donor, with donations totaling

\$3.6 million between 1999 and 2012. As early as 2001, Purdue grant letters informed APF that the contributions reflected Purdue's effort to "strategically align our investments in nonprofit organizations that share our business interests," making clear that funding depended on APF continuing to support Purdue's objectives. Purdue also engaged APF as a paid consultant on various initiatives.

421. Among the APF publications Purdue sponsored was Exit Wounds, a 2009 book written as a personal narrative of one veteran recovering from war injuries. Exit Wounds described opioids as the "'gold standard' of pain medications" and minimized the risk of addiction, emphasizing that physical dependence often is mistaken for addiction and claiming that "[l]ong experience with opioids shows that . . . people who are not predisposed to addiction are very unlikely to become addicted to opioid pain medications." With Purdue's financial support, APF promoted and distributed Exit Wounds to veterans throughout the country, including, on information and belief, veterans in New Jersey.

422. Purdue also sponsored APF's A Policymaker's Guide to Understanding Pain & Its Management, a 2011 publication that claimed pain generally had been "undertreated" due to "[m]isconceptions about opioid addiction" and asserted, without basis, that "less than 1 percent of children treated with opioids become addicted." In addition to mischaracterizing the risk of addiction, A Policymaker's Guide perpetuated the misleading concept of pseudoaddiction, stating that "[p]seudo-addiction describes patient behaviors that may occur when pain is undertreated" and that "[p]seudo-addiction can be distinguished from true addiction in that this behavior ceases when pain is effectively treated"—i.e., with more opioids. On information and belief, Purdue distributed or made A Policymaker's Guide available to New Jersey prescribers.

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

424. Purdue's claims regarding addiction are contrary to longstanding scientific evidence, and its failures to disclose the risk of addiction are material given both the magnitude of the risk and the grave consequences of addiction.

425. Studies have shown that at least 8-12%, and as many as 30% or even 40%, of long-term users of opioids experience problems with addiction. In requiring a new black-box warning on the labels of all IR opioids in March 2016, similar to the warning already required for ER/LA opioids, the FDA emphasized the known, "serious risks of misuse, abuse, [and] addiction . . . across opioid products." That same month, after a "systematic review of the best available evidence" by a panel excluding experts with conflicts of interest, the CDC published its guideline for prescribing opioids for chronic pain. The CDC found that "[o]pioid pain medication use presents serious risks, including overdose and opioid use disorder," an alternative diagnostic term for addiction. The CDC also emphasized that "continuing opioid therapy for 3 months substantially increases risk for opioid use disorder."

b. Overstating the efficacy of screening tools

426. In furtherance of the strategic narrative set by the Sacklers to deny addiction risk and deflect addiction concerns, Purdue also falsely instructed New Jersey prescribers and patients that addiction risk screening tools—such as patient contracts, urine drug screens, and pill counts—allow health care providers to safely prescribe opioids to patients, including patients predisposed to addiction.

427. Such misrepresentations made health care providers more comfortable prescribing opioids to their patients, and patients more comfortable starting on chronic opioid therapy. These misrepresentations were critical to assure doctors, who were beginning to see or hear about the rising tide of opioid addiction, that they could safely prescribe opioids in their own practices and that addiction was not unavoidable, but the result of other prescribers' failing to rigorously manage and weed out problem patients.

428. Purdue conveyed these messages in its in-person sales calls. A former Purdue sales representative in New Jersey acknowledged discussing with health care providers that they could screen out patients at high risk of addiction through urine tests and patient agreements. Many New Jersey prescribers report using screening tools to manage addiction risk.

429. Sales representatives in New Jersey had at their disposal the Partners Against Pain "Pain Management Kit," which contained several drug abuse screening tools they could show to prescribers. One of these is the "Opioid Risk Tool" created by prominent opioid advocate Dr. Lynn Webster, who received research funding from Purdue. It is a five-question, one-minute screening tool that relies on patient self-reports (particularly unlikely given the sensitive topic and the nature of addiction) to purportedly allow doctors to manage the risk that their patients will become addicted to or abuse opioids. Sales representatives distributed the kit to prescribers in New Jersey.

430. Purdue also promoted screening tools as a reliable means to manage addiction risk in CME and scientific conferences available to New Jersey prescribers. For example, Purdue sponsored a 2011 CME taught by Dr. Lynn Webster via webinar titled "Managing Patient's Opioid Use: Balancing the Need and Risk." This presentation deceptively instructed prescribers that screening tools and urine tests prevented "overuse of prescriptions" and "overdose deaths."

Purdue also funded a 2012 symposium called “Chronic Pain Management and Opioid Use: Easing Fears, Managing Risks, and Improving Outcomes,” which taught doctors that, through the use of screening tools, more frequent refills, and other techniques, high-risk patients showing signs of addictive behavior could be safely treated with opioids.

431. The 2016 CDC Guideline confirms the lack of substantial scientific evidence to support Purdue’s claims regarding the utility of screening tools and patient management strategies in managing addiction risk. The Guideline notes that there are no studies assessing the effectiveness of risk mitigation strategies such as screening tools, patient agreements, urine drug testing, or pill counts—all widely believed by doctors, including doctors in New Jersey, to detect and deter abuse—“for improving outcomes related to overdose, addiction, abuse, or misuse.” As a result, the Guideline recognizes that available risk screening tools “show insufficient accuracy for classification of patients as at low or high risk for [opioid] abuse or misuse” and counsels that doctors “should not overestimate the ability of these tools to rule out risks from long-term opioid therapy.” (Emphasis added.)

c. Overstating the efficacy of “abuse-deterrent” properties

432. In furtherance of the strategic narrative set by the Sacklers to deny addiction risk or deflect addiction concerns, Purdue deceptively marketed its “abuse-deterrent” opioids—a reformulated version of OxyContin, and Hysingla ER—to New Jersey prescribers in a manner falsely implying that these drugs can curb abuse and even addiction. As described in Section V.C,

[REDACTED]

[REDACTED]

433. Oral abuse is the most common form of prescription opioid abuse. It includes not only using the drugs without a prescription, but also swallowing higher or more frequent doses than prescribed. Rather than focus on the oral abuse associated with the widespread prescribing

of OxyContin for chronic pain, Purdue claimed that abuse and addiction result from product diversion, with abusers snorting or injecting the drug. Purdue's proffered solution was a new coating and elements to make its opioids more difficult to crush or inject. Purdue's marketing misleadingly assured prescribers that they could prescribe Purdue's opioids without contributing to the epidemic of misuse and abuse.

434. The FDA approved the reformulated OxyContin in 2010. In its medical review of Purdue's application, however, the FDA found that "the tamper-resistant properties will have no effect on abuse by the oral route (the most common mode of abuse)" and that "[w]hile the reformulation is harder to crush or chew, possibly mitigating some accidental misuse, oxycodone HCl is still relatively easily extracted." In 2013, Purdue persuaded the FDA to permit reference to the abuse-deterrent properties in the OxyContin label. When Hysingla ER (extended-release hydrocodone) launched in 2014, the product included similar properties.

435. Purdue regularly cites its introduction of abuse-deterrent opioids as evidence of its commitment to addressing the opioid crisis, as described in Section V.F. In fact, the reformulation, and the change in labeling, solved an important business problem for Purdue: how to keep the money flowing after April 2013, when OxyContin's patent was set to expire. Generic versions of OxyContin became available in February 2011, threatening to erode Purdue's share of the long-acting opioid market as well as the price Purdue could charge. However, Purdue convinced the FDA in April 2013 that original OxyContin should be removed from the market as unsafe because it lacked abuse-deterrent properties—meaning generic equivalents of the old formulation also could not be sold. Purdue thus secured brand exclusivity for OxyContin through at least 2017; successful patent challenges now have competitors petitioning the FDA for approval of generic versions.

436. Purdue also used the abuse-deterrent properties of its opioids as a primary selling point to differentiate its products from its competitors, including generic opioids. Purdue sales representatives falsely claimed or implied to New Jersey prescribers that Purdue's abuse-deterrent formulations (a) prevent tampering and that these products cannot be crushed or snorted; (b) prevent or reduce opioid abuse, diversion, and addiction overall; and (c) are safer than other opioids. Purdue's sales representatives also either failed to disclose that the abuse-deterrent formulations would not impact the most common form of abuse—oral ingestion—or affirmatively misrepresented that most abuse is by non-oral means.

437. Purdue knew or should have known that its abuse-deterrent drugs were regularly tampered with and abused. In online forums such as bluelight.org and Reddit, drug abusers discuss a variety of ways to tamper with OxyContin and Hysingla ER, including by grinding the pills, microwaving and then freezing them, or dissolving them in soda or lemon juice. A 2015 study by researchers at Washington University in St. Louis found that many addicts continued to abuse reformulated OxyContin.

438. As discussed in Section V.C, it appears from contemporaneous correspondence that [REDACTED] [REDACTED] And yet, abuse deterrence became a point of product differentiation and a key marketing message as soon as OxyContin was re-formulated. After the product was launched, [REDACTED] [REDACTED] the new formulation did nothing to curb the most common way to consume oxycodone for purposes of abuse—swallowing it.

439. There remains no substantial scientific evidence that Purdue's abuse-deterrent opioids actually reduce opioid abuse. As the 2016 CDC Guideline states, "[n]o studies" support

the notion that “abuse-deterrent technologies [are] a risk mitigation strategy for deterring or preventing abuse,” and the technologies—even when they work—“do not prevent opioid abuse through oral intake, the most common route of opioid abuse, and can still be abused by nonoral routes.”

440. Purdue knew that its marketing should not go beyond the words “abuse-deterrent properties” to claim that OxyContin and Hysingla actually deter abuse. FDA policy on such representations is clear. In 2013, the FDA warned Purdue competitor Endo over advertising implying that the “crush resistant” property of its Opana ER opioid actually made the drug more difficult to abuse. Because of their questionable benefits, any discussion of abuse-deterrent technologies had a high potential to mislead practitioners and create a false sense of security about prescribing opioids.

441. Notwithstanding these concerns, Purdue’s sales representatives made claims about abuse deterrence that go well beyond the drugs’ labeling, including that Purdue’s abuse-deterrent formulations were more difficult to abuse and less likely to be diverted. One New Jersey prescriber recalled a sales representative telling her that the majority of OxyContin abuse happens through snorting or injecting; another was told that street use is usually non-oral; and several were told that reformulated OxyContin is rendered inactive if crushed, so a user would not be able to get high from it. Representatives made similar claims about Purdue’s other oral opioid, Hysingla, claiming that Purdue studies found that abusers do not like this drug. Even more troublingly, sales representatives stated or implied to New Jersey prescribers that opioids with abuse-deterrent formulations are “helping thwart addiction.”

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

their opioid prescribing—to continue prescribing Purdue’s opioids in the mistaken belief they were safer. It also allowed prescribers and patients to discount evidence of opioid addiction and attribute it to other, less safe opioids—i.e., to believe that while patients might abuse or overdose on non-abuse deterrent opioids, Purdue’s opioids did not carry that risk.

2. At the Direction and Under the Supervision of the Sacklers, Purdue Misleadingly Promoted OxyContin as Supplying 12 Hours of Pain Relief.

443. To convince New Jersey prescribers and patients to use OxyContin, Purdue misleadingly promoted the drug as providing 12 continuous hours of pain relief with each dose. Purdue pointed to labeling that it sought from the FDA, and for which the company is legally responsible, directing 12-hour dosing. Purdue, however, sought that dosing to maintain a competitive advantage over more-frequently dosed opioids, despite knowing that it was inadequate—and dangerous—for many patients. Moreover, Purdue went well beyond the label’s instructions to take OxyContin every 12 hours by affirmatively claiming that OxyContin lasts for 12 hours and by failing to disclose that OxyContin does not provide 12 hours of pain relief to many patients. In reality, Purdue had known since OxyContin’s launch that it does not last for 12 hours in many patients, a phenomenon known as “end-of-dose failure.”

444. The Sacklers [REDACTED] As described in Section V.C, the Sacklers [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED] On information and belief, based on the existential threat posed to Purdue by a 2004 citizens’ petition submitted to the FDA by the Connecticut Attorney

General, ██████ Sacklers knew about the end-of-dose failure problem as well. That petition complained that many patients were being prescribed unsafe amounts of OxyContin, in part because doctors were prescribing dosing more frequent than twice a day to compensate for the shorter duration of pain relief. In response to that petition, the FDA in 2008 declined to change the label but found that a “substantial number” of chronic pain patients taking OxyContin experienced end-of-dose failure.

445. The misrepresentations about OxyContin’s efficacy for 12 hours, which Purdue made since 1996, were particularly dangerous because the inadequate dosing helps fuel addiction, as laid out below. And Purdue doubled down on both its misstatements and the resulting harm to patients by suggesting to prescribers that the solution to end-of-dose failure was not more-frequent dosing but higher doses—which themselves pose greater risks, as discussed in Section V.D.4.

446. OxyContin has been FDA-approved for twice-daily—“Q12”—dosing since its debut in 1996. Yet it was a business decision that drove the company to submit OxyContin for approval with 12-hour rather than 8-hour dosing. Internal Purdue marketing documents indicate that 12-hour dosing was considered key to differentiating the drug from the competition—generic, short-acting opioids that require patients to wake in the middle of the night to take the next dose.

447. Under FDA guidelines for establishing dosing, Purdue merely had to show that OxyContin lasted for 12 hours for at least half of patients, and Purdue submitted a single study that cleared the bar. While the OxyContin label indicates that “[t]here are no well-controlled clinical studies evaluating the safety and efficacy with dosing more frequently than every 12 hours,” the reason is that it was not in Purdue’s business interest to conduct any such studies.

448. From the outset, Purdue leveraged 12-hour dosing to promote OxyContin as providing continuous, round-the-clock pain relief with the convenience of not having to wake to

take a third or fourth pill. The 1996 press release for OxyContin touted 12-hour dosing as providing “smooth and sustained pain control all day and all night.” But the FDA has never approved such a marketing claim, which contradicts the FDA’s 2008 finding regarding end-of-dose failure.

449. Moreover, Purdue itself long has known, dating to its development of OxyContin, that the drug wears off well short of 12 hours in many patients. According to a 2016 Los Angeles Times investigation, Purdue’s own early studies showed many patients asking for more medication before their next scheduled dose. In one clinical trial, a third of patients dropped out because the treatment was ineffective. Researchers changed the rules to allow patients to take supplemental short-acting opioids—“rescue medication”—in between OxyContin doses. In another study, most patients used rescue medication, and 95% resorted to it at least once. Prescribers, including prescribers in New Jersey, likewise have complained to Purdue sales representatives that OxyContin does not supply 12 hours of pain relief in a significant number of the prescribers’ patients.

450. End-of-dose failure renders OxyContin even more dangerous because patients experience the early stages of psychological and physical withdrawal symptoms on a daily basis, followed by a euphoric rush when they take their next dose—leading to a cycle that fuels a craving for OxyContin. For this reason, Dr. Theodore Cicero, a neuropharmacologist at the Washington University School of Medicine in St. Louis, has called OxyContin’s 12-hour dosing “the perfect recipe for addiction.” [REDACTED]

[REDACTED]

[REDACTED]

451. Purdue has held fast to 12-hour dosing not because it is true, but because it is key to OxyContin's market dominance and comparatively high price; without this advantage, the drug had little to offer over less expensive, short-acting opioids. In a 2004 letter to the FDA, Purdue acknowledged that it had not pursued approval for a recommendation of more frequent dosing in the label (e.g., every 8 hours) because 12-hour dosing was "a significant competitive advantage."

452. Without appropriate caveats, promotion of 12-hour dosing by itself is misleading because it implies that the pain relief supplied by each dose lasts 12 hours, which Purdue knew to be untrue for many patients. Yet 12-hour dosing—without further explanation—was a principal feature of Purdue's marketing. According to multiple former Purdue employees in New Jersey, the company trained its sales force to explain to doctors that, if the Q12 dose did not last the full 12 hours, the sales representative should encourage the doctor to increase the dose. The sales representatives confirmed that they did, in fact, deliver this message to prescribers in New Jersey.

453. Moreover, Purdue sales representatives in New Jersey went even farther than promoting dosing, falsely stating in sales calls that a key feature of OxyContin was that it provided a full 12 hours of pain relief—in one representative's words, "truly a Q12."

454. Twelve-hour dosing also is featured in most OxyContin promotional pieces. A 2012 version of the Conversion and Titration Guide, for example, contains the tag line: "Because each patient's treatment is personal / Individualize the dose / Q12 OxyContin Tablets." And a 2014 visual aid used by sales representatives repeatedly refers not merely to OxyContin, but to "every 12-hour OxyContin" and "Every-12-Hour OxyContin Tablets." None of these pieces disclosed that the pain relief from each 12-hour dose will last well short of 12 hours for many patients, thereby leaving prescribers and patients unprepared for end-of-dose failure and the

craving for more opioids that it creates. This is both an affirmative misrepresentation and a material omission.

455. Purdue's promoted solution to end-of-dose failure—increasing the dose, rather than the frequency, of prescriptions—exacerbates the risks of addiction, overdose, and death. Because the pain relief still does not last 12 hours, taking higher doses simply means that patients will experience higher highs and lower lows, increasing their craving for their next pill.

456. The OxyContin label and the Conversion and Titration Guide expressly direct this approach, advising prescribers that they can increase the dosage to achieve adequate pain relief “as clinical need dictates, while maintaining every 12-hour dosing.” Purdue's representatives offered this advice—to “titrate up”—in their sales calls to New Jersey physicians. But this advice was not accompanied by appropriate warnings regarding increased risk of addiction associated with increased doses, as discussed in Section V.D.4.

457. As a result, health care providers routinely prescribe OxyContin in doses above the recommended daily limit. Based on a nationwide analysis by the Los Angeles Times, more than 52% of patients taking OxyContin longer than three months are on doses greater than 60 milligrams per day—which converts to the 90 milligrams of morphine equivalent that the 2016 CDC Guideline urges prescribers to “avoid” or “carefully justify.” Such doses are similarly prevalent in New Jersey. About 63% of OxyContin and Hysingla prescriptions covered by Medicaid in New Jersey in the last decade exceeded the CDC threshold.

3. At the Direction and Under the Supervision of the Sacklers, Purdue Targeted the Elderly and Opioid-Naïve Patients to Expand Market Share and Profits.

458. A key element of Purdue's effort to satisfy the Sacklers' demands for more sales and more revenue was to target two, overlapping markets in particular: the elderly and opioid-naïve patients—those who previously had not taken opioids. At the core of this strategy were the

lowest strengths of OxyContin—the 10 and 15 mg pills. Purdue marketed these low doses as a way of assuaging concerns about side effects and addiction risk for patients new to opioids, even though it had no evidence demonstrating that these doses were effective and knew that patients were overwhelmingly likely to require higher and ever-increasing doses. As described above in Section V.C, the Sacklers were briefed extensively on the plans to target the elderly and opioid-naïve, even as they continued to demand more sales and to approve more sales representatives and more detailer visits.

459. Implementing the Sacklers' strategic direction, Purdue trained its sales representatives to focus on the elderly in their visits to doctors. Training materials and sales goals for Purdue's sales representatives, as well as New Jersey detailer call notes and sales manager "ride-along" reports from 2008 through at least 2014, include multiple references to Purdue's efforts to persuade doctors to start prescribing its ER/LA opioids to elderly patients.

460. Purdue trained its sales representatives to help doctors identify elderly patients who would fit Purdue's desired patient profile for beginning long-term opioid treatment. For example, according to training materials provided by one former detailer in New Jersey, Purdue sales representatives were taught to ask questions like: "Doc, can an elderly patient have chronic pain and not be on an opioid?" and "[Doctor,] do you have patients over the age of 65 who are being treated with an opioid that would meet OxyContin's indication[?]" Manager ride-along notes from New Jersey encourage and applaud detailers for working with doctors to identify "opioid-naïve" elderly patients for "conversion" from NSAIDs to Oxycontin, Butrans, and Hysingla. Other records demonstrate Purdue's efforts to persuade doctors currently prescribing IR opioids such as Percocet to prescribe OxyContin instead. This practice increases patients' risk for addiction and overdose, since the risks are dose-dependent. As the CDC has explained, use of ER/LA opioids

such as OxyContin, which are indicated only for round-the-clock use, tends to be associated with higher daily dosages than use of as-needed IR opioids.

461. When sales representatives reported that a doctor was reluctant to prescribe OxyContin, their managers gave them instructions for their next visit, specifically that they should keep the doctor focused on starting with low-dose OxyContin to allay the doctor's concerns. These instructions even included an aptly named "Coaching Tip" that the detailer should say: "Doc, I am not asking you to prescribe OxyContin 80, 60, or 40 mg . . . I am asking you to prescribe our lowest dose, OxyContin 10 mg for the elderly patients that would benefit from q12 dosing."

462. Purdue focused heavily on marketing its opioids in New Jersey as medications that were covered by insurance plans, with an emphasis on educating physicians about Medicare Part D (prescription benefit) coverage for opioids. Examples include managers praising this focus, stating "Desired behavior: great job pre-call planning—identifying doc's opportunity to rx OxyContin lower strengths and Butrans for elderly patients—AARP." A Purdue "Sales Performance Plan" provided by one former representative in New Jersey contained the goal to "[e]xpand my Hysingla and Butrans prescribers and loyalists," including by "[f]ocus[ing] on Med D coverage and elderly patients." Another Purdue training document provided by this representative suggested sharing the profile of "Pam," an elderly patient, then asking, "[D]oc, are you aware that 3 of your biggest Med D plans have added Butrans and it is now preferred?"

463. Purdue managers also praised sales representatives for focusing on the nursing home market. One ride-along note offers these congratulations: "Doc said that he spends the majority of his time in nursing homes. Good job playing the role of the challenger rep, asserting control, asking doc to prescribe OxyContin in the nursing homes."

464. Purdue has targeted seniors for a reason—they are a growth sector. In 2016, fully one in three enrollees in Medicare Part D received at least one opioid prescription. And more than 500,000 enrollees nationwide were on a high dose of at least 120 MME—well above the 90 MME level the CDC recommends avoiding. These high doses underscore the eventuality that elderly patients will not simply remain on OxyContin 10 milligrams but will require escalating doses.

465. The Sacklers' push to expand OxyContin's market meant pressing the sales force to target not just the elderly, but also an overlapping group, the opioid-naïve—even when sales representatives were faced with reluctant practitioners.

466. Implementing the Sacklers' strategy, Purdue pushed its sales representatives to focus on opioid-naïve patients as a new source of prescriptions. A former Purdue sales representative in New Jersey expressed significant concern about the intense pressure Purdue asked her to put on doctors to convert opioid-naïve patients to OxyContin. If a doctor was not already prescribing opioids for patients deemed "appropriate" by Purdue, sales representatives were supposed to persuade the doctor to start those patients on a low dose of OxyContin.

467. The deliberate implication was that this low dose was safe. The same sales representative explained that she knew once a patient started on OxyContin for chronic pain, it was likely that the dose would need to be increased as the patient developed a tolerance for the drug over time. Her personal view was, "Why go down that road if there was something else that the doctor felt was safer that they could prescribe?" This sales representative stated that she had difficulty meeting her OxyContin quarterly sales quotas as a result of her reluctance to push doctors to convert opioid-naïve patients to OxyContin.

468. Manager ride-along notes from New Jersey reflect Purdue's focus on expanding prescriptions through the conversion of opioid-naïve patients to OxyContin. Purdue managers

frequently praised sales representatives for doing a “nice job” recommending OxyContin 10 milligrams for opioid-naïve patients. Managers also advised sales representatives on how to be more effective in these “conversion” conversations.

469. Purdue’s decisions to target the elderly and opioid-naïve patients reflected, yet again, a business strategy that placed little, if any, value on the well-being and safety of consumers. An objective risk-benefit analysis of opioid use by either of these populations provides even less justification for initiating ER/LA opioid therapy than might arguably exist among patients who were already using ER/LA opioids.

470. Elderly patients taking opioids are at greater risk for fracture and hospitalization, and they have increased vulnerability to adverse drug effects such as respiratory depression, which Purdue acknowledges in its opioids’ labels (but not in its marketing). A 2010 paper reported that elderly patients who used opioids had a significantly higher rate of death, heart attacks, and strokes than users of NSAIDs.

471. Purdue’s specific focus on opioid-naïve patients, meanwhile, is particularly disconcerting in light of the steady drumbeat of information over the past decade emphasizing, as the CDC summarized in 2016, that “for the vast majority of patients, the known, serious, and too-often-fatal risks far outweigh the unproven and transient benefits [of opioids for chronic pain].” Opioid-naïve patients need never experience the serious consequences of chronic opioid therapy. Yet, through its marketing efforts, Purdue sought to add them to its captive customer base of patients who will continue to require opioids as they become dependent and, perhaps, addicted.

472. In targeting the elderly and opioid-naïve, Purdue recognized that it would need to overcome the reservations of prescribers who preferred to treat these vulnerable patients’ chronic pain with other classes of pain medications and non-pharmacologic therapies (e.g., exercise,

improved ergonomics, and physical therapy) rather than expose them to the increasingly notorious risks of addiction and overdose associated with opioids. Purdue marketed the lowest strengths of OxyContin, the 10mg and 15mg pills, as safe and effective for treating pain precisely to assuage physicians' concerns about opioid side effects and addiction risks.

473. Purdue call notes from New Jersey detailers show that sales representatives regularly promoted the 10mg and 15mg doses of OxyContin to New Jersey prescribers without disclosing the lack of evidence of efficacy or distinguishing them as merely "starter doses" that would require escalation for effective analgesia. On information and belief, Purdue specifically encouraged detailers to promote these doses by using a (.20) multiplier for any growth in sales of the 10mg and 15mg doses when calculating bonus compensation.

474. In fact, Purdue has never established the efficacy of the 10mg and 15mg pills, which were always intended as "starter" doses or means to fine-tune the strength of doses between 20mg and 80mg. At the same time, Purdue had to know that once patients started on OxyContin, dose escalation ("titrating up")—with the attendant increased risks of dependence and addiction—was likely, if not inevitable.

475. The OxyContin package insert lists only one study about the efficacy of the 10mg dose in adults—and the results showed that the 10mg dose was not effective. As printed on the OxyContin package insert, this study concluded that "OxyContin 20mg, but not 10mg, was statistically significant in pain reduction compared with placebo."

476. The 10mg pills (and later, 15mg pills) should only have been marketed for limited purposes: (a) to allow precise doses with a minimum combination of pills, something Purdue markets as "dosing convenience"; and (b) to permit physicians to manage the most serious side effects (like respiratory depression) by starting patients on a very low dose and allowing the body

to adjust to the drug, with the expectation that the dose would soon be increased to a therapeutic pain-relief level. Reflecting that latter purpose, the package insert instructs prescribers that “[t]he starting dosage for patients who are not opioid tolerant is OxyContin 10mg orally every 12 hours. Use of higher starting doses in patients who are not opioid tolerant may cause fatal respiratory depression,” but that thereafter “[c]lose observation and frequent titration are warranted until pain management is stable on the new opioid.”

477. In 2000, the FDA warned Purdue that an advertisement showing an image of the 10mg OxyContin pill placed beneath statements about the drug’s efficacy misleadingly implied that the drug was effective at this dose. From the FDA:

You present the headline, “IN A STUDY OF 133 PATIENTS WITH MODERATE TO SEVERE OSTEOARTHRITIS PAIN*,” followed by bulleted claims about this study. This presentation is followed by the product logo for OxyContin along with various doses of OxyContin that are available. This presentation suggests that any dose of OxyContin can be used for the treatment of moderate to severe osteoarthritis pain. However, the study only demonstrated OxyContin 20mg given twice daily to be significantly more effective than placebo at day 7 and 14. In fact, Oxycontin 10mg given twice daily was no better than placebo in reducing pain intensity. Therefore, your suggestion that any dose of OxyContin can be used in the treatment of moderate to severe osteoarthritis pain is unsubstantiated, and consequently misleading.

478. Despite this FDA warning, Purdue made similar misrepresentations in 2012 and later as to the efficacy of the 10mg and 15mg doses for the treatment of pain. Purdue made these representations directly to prescribers, through a visual aid used by detailers during in-office visits that was specifically labeled as “retained” and “not for distribution.” On information and belief, this visual aid was sent by Purdue to sales representatives in New Jersey.

479. As described in Section V.C, similar marketing materials from the Options and Individualize the Dose campaigns were presented to the Sacklers, who continued to press for more sales representatives and more sales representative visits to prescribers.

480. Even worse than the lack of scientific evidence for these low doses, Purdue knew that even the 10mg and 15mg doses still carried significant risks. In 2007, Purdue admitted that as early as 2000, it had received numerous complaints about physical dependence and withdrawal symptoms occurring with usage of 10mg pills. Moreover, low-dose OxyContin had the same potential for diversion, misuse, and abuse as higher dosages.

481. Purdue's 10mg and 15mg OxyContin marketing strategy has not simply exposed patients to short-term inconvenience and discomfort for little or no therapeutic benefit. The misleading and dangerous implication of marketing 10mg and 15mg doses as effective for treating pain is that doctors can reduce the risks of addiction and overdose to acceptably safe levels while still providing their patients the pain-relief benefits of OxyContin.

482. Purdue knew that patients were highly likely to require increases of their doses of opioids over time—i.e., “titrating up”—to obtain adequate pain relief. In fact, that is what the label itself described. Indeed, Purdue trained its detailers to recommend titrating up as the solution to a variety of complaints about inadequate pain control. But Purdue did not train its detailers to advise or discuss with doctors the complete lack of evidence that the 10mg and 15mg doses were effective at treating pain.

483. Purdue also knew that the risks of dependence, overdose, and addiction rise with the dose, as discussed in Section V.D.4. By promoting low-dose OxyContin over other treatments, Purdue purposefully opened a gateway to dependence, addiction, misuse, and abuse—building a captive market of patients who it exposed to escalating risks over time.

4. At the Direction and Under the Supervision of the Sacklers, Purdue Pushed Its Highest-Strength Pills Without Disclosing the Risks of Higher Doses.

484. Although Purdue used the lowest strengths of OxyContin to expand its captive customer base, the Sacklers' ultimate goal was to move more and more patients up the dose

“ladder” of Purdue’s opioids, including to the 60mg and 80mg OxyContin pills—the most lucrative strengths for both the company and its owners. As described in Section V.C, the Sacklers extensively tracked prescriptions of Purdue’s highest-strength pills in particular. Purdue also recognized and rewarded those sales representatives who were most successful at convincing physicians to prescribe 60mg and 80mg OxyContin.

485. Implementing the Sacklers’ strategic focus on sales of the most profitable strengths of OxyContin, Purdue falsely claimed to New Jersey prescribers and consumers that opioids can be taken at ever-increasing doses for better pain relief, without disclosing that higher doses carry greater risk of addiction and overdose. They did so at the express direction of the Sacklers, who viewed higher doses as a clear pathway to increased sales and revenue. Further, as described in Section V.D.2, Purdue encouraged physicians to increase the dose of OxyContin rather than prescribe it more frequently, despite knowing that higher doses posed greater risks and that OxyContin often did not provide 12 hours of pain relief.

486. The ability to escalate doses was critical to Purdue’s efforts to market opioids for long-term use to treat chronic pain. Unless doctors felt comfortable prescribing increasingly higher doses of opioids to counter tolerance to the drugs’ effects, they may not have chosen to initiate opioid therapy at all. Numerous Purdue marketing materials depict the seven OxyContin tablet strengths—in a line or even a series of steps—and instruct prescribers that they can titrate, *i.e.*, increase the dose, “as clinical need dictates.” The Sacklers, who were extensively briefed on these materials (from the Options and Individualize the Dose campaigns), knew and intended that the sales force would use them to promote higher doses.

487. Purdue’s sales representatives omitted from their sales conversations any discussion of increased risk from higher doses of opioids, despite knowing that dose escalation—

“titrating up,” in Purdue’s parlance—was virtually inevitable. A key sales strategy was to persuade prescribers to convert patients from other pain relievers to the lowest dose of OxyContin, without discussing that the dose would need to be increased over time. One former Purdue sales representative in New Jersey recalled that she was uncomfortable with this tactic, because she knew the natural progression was higher and higher doses.

488. Purdue and Purdue-sponsored publications and CMEs available in New Jersey also misleadingly suggested that higher opioid doses carried no added risk.

489. Through at least June 2015, Purdue’s In the Face of Pain website promoted the notion that if a patient’s doctor did not prescribe what, in the patient’s view, was a sufficient dose of opioids, the patient should find another doctor who would. This approach accords with the advice provided to the Sacklers by McKinsey in 2013: to use “patient pushback” to influence hesitant prescribers.

490. A Policymaker’s Guide, the 2011 publication on which Purdue collaborated with APF, asserted that dose escalations—even unlimited ones—are “sometimes necessary,” but did not disclose the risks from high doses of opioids.

491. Purdue also deceptively presented the risks of opioids in comparison to the risks presented by non-steroidal anti-inflammatory drugs (“NSAIDs” like Advil or Motrin) or acetaminophen (Tylenol). Call notes from New Jersey sales representatives reflect that they frequently touted the absence of a “ceiling dose” of OxyContin to physicians—whose training told them that other painkillers did have safety ceilings—without disclosing the risks associated with higher doses of opioids.

492. Purdue also sponsored a 2013 CME titled “Overview of Management Options” that highlighted the evidence of adverse effects from high doses of NSAIDs but did not discuss the

increased risk from using high doses of opioids. The CME was edited by Dr. Portenoy, who received research support, honoraria, and consulting fees from Purdue. Issued by the American Medical Association in 2013, the CME remains available from the AMA online. A Purdue-sponsored pain pamphlet for physician assistants similarly emphasized the risk of liver damage from acetaminophen at higher doses, while omitting any comparable discussion of the risks of opioids at high doses.

493. Even where Purdue marketing pieces acknowledged that certain serious risks rose with the dose, they failed to disclose the increased risk of addiction. For example, a 2009 brochure for prescribers stated that “there is no defined maximum daily dose” and “[t]he ceiling to analgesic effectiveness is imposed only by side effects.” Side effects were defined to include respiratory depression and various non-serious events such as constipation, but not addiction or opioid abuse.

494. There is no substantial scientific evidence that doses of opioids can be continuously titrated upward without significant added risk. On the contrary, patients receiving high doses of opioids as part of long-term opioid therapy are three to nine times more likely to suffer overdose from opioid-related causes than those on low doses. As compared to available alternative pain remedies, patients develop a tolerance to opioids’ analgesic effects quicker than they develop a tolerance to opioids’ depressive effects on respiration. Accordingly, the practice of continuously escalating doses to match pain tolerance can, in fact, lead to overdose even where opioids are taken as recommended.

495. As confirmed by the CDC in its 2016 Guideline, the “[b]enefits of high-dose opioids for chronic pain are not established,” while the risks for serious harms are clear and dose-dependent. More specifically, the CDC explains that “there is now an established body of scientific evidence showing that overdose risk is increased at higher opioid doses.” The CDC also

states that there are “increased risks for opioid use disorder, respiratory depression, and death at higher dosages.”

496. Because of these risks, the 2016 CDC Guideline advises doctors to “avoid increasing doses” above 90 morphine milligram equivalents (MME) per day. Yet many patients continue to receive dangerously high doses of opioids. Among New Jersey patients insured by Medicaid, for example, 52% of patients taking OxyContin or Hysingla between 2008 and 2016 ultimately were prescribed doses exceeding the CDC’s recommended limit.

497. Escalation to dangerous doses is built into the OxyContin and Hysingla product lines. Of the seven available OxyContin tablet strengths, the three strongest—40 milligrams (120 MME), 60 milligrams (180 MME), and 80 milligrams (240 MME)—all exceed the CDC limit when taken (as directed) twice daily. Patients on the twice-daily 80 milligram dose receive nearly three times the recommended ceiling of 90 MME. The two highest strengths of Hysingla—a once-a-day pill—provide 100 and 120 MME, also exceeding the CDC threshold.

5. At the Direction and Under the Supervision of the Sacklers, Purdue Encouraged Long-term Use of Opioids – Including with Savings Cards – Despite the Known Risks and Absence of Benefits of Such Use.

498. In addition to convincing physicians to prescribe the highest doses of Purdue’s opioids, the company also sought to keep patients on Purdue’s opioids for longer periods of time—an explicit sales goal of the Sacklers. These two pursuits were complementary: as discussed in Section V.C, the Sacklers and Purdue knew that patients on opioids inevitably required higher and higher doses, and that patients on the highest doses tended to remain on opioid therapy the longest. The Sacklers aggressively encouraged long-term use—measured in months and years—despite the serious risks attendant to such use and the absence of scientific evidence supporting the efficacy of long-term opioid therapy.

499. As a central component of the Sacklers' deliberate marketing strategy to encourage, initiate, and extend long-term use of these drugs, Purdue relied heavily on prescription discount "Savings Cards," which were known to boost so-called "continuing prescriptions." Purdue carried out this specific strategy at the direction of the Sacklers, who, as described in Section V.C, had studied the use of savings cards and urged Purdue to optimize their use to meet long-term sales goals.

500. Implementing the Sacklers' strategy, Purdue promoted, marketed, advertised, or distributed Savings Cards [REDACTED] that offered patients discounts on their out-of-pocket costs for OxyContin, Butrans, and Hysingla and encouraged long-term use of these drugs. [REDACTED]

[REDACTED]

The OxyContin Savings Card

Patient must retain card for future savings • Program expiration 3/31/2015

Prescription Savings Card

OXYCONTIN[®] CR
(OXYCODONE HCl EXTENDED-RELEASE TABLETS)

Pharmacist: Utilize this information when submitting claim to Therapy First Plus:

Bin#: 004682 RxPCN: CN

Group#:

ID#:

Other Coverage Code indications required.

SAVE UP TO \$70 off your out-of-pocket expenses on each eligible prescription for OxyContin after your initial out-of-pocket payment of \$30.

Patient Savings Cards are good only with valid prescription for OxyContin Tablets and cannot be used more than once per 14-day period.

Patients with questions please call 1-800-615-4987 9:00 am-5:00pm EST Mon.-Fri.

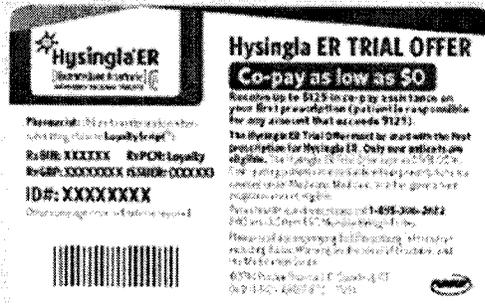
Please read Boxed Warning on the cover of brochure. Please read accompanying Full Prescribing Information.

This card must be activated for use.
Please call 1-866-888-3657
to activate your card.

© 2014 Purdue Pharma L.P., Stamford, CT 06901-0401 OAB05-C 6/14

- Patients with questions about the card should call 1-800-615-4987, 9:00 AM to 5:00 PM EST, Monday through Friday
- If you lose your card, please call 1-800-615-4987

Help Lower Patients' Costs With the Hysingla ER Patient Savings Program*



Hysingla ER
[Purdue Pharma Logo]

Hysingla ER TRIAL OFFER
Co-pay as low as \$0

Receive up to \$125 in co-pay assistance on your first prescription (patient is responsible for any amount that exceeds \$125).

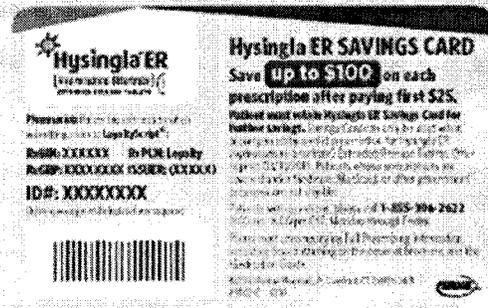
The Hysingla ER Trial Offer must be used with the first prescription for Hysingla ER. Only new patients are eligible. The Hysingla ER Trial Offer expires 12/31/14. The program is subject to change without notice. Not available under Medicare, Medicaid, or for generic brand prescriptions only.

Patient must be a resident of the United States and be at least 18 years old. For more information, call 1-800-394-2622. *Offer not available in all states. © 2014 Purdue Pharma L.P. All rights reserved.

Pharmacy: Name and address for submitting claim: **Loyalty Script™**
 Rx#R: XXXXXX In-PDR: Loyalty
 RxID#: XXXXXXXX (S/NR): XXXXXX
 ID#: XXXXXXXX

One-time use only. Not for resale.





Hysingla ER
[Purdue Pharma Logo]

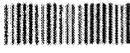
Hysingla ER SAVINGS CARD
Save up to \$100 on each prescription after paying first \$25.

Patients must use Hysingla ER Savings Card for Patient Savings. Savings Card is only for use with Hysingla ER. Savings Card is not valid with other insurance programs. Savings Card is not valid with Medicare, Medicaid, or other government programs. Savings Card is not valid with other insurance programs.

Patient must be a resident of the United States and be at least 18 years old. For more information, call 1-800-394-2622. *Offer not available in all states. © 2014 Purdue Pharma L.P. All rights reserved.

Pharmacy: Name and address for submitting claim: **Loyalty Script™**
 Rx#R: XXXXXX In-PDR: Loyalty
 RxID#: XXXXXXXX (S/NR): XXXXXX
 ID#: XXXXXXXX

One-time use only. Not for resale.




To learn more and download cards visit Hysingla.ER.com

***ELIGIBILITY REQUIREMENTS:**

This card cannot be used if prescriptions are covered by: (i) any federal or state healthcare program, including a state medical or pharmaceutical assistance program (Medicare, Medicaid, Medigap, VA, DOD, TRICARE, etc.); (ii) Medicare Prescription Drug Program (Part D Program); (iii) insurance in states that have an "all payer" anti-kickback law or insurance that is paying the entire cost of the prescription. Card use must comply with all Terms and Conditions. Patients must meet eligibility requirements. Void where prohibited by law. Patients in VT are not eligible. Patients must meet eligibility requirements. Other restrictions may apply.

TERMS AND CONDITIONS:

Patients must meet eligibility requirements. Patient agrees to report their use of this card to any third party that reimburses them or pays for any part of the prescription price. Patient additionally agrees to not submit any portion of the product dispensed pursuant to this card to a federal or state healthcare program for purposes of counting it toward their out-of-pocket expenses (such as TrOOP under Medicare Part D or Medicaid). This card is not valid with any other program, discount, or incentive involving the covered medication. This offer is not contingent upon any past, present, or future purchases of the covered drug or any other product, and this offer may be rescinded, revoked, or amended without notice. No reproductions. This card is not insurance. This card is void where prohibited or where restricted beyond the terms herein.

RelayHealth eVoucherRx™ Purdue has partnered with RelayHealth to provide automatic savings at the pharmacy on qualified claims with commercial insurance coverage. For convenience, patients who have third-party insurance and visit a participating eVoucher pharmacy will have savings applied automatically for qualified claims—no Savings Card Required. At participating pharmacies, simply submit the patient's prescription and the patient will automatically receive the co-pay savings on qualified claims. For information, please call RelayHealth Customer Support at 1-800-388-2316.

Help Lower Your Patients' Costs With the Butrans Patient Savings Program

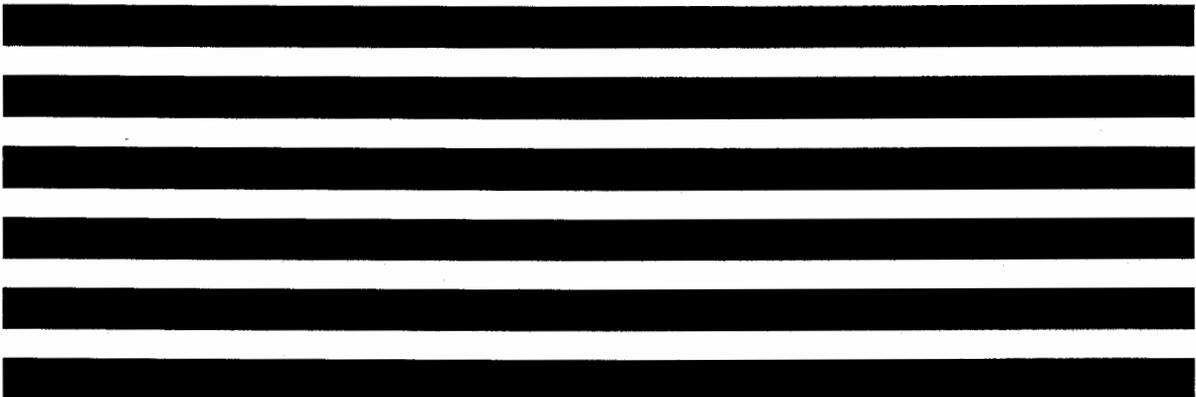


Savings on Each Prescription With the Butrans Savings Card

- The **Butrans Savings Card** is valid for use with eligible prescriptions for Butrans issued during the time of offer (expiration 3/31/2016)
- The **Butrans Savings Card** will save eligible patients up to \$70 on each prescription. The patient is responsible for the first \$30 and any amount that exceeds the total Butrans Patient Savings Program offer, and patient must have a co-pay of less than \$250 to qualify
- Patients can use the **Butrans Savings Card** one time for each dosage strength every 21 days until the offer expires on 3/31/2016. There is a limit of one Butrans Savings Card per patient during time of offer
- Not all patients are eligible to use the **Butrans Savings Card**. Patients whose prescriptions are covered under Medicare, Medicaid, or other government programs are not eligible. Please see Eligibility Requirements and Terms and Conditions

Visit Butrans.com to print cards for your patients and for full eligibility requirements and terms and conditions

501. Purdue trained sales representatives to discuss Savings Cards on every sales call.



[REDACTED]

[REDACTED]

502. In 2012, Purdue introduced what it described in internal documents as “new channels to broaden access to Patient Savings Card Program”: Relay Health, which provided automatic rebates at pharmacies, and downloadable savings cards on PurdueHCP.com. This training document identified the Savings Cards as being downloadable by “HCP” (healthcare providers). Purdue sales representatives [REDACTED] discussed downloadable savings cards with pharmacists, informing them that patients could download the cards directly from Purdue websites—a workaround when prescribers chose not to offer them.

503. Purdue’s emphasis on Savings Cards helped to boost the “continuing prescriptions” group of patients—which constituted 80% of its OxyContin sales—beyond 90 days of use. [REDACTED]

[REDACTED]

[REDACTED]

504. The Savings Card program was a key tool that Purdue used to capture a long-term, dependable customer base. A 2012 Purdue sales training document asserted that “market research has shown that ~60% more patients stay on therapy >90 days if a savings card is redeemed.”

505. Purdue also used Savings Cards to encourage new patients to try its opioids, by making the drugs significantly cheaper, or in some instances free. In a 2012 sales training presentation, Purdue described its rationale for subsidizing a \$0 (i.e., free) Butrans copayment through Savings Cards for new patients: that a Savings Card was “effectively acting as a sample.” In the 2007 Settlements, Purdue had expressly agreed to stop distributing samples of OxyContin.

506. Undergirding all of the efforts of the Sacklers and Purdue to keep patients on opioids was the baseline proposition that that there is a significant upside to long-term opioid use.

But as the 2016 CDC Guideline makes clear, there is “insufficient evidence to determine long-term benefits of opioid therapy for chronic pain.” (Emphasis added.) In fact, the CDC found that “[n]o evidence shows a long-term benefit of opioids in pain and function versus no opioids for chronic pain with outcomes examined at least 1 year later (with most placebo-controlled randomized trials \leq 6 weeks in duration)” and that other treatments were more or equally beneficial and less harmful than long-term opioid use. The FDA similarly has recognized the lack of evidence to support long-term opioid use, stating in 2013 that it was “not aware of adequate and well-controlled studies of opioids use longer than 12 weeks.”

507. On the contrary, the available evidence indicates opioids are not effective to treat chronic pain, and may worsen patients’ health. A 2006 analysis of studies found that “[f]or functional outcomes . . . other [non-addictive] analgesics were significantly more effective than were opioids.” Increasing duration of opioid use is strongly associated with an increasing prevalence of mental health conditions (depression, anxiety, post-traumatic stress disorder, or substance abuse), increased psychological distress, and greater health care utilization. Moreover, as reflected in the same study, efficacy trials do not typically include data on opioid addiction. In many cases, patients who may be more prone to addiction are pre-screened out of the study pool, which does not reflect how doctors actually prescribe the drugs.

508. Purdue long was aware of the disconnect between the academic literature, which assesses efficacy only as far out as 12 weeks, and the reality—which it helped create—that many patients use OxyContin and other opioids for months or years. For example, a 2011 internal email among Purdue researchers discussed the need for “new research studies of not less than 12 months duration to determine the long-term effectiveness of opioids for chronic non-cancer pain”—an acknowledgement that such evidence did not exist.

509. Nevertheless, building on its earlier marketing, Purdue continued to tout the purported benefits of long-term opioid use, while falsely and misleadingly implying that these benefits were supported by scientific evidence. In their sales conversations with New Jersey prescribers, Purdue sales representatives did not disclose the lack of evidence supporting long-term use. And Purdue promotional materials likewise promoted long-term use without disclosing the absence of long-term studies.

510. For example, the OxyContin “Conversion and Titration Guide,” which sales representatives widely distributed in New Jersey, implied that use can continue safely for years. A 2007 version of that guide recommended that “the need for around-the-clock opioid therapy should be reassessed periodically (e.g., every 6 to 12 months) as appropriate for patients on chronic therapy,” but did not disclose the absence of evidence supporting safety and efficacy of use for 6 to 12 months. Later versions of this guide omitted the parenthetical “(e.g., every 6 to 12 months)” and simply stated that prescribers should “periodically reassess the continued need for opioid analgesics.” However, Purdue continued to train sales representatives to tell prescribers to reassess every “6 to 12 months.”

511. Purdue specifically claimed—also without evidence—that long-term opioid use will improve patients’ daily function and quality of life. As discussed in Section V.B, this was the same message that Richard Sackler had pushed since the 1990s. Promotional materials with this message were distributed to New Jersey prescribers, and Purdue’s sales representatives delivered this message in their New Jersey sales visits.

512. Purdue and Purdue-sponsored materials distributed or available in New Jersey reinforced this message. The 2009 APF book Exit Wounds asserted unequivocally that “[w]hen used correctly, opioid pain medications increase a person’s level of functioning” and that opioids

“can go a long way toward improving your functioning in daily life.” And the 2011 publication A Policymaker’s Guide erroneously claimed that “multiple clinical studies have shown that long-acting opioids, in particular, are effective in improving [d]aily function . . . [and] quality of life for people with chronic pain.”

513. Purdue’s claims of functional improvement, which echoed Richard Sackler’s direction to Purdue executives that OxyContin would “enhance personal performance,” were both unsubstantiated by and contrary to the scientific evidence at the time. The sole study the Guide cited for this claim expressly noted the absence of long-term studies and actually found that “[f]or functional outcomes, . . . other analgesics were significantly more effective than were opioids.” The FDA has made clear for years that opioid manufacturers should not make claims regarding functional improvement and ability to perform daily activities, warning Purdue competitors in public letters that such claims lacked substantial scientific evidence.

514. Most recently, the 2016 CDC Guideline approved by the FDA concluded that “there is no good evidence that opioids improve pain or function with long-term use.” (Emphasis added.) The CDC reinforced this conclusion throughout the Guideline, finding, for example, that “[n]o evidence shows a long-term benefit of opioids in pain and function versus no opioids for chronic pain with outcomes examined at least 1 year later.”

E. The Sacklers, Through Purdue, Have Caused Significant Harm to Public Health, Welfare, and Safety in New Jersey.

515. As a direct result of the Sackler- and Purdue-driven overprescribing of opioids, New Jersey and its citizens have experienced an epidemic of drug addiction, abuse, overdose, and other injuries, with their attendant societal costs. In addition, the State of New Jersey, through its State-funded health programs, has been forced to pay hundreds of millions of dollars for opioid prescriptions, attendant treatment, and other costs, even though many of these prescriptions were

not medically necessary and would not have been written but for Purdue's fraudulent scheme. Consumers, private employers, and insurers have suffered similar financial impacts.

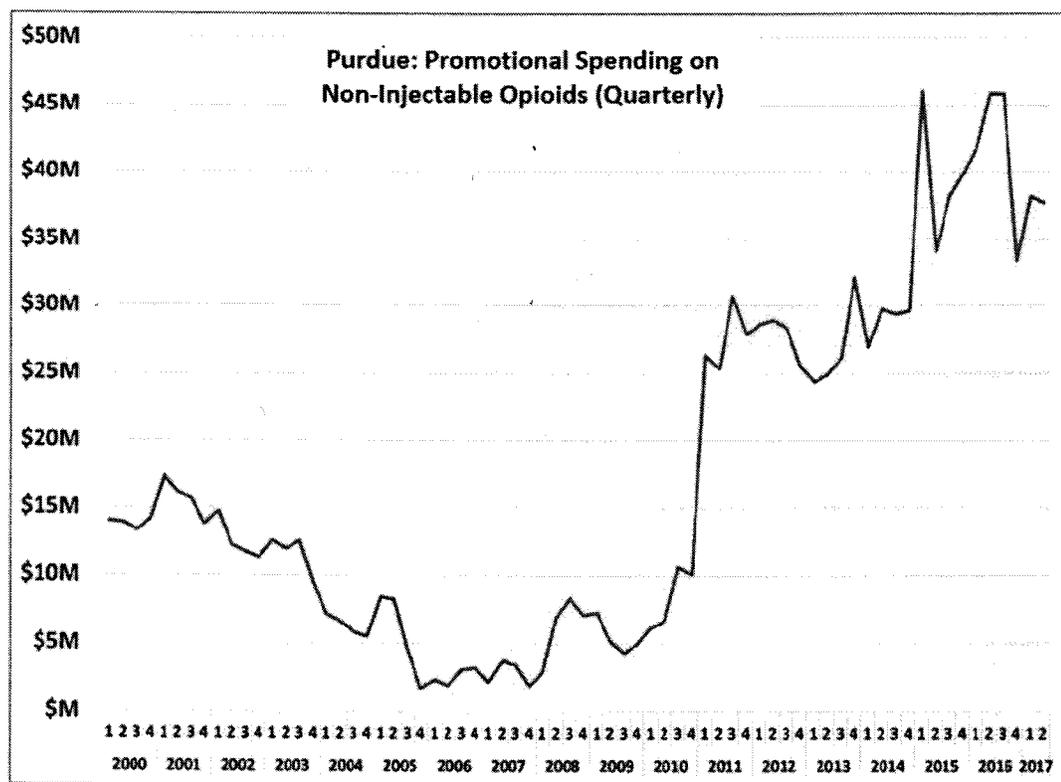
1. Purdue's Deceptive Marketing Fueled the Opioid Epidemic, Resulting in Addiction, Overdose, and Other Injuries to New Jersey Citizens.

516. Purdue's misrepresentations, made at the direction and under the supervision of the Sacklers, have prompted New Jersey health care providers to prescribe, patients to take, and payors to cover opioids for the treatment of chronic pain. Through its marketing, Purdue overcame barriers to widespread prescribing of opioids for chronic pain. The company's deceptive messages under-represented the risks of opioids, overstated their benefits, and expanded the perception of who was an "appropriate patient" for opioid use—successfully creating a self-sustaining opioid economy for Purdue.

517. Purdue's deceptive marketing has directly contributed to an explosion in the use of opioids. In the United States, opioids are the most common treatment for chronic pain. As the CDC has reported, by 2012 health care providers were writing some 259 million opioid prescriptions annually—"enough for every adult in the United States to have a bottle of pills."

518. Purdue accounts for the lion's share of sales of brand name opioids. Nationwide in 2013, there were 6 million prescriptions of OxyContin, resulting in \$2.6 billion in sales—giving Purdue 44% of market value for all ER/LA opioids, and 24% of the overall opioid market (which includes widely prescribed generics). By comparison, no other branded drug accounted for more than 3% of ER/LA prescriptions annually. In New Jersey, from 2008 to 2016, Purdue accounted for 73% of branded opioid prescriptions paid by the State's largest Medicaid provider and for 37% of those paid by the Workers' Compensation Program. Purdue opioids also accounted for 61% of the branded opioid prescriptions paid by the State's employee and retiree health plans between 2012 and 2016.

519. Nationwide, opioid prescribing quadrupled between 2000 and 2016, a gigantic increase that corresponds to Purdue's equally massive marketing push. As depicted in the chart below, data obtained from a marketing research company show Purdue's spending nationally on opioid marketing stood at roughly \$15 million per quarter in 2000. Its spending actually decreased from 2000 to 2007, as the company came under investigation by the U.S. Department of Justice and various state attorneys general. But by 2010, with the introduction of Butrans and the reformulated OxyContin, Purdue again kicked its marketing machine into overdrive. In 2011, Purdue's marketing spiked to more than \$25 million per quarter, and by 2016, with the introduction of Hysingla, it soared to more than \$40 million per quarter—\$167 million annually, just on marketing opioids.



520. By far, the largest component of this spending was the cost of sales representatives, with total detailing expenditures nationwide rising from roughly \$45 million annually in 2000 to \$156 million in 2014. As described in Section V.C, the Sacklers tracked the size, performance, and cost of the sales force in extensive detail, as well as—most importantly—its impact on sales.

521. Many physicians are unwilling to acknowledge the impact of detailing on their prescribing because of the uncomfortable conclusion that their medical judgment is influenced by pharmaceutical marketing. Yet Purdue devoted enormous resources to detailing—notwithstanding increasing efforts of hospitals and physician practice groups to restrict access in recent years—because it knew that in-person marketing works. The effects of sales calls on prescribing behavior are well-documented in the literature, including in a 2009 study correlating the nearly 10-fold increase in OxyContin prescriptions between 1997 and 2002 with Purdue’s doubling of its sales force and trebling of sales calls. The lockstep pattern between detailing and prescribing of Purdue’s opioids is apparent through 2016.

522. Purdue’s aggressive marketing affected even those physicians whom Purdue did not target or whose practices do not permit detailing. The vast new market for opioids is sustained today not only by Purdue’s recent marketing, but also by its past, deception-fueled success in establishing opioids as a first-line treatment for chronic pain. In direct consequence of commonplace opioid prescribing, many patients have come to believe they will not become addicted; addicts demand more drugs; and health care providers refill opioid prescriptions that maintain dependence and addiction in the belief they are doing the best for their patients or have no other option but to prescribe more opioids. Purdue’s marketing of opioids as the best, first-choice answer to pain reinforced the psychological incentives for doctors who wanted to make their patients feel better—if they provided opioids, the patient was satisfied; if they did not, they

faced a patient who feels underserved and may, with Purdue's encouragement, seek another doctor who would.

523. As a result of the long-running and massively successful marketing campaign overseen by the Sacklers and implemented by Purdue, opioids become entrenched as a routine treatment for chronic pain conditions, despite their serious risks and the absence of evidence that they improve patients' pain and quality of life over the long term. As of 2010, an estimated 20% of patients presenting to physician offices with non-cancer pain symptoms or pain-related diagnoses (including acute and chronic pain) received an opioid prescription. Nationwide, opioid prescribing steadily increased through 2012. In New Jersey, while the State's years-long efforts to curb overprescribing have borne some fruit, prescribing rates—as measured in MME—stubbornly remained constant or even increased in a majority of counties through 2015. The problem of overprescribing is particularly acute in six New Jersey counties—Atlantic, Burlington, Cape May, Cumberland, and Gloucester—all of which had prescribing rates ranked in the top 30% nationally in 2015.

524. The sharp increase in opioid use resulting from Purdue's marketing led directly to a dramatic increase in opioid abuse, addiction, overdose, and death throughout the United States, including in New Jersey.

525. In August 2016, then-U.S. Surgeon General Vivek Murthy published an open letter to be sent to physicians nationwide, enlisting their help in combating this “urgent health crisis” and linking that crisis to deceptive marketing. He wrote that the push to aggressively treat pain, and the “devastating” results that followed, had “coincided with heavy marketing to doctors . . . [m]any of [whom] were even taught—incorrectly—that opioids are not addictive when prescribed for legitimate pain.”

526. Scientific evidence demonstrates a close link between opioid prescriptions and opioid abuse. For example, a 2007 study found “a very strong correlation between therapeutic exposure to opioid analgesics, as measured by prescriptions filled, and their abuse,” with particularly compelling data for extended release oxycodone—i.e., OxyContin.

527. In a 2016 report, the CDC explained that “[o]pioid pain reliever prescribing has quadrupled since 1999 and has increased in parallel with [opioid] overdoses.” Patients receiving opioid prescriptions for chronic pain account for the majority of overdoses. For these reasons, the CDC concluded that efforts to rein in the prescribing of opioids for chronic pain are critical to “reverse the epidemic of opioid drug overdose deaths and prevent opioid-related morbidity.”

528. Nationwide, drug overdoses claimed the lives of more than 70,000 Americans in 2017. In recent years, two-thirds of all such deaths were attributable to opioids (including both prescription opioids and heroin). According to the CDC, between 1999 and 2015, more than 183,000 people in the United States died from prescription opioid-related overdoses alone—more Americans than died in the Vietnam, Iraq, and Afghanistan wars combined. In New Jersey, there were 2,737 drug overdose deaths overall in 2017, reflecting a 124% rise since just 2012. As reported by the New Jersey 101.5 FM radio station, the epidemic has gotten so bad that staff at the State’s libraries—typically the most open buildings in their communities—are being instructed to watch out for users “overdosing inside . . . bathrooms or behind rows of books.”

529. According to national 2009 data analyzed by the National Institute on Drug Abuse, overdose deaths represent only the tip of the iceberg. For every overdose death that year, there were 9 abuse treatment admissions, 30 emergency department visits for opioid abuse or misuse, 118 people with abuse or addiction problems, and 795 non-medical users of opioids. In New Jersey, opioid-related emergency department visits doubled between 2005 and 2014 and rose

another 13% in 2015. Emergency medical technicians have administered naloxone—the emergency antidote to opioid overdoses—more than 18,000 times since its use was approved in New Jersey in 2014. According to a 2015 report by a national economics consulting firm, New Jersey’s annual health care costs related to opioid abuse were estimated to exceed \$683 million.

530. Rising opioid use, abuse, and addiction have had negative social and economic consequences far beyond overdoses and hospital visits. According to a 2016 study by a Princeton economist, unemployment increasingly is correlated with use of prescription pain medications. Nearly half of surveyed men not in the labor force said they took pain relievers daily, and two-thirds of them were on prescription medications—compared to just 20% of employed men who reported taking pain medications. Worse still, many of those taking pain medications still said they experienced pain daily—an echo of the CDC’s recent conclusion that “there is no good evidence that opioids improve pain or function with long-term use, and . . . complete relief of pain is unlikely.” (Emphasis added.)

531. There are also swelling costs from the growing universe of medications aimed at treating secondary effects of opioids—including not only addiction and overdose, but also side effects like constipation and sedation. According to a 2016 analysis by The Washington Post, working-age women and men on opioids are much more likely to have four or more prescriptions from a physician (57% and 41%, respectively) than are their counterparts who do not take opioids (14% and 9%, respectively). According to The Washington Post, secondary-effects medications—essentially, drugs to treat the effects of drugs—generated at least \$4.6 billion in spending in 2015, on top of \$9.57 billion in spending on opioids themselves.

532. The deceptive marketing and consequent overprescribing of opioids also have had a significant detrimental impact on young people in New Jersey. The overprescribing of opioids

for chronic pain has given children access to opioids, nearly all of which were prescribed for adults in their household. In New Jersey, roughly one in four teenagers has abused prescription drugs, according to 2012 data.

533. Even infants have not been spared the impact of widespread opioid use and abuse. There has been a dramatic rise in the number of infants who are born addicted to opioids due to prenatal exposure and suffer from neonatal abstinence syndrome (“NAS,” also known as neonatal opioid withdrawal syndrome, or “NOWS”). These infants painfully withdraw from the drug once they are born and cry nonstop from the pain and stress of withdrawal, experience convulsions or tremors, have difficulty sleeping and feeding, and suffer from diarrhea, vomiting, and low weight gain, among other serious symptoms. The long-term developmental effects are still unknown, though research in other states has indicated that these children are likely to suffer from continued, serious neurological and cognitive impacts, including hyperactivity, attention deficit disorder, lack of impulse control, and a higher risk of future addiction. When untreated, NAS can be life-threatening.

534. Nationwide, more than 21,732 infants in the United States were born with NAS in 2012, or about one every 25 minutes. According to an analysis by NJ.com, 6.4 of every 1,000 babies in New Jersey were born with NAS in 2014—more than double the 2008 figure. The problem is particularly acute in Atlantic, Cape May and Cumberland counties, where more than one out of every 50 babies in 2014 was born addicted to opioids.

535. Opioid addiction now outpaces other forms of addiction in demand for substance abuse treatment, and treatment providers are struggling to keep up. In 2016, prescription opioid and heroin abuse accounted for half of the substance abuse treatment admissions (including admissions for alcohol abuse) in New Jersey—more than 37,000 admissions—and accounted for

the overwhelming majority of drug abuse admissions. Yet the demand for treatment far outstrips the supply. The New Jersey Department of Human Services estimates that 37,000 New Jersey residents needed and wanted substance abuse treatment in 2016 but did not receive it.

536. Purdue's deceptive and unconscionable conduct, performed at the direction and under the supervision of the Sacklers, has imposed significant burdens on the community at large. Purdue's success in extending the market for opioids to new patients and chronic conditions has created an abundance of drugs available for non-medical or criminal use and fueled a new wave of addiction, abuse, and injury. It has been estimated that 60% of the opioids that are abused come, directly or indirectly, through physicians' prescriptions.

537. Various studies report that as many as 80% of heroin addicts used prescription opioids before crossing over to heroin. In New Jersey, too, many of those who have overdosed started out on opioids with a prescription to treat chronic pain. Although prescribed opioids are prized among drug abusers because they are legal and predictable (*i.e.*, the dose is clearly specified), recent years have seen a surge in prescription opioid abusers shifting to heroin because it is cheaper and easier to obtain than prescription opioids.

538. A recent, even more sinister problem stemming from the prescription opioid epidemic involves fentanyl—a powerful opioid carefully prescribed for cancer pain or in hospital settings that, in synthetic form, is now making its way into New Jersey communities through a booming trafficking network. Drug dealers are mixing fentanyl into heroin because it can be cheaply produced and creates an intense high. Patients who moved from prescription opioids to heroin may now find themselves graduated to heroin plus fentanyl. In 2015, 72% of heroin seized by law enforcement authorities in New Jersey was adulterated with fentanyl.

539. Fentanyl has been linked to an increasing number of the State's overdoses. Fentanyl is 50 times more potent than heroin, and can quickly induce death in opioid-naïve users. And fentanyl abuse is often a game of Russian roulette, with users not knowing what mixture of fentanyl and heroin they are taking.

540. In addition to presenting heightened risks to persons addicted to opioids, the rise in the criminal market for opioids has burdened the State, as well as localities, with increased law enforcement costs.

541. Many patients who abuse or become addicted to opioids will lose their jobs, and some will lose their homes and their families. Some will get treatment, and fewer will successfully complete it; many of those patients will relapse, returning to opioids or some other drug. Of those who continue to take opioids, some will overdose—some fatally, some not. Others will die prematurely from related causes—falls, traffic accidents, or assaults or from premature heart or neurological diseases—that hasten their death by 10 or 20 years.

542. In addition to the personal and familial burdens of opioid-related disability and death, such disability and death have diminished worker productivity. The CDC estimates the national cost of lost productivity associated with opioid use at approximately \$40 billion annually.

2. Purdue's Deceptive Marketing Has Burdened the State of New Jersey with Direct Financial Costs.

543. Purdue's misrepresentations, made at the direction and under the supervision of the Sacklers, also have caused damage directly to the State. The State has been damaged through the payment of false claims for chronic opioid therapy under (a) the State's Medicaid programs, (b) the State's employee and retiree health plans, and (c) the State's Workers' Compensation Program. The State has also been damaged by the payment of additional claims for drugs and medical

services to treat conditions and injuries caused by chronic opioid use. These include treatments for neo-natal abstinence syndrome, addiction, and drug overdose.

a. The State's spending on opioids under comprehensive health care plans

544. Commensurate with Purdue's heavy promotion of opioids and the resultant, massive upswing in prescribing of opioids nationally and in New Jersey, the State has seen its own spending on opioids—through claims paid by its Medicaid and Workers' Compensation programs—rise dramatically between 2008 and 2014, with particularly sharp increases, year-over-year, in 2011, 2012, and 2014.

(1) New Jersey Medicaid

545. The State provides comprehensive health care benefits, including prescription drug coverage, to low- and moderate-income residents through its Medicaid programs. Approximately 1.94 million New Jersey residents are enrolled in these publicly funded programs; the State funds prescription drug benefits for approximately 1.6 million of these enrollees. These programs are largely administered through five managed care organizations—Horizon NJ Health, United Health Care, Amerigroup, Wellcare, and Aetna (collectively “the Medicaid Contractors” or “MCOs”).²

546. Under the State's contract with the Medicaid Contractors, the Contractors are required to provide healthcare services and products to program beneficiaries “in accordance with medical necessity.” “Medically necessary services” are defined as

services or supplies necessary to prevent, evaluate, diagnose, correct, prevent the worsening of, alleviate, or cure a physical or mental illness or condition . . . The services provided . . . must be

² A small percentage of the State's Medicaid recipients are enrolled in a fee-for-service plan. That plan is administered by Molina Medicaid Solutions. The only pertinent difference between the MCO plans and the fee-for-service plan is that the State reimburses doctors and pharmacies directly for the cost of all medical services and drugs provided to Medicaid beneficiaries.

reflective of the level of services that can be **safely provided**, must be consistent with the diagnosis of the condition and **appropriate to the specific medical needs** of the enrollee and **not solely for the convenience of the enrollee or provider of service** and in accordance with standards of good medical practice and **generally recognized by the medical scientific community as effective . . .** Medically necessary services provided must be based on **peer-reviewed publications**, expert pediatric, psychiatric, and medical opinion, and medical/pediatric community acceptance. (Emphasis added.)

547. The Medicaid Contractors enlist health care providers (“Medicaid Providers”)—including doctors and pharmacies—to provide services to New Jersey Medicaid beneficiaries. Among other things, these Medicaid Providers agree to comply with all State and federal Medicaid requirements under a Provider Agreement that is “subject to the applicable material terms and conditions of the contract between the Contractor and the State and shall also be governed by and construed in accordance with all laws, regulations and contractual obligations incumbent upon the Contractor.”

548. Opioids are only dispensed based on a licensed medical practitioner’s prescription, which a practitioner will not write without first examining and diagnosing a patient. A Medicaid Provider submits a standardized form—the CMS 1500—to the Medicaid Contractor seeking reimbursement for such an office visit. By submitting a CMS 1500 form, the signatory certifies “that the services listed above were medically indicated and necessary to the health of this patient and were personally furnished by me or my employee under my personal direction.” Pharmacies participating in Medicaid submit their requests for reimbursement of prescriptions electronically, using the NCPDP v.D.0 format.

(2) The State Employee Health Plans

549. The State provides comprehensive health care benefits, including prescription drug coverage, to its current and retired employees and their dependents through two programs, the

State Health Benefits Program and the School Employees' Health Benefits Program (collectively, the "Employee Health Plans"). Approximately 830,000 persons are enrolled in these plans. The Employee Health Plans are self-funded, meaning that the State bears the charges for all services and products used by beneficiaries.

550. The medical benefits provided to State employees are administered by two private companies: Horizon and Aetna. Employees are offered an array of plans, which are structured as preferred provider organizations ("PPOs") and health maintenance organizations ("HMOs"). The plans vary in terms of flexibility and cost (i.e., employee contributions, deductibles, and co-payments), but coverage under all plans is restricted to medically necessary care, which is defined by Horizon as a service or supply

- that is ordered by a doctor for the diagnosis or treatment of an illness or injury;
- **the prevailing opinion within the appropriate specialty** of the United States medical profession is that it is **safe and effective** for its intended use, and that its omission would adversely affect the person's medical condition;
- that it is the **most appropriate level** of service or supply considering the **potential benefits and harm** to the patient; **and**
- it is **known to be effective in improving health outcomes** (for new interventions, effectiveness is determined by **scientific evidence**; then, if necessary, by professional standards; then, if necessary, by expert opinion).

551. Aetna uses an equivalent definition, covering as "medically necessary" treatments that are "clinically appropriate," supported by "generally accepted standards of medical or dental practice," supported by "credible scientific evidence," and cost-effective when compared to alternatives likely to produce the same result.

552. The providers participating in the Employee Health Plans use the CMS 1500 when seeking payment for office visits, thereby certifying that the services provided were "medically

indicated and necessary” to the health of the beneficiary. The claims are reviewed by the administrators, paid, and then forwarded to the State for reimbursement.

553. State employees’ prescription drug benefits are administered by Express Scripts. Express Scripts covers all medically necessary and appropriate prescription drugs for plan participants. The terms of coverage are:

[P]rescription drugs must meet federal Food and Drug Administration (FDA) approved indications and be **safe and effective for their intended** use . . . A prescription drug is medically necessary and appropriate if, as recommended by the treating practitioner and as determined by Express Scripts medical director or designee(s) it is **all of the following**:

- A health intervention for the purpose of treating a medical condition;
- The most **appropriate** intervention, considering potential **benefits and harms** to the patient;
- **Known to be effective in improving health outcomes.** (For new interventions, effectiveness is determined by **scientific evidence**. For existing interventions, effectiveness is determined first by **scientific evidence**; then, if necessary, by professional standards; then, if necessary, by expert opinion);
- **Cost effective** for the applicable condition, compared to alternative interventions, including no intervention. “Cost effective” does not mean lowest price.

The fact that an attending practitioner prescribes, orders, recommends, or approves the intervention, or length of treatment time, does not make the intervention “medically necessary and appropriate.” (Emphasis added.)

554. Pharmacists providing services for the Employee Health Plans use the NCPDP v.D.0 format to submit claims for prescription drugs to Express Scripts. Express Scripts pays the pharmacies for all prescriptions that comply with plan guidelines. The claims are then submitted to the State for reimbursement.

(3) The false claims against these State-funded comprehensive health benefits plans

555. Most long-term use of opioids to treat chronic pain is not medically necessary as defined by the State's comprehensive health benefits plans. As described above in Section V.D.5, the long-term safety and efficacy of such use is not supported by substantial scientific evidence and is generally not the most appropriate treatment for moderate, chronic pain considering potential benefits and harms. Yet Purdue undertook a systematic marketing campaign—at the direction and under the supervision of the Sacklers—to encourage doctors to use opioids as the first line of treatment for chronic pain. In doing so, the Sacklers caused doctors and pharmacies to submit claims to its health plans that were false by:

- (a) causing doctors to write prescriptions for chronic opioid therapy supported by Purdue's deceptive, false, and incomplete representations regarding the risks, benefits, and superiority of those drugs;
- (b) causing doctors to certify that these prescriptions were “medically necessary” when, in fact, the prescriptions were not supported by substantial scientific evidence showing either that the risks associated with the drugs were outweighed by benefits or that the drugs were safe and effective for long-term, chronic use; and
- (c) causing doctors to write opioid prescriptions when long-term opioid use renders patients dependent upon the continued and increased use of the drugs.

556. Alternatively, to the extent that chronic opioid therapy was considered “medically necessary” because it was consistent with the generally accepted professional and community standards that prevailed between the late 1990s and 2016, that medical consensus existed only because standards of practice had been re-written to conform to the false reality created by Purdue's deceptive marketing. Purdue's marketing coopted and subverted every input that physicians rely upon in making prescribing decisions: medical literature, licensing board guidelines, insurers' formularies, and patient expectations.

557. For the majority of patients experiencing moderate chronic pain, long-term opioid use should not have been prescribed because it was neither necessary nor appropriate. As such, long-term opioid prescriptions would not have been eligible for reimbursement. The State would not have knowingly reimbursed claims for prescription drugs that were not eligible for coverage. For example, the State paid the following Medicaid and Employee Health claims:

- (a) New Jersey Medicaid Patient A received 84 opioid prescriptions for chronic pain between December 2015 and July 2017, at a cost of \$10,999 in claims paid by the State's Medicaid Contractor and subsequently presented to the State. These prescriptions were written by a doctor who received 176 visits from Purdue detailers over a period of 10 years.
- (b) New Jersey Medicaid Patient B received 59 opioid prescriptions for chronic pain between January 2015 and May 2017, at a cost of \$12,522 in claims paid by the State's Medicaid Contractor and subsequently presented to the State. These prescriptions were written by a doctor who received 151 visits from Purdue detailers over a period of 7 years.
- (c) New Jersey Employee Health Patient E was diagnosed with unspecified back pain and chronic pain and received 37 opioid prescriptions between September 2014 and July 2017, at a cost of \$16,311 in claims presented to and paid by the State. These prescriptions were written primarily by a doctor who received 117 visits from Purdue detailers over a period of 10 years.
- (d) New Jersey Employee Health Patient F was diagnosed with lumbar radiculopathy and received 67 opioid prescriptions between January 2012 and July 2017, at a cost of \$31,814 in claims presented to and paid by the State. These prescriptions were written primarily by a doctor who received 176 visits from Purdue detailers over a period of 10 years.
- (e) New Jersey Employee Health Patient G was diagnosed with myalgia and myositis and received 57 opioid prescriptions between February 2012 and November 2016, at a cost of \$10,061 in claims presented to and paid by the State. These prescriptions were written primarily by a doctor who received 117 visits from Purdue detailers over a period of 10 years.
- (f) New Jersey Employee Health Patient H was diagnosed with spondylosis and received 35 opioid prescriptions between March 2014 and May 2017, at a cost of \$43,599 in claims presented to and paid by the State. These prescriptions were written primarily by a doctor who received 149 visits from Purdue detailers over a period of 4 years.

558. Based on a preliminary review, the State's largest Medicaid MCO spent more than \$109 million for over 2.9 million claims for opioid prescriptions submitted during the period January 2008 through June 2017. This includes approximately \$37 million for Purdue opioids, as well as brand-name and generic opioids produced by other manufacturers. The State estimates that hundreds of thousands of claims were submitted during the same time period to the State's other Medicaid MCOs. The State estimates that a substantial percentage of these claims were false claims because they were for opioids prescribed for a period longer than 90 days and were prescribed: (a) at a strength of 90 MME or more; or (b) to treat moderate, rather than severe, pain; or (c) without exploration of alternative therapies like non-opioid medications and physical therapy.

559. Based on a preliminary review, the State spent more than \$136 million for over 220,000 claims for opioid prescriptions submitted to the Employee Health Plans during the period January 2012 to August 2017. This includes approximately \$80 million for Purdue opioids, as well as brand-name and generic opioids produced by other manufacturers. The State estimates that a substantial percentage of these claims were false claims because they were for opioids prescribed for a period longer than 90 days and were prescribed: (a) at a strength of 90 MME or more; or (b) to treat moderate, rather than severe, pain; or (c) without exploration of alternative therapies like non-opioid medications and physical therapy.

560. As a result of Purdue's deceptive marketing, New Jersey patients who used opioids long-term to treat chronic pain required additional services and supplies—in the form of office visits, toxicology screens, hospitalization for overdoses and infections, rehabilitation and addiction-related therapy, and other treatments—necessitated by the adverse effects of opioids. These additional services and supplies caused the State to incur additional and consequential costs.

b. The State's spending under the Workers' Compensation Program

561. When a State employee is injured on the job, he or she may file a claim for workers' compensation; if the injury is deemed work-related, the State is responsible for paying its share of the employee's medical costs and lost wages. The State pays these claims through a self-funded program that is managed by Horizon Casualty Services ("HCS").

562. The State's Workers' Compensation Program has three overarching goals: to ensure prompt medical treatment for workers injured on the job; to maximize the likelihood that those workers can return to work; and to compensate workers for injuries that cannot be cured and wages lost during periods of disability.

563. The costs of opioid prescribing in the context of workers' compensation are substantial. In 2011, First Script, a national pharmacy managed care organization, prepared a Drug Trends Report outlining pharmaceutical trends identified in its workers' compensation book of business. In this report, First Script explained that short-acting and long-acting opioids represent the two most-prescribed drug classes within its workers' compensation program, representing 37% of its drug spending. The report also noted: "The nation's liberal consumption of narcotic pain relievers continues to gain recognition for its detrimental impact on injured workers—particularly those treated for chronic pain—and their employers."

(1) Medical and prescription drug benefits under Workers' Compensation

564. Horizon Casualty Services' provider agreement limits covered, or reimbursable, services and supplies to those that are: (a) causally linked to the worker's injury or condition, (b) medically necessary, and (c) reasonable. Consistent with the goals of the program, services and supplies are also intended to yield "maximum medical improvement," which is achieved when

“[t]he patient has reached maximal benefit from a curative treatment plan, or further medical treatment will not provide any improvement in the patient’s current condition.”

565. The State’s Workers’ Compensation Program covers all costs associated with treatment for workplace injuries and conditions. This coverage includes opioids, when prescribed by a doctor as medically necessary, and treatment related to any adverse outcomes from chronic opioid therapy, such as addiction treatment. Doctors submitting claims for services to Horizon Casualty Services use the CMS-1500 form.

566. Advancing the Sacklers’ directives, Purdue caused doctors and pharmacies in New Jersey to submit, and the State to pay, claims to the State’s Workers’ Compensation program that were false by:

- (a) causing doctors to write prescriptions for chronic opioid therapy supported by Purdue’s deceptive, false, and incomplete representations regarding the risks, benefits, and superiority of those drugs;
- (b) causing doctors to certify that these prescriptions and associated services were medically necessary, likely to improve functional capacity, or otherwise reasonably required, when, in fact, the prescriptions were not supported by substantial scientific evidence showing either that the risks associated with the drugs were outweighed by benefits or that the drugs were safe and effective for long-term, chronic use; and
- (c) causing doctors to write subsequent prescriptions when long-term opioid use rendered patients dependent upon the continued and increased use of the drugs.

567. In the alternative, to the extent that chronic opioid therapy was considered “medically necessary” because it was consistent with the generally-accepted professional and community standards that prevailed between the late 1990s and 2016, Purdue engineered that medical consensus, causing doctors to believe that such long-term use of opioids to treat chronic pain was not simply permissible or appropriate but required.

568. As explained above, however, in many instances, the long-term use of opioids to treat moderate chronic pain is not medically necessary, reasonably required or appropriate because:

(a) the risks do not materially exceed the benefits and (b) such use is not supported by substantial scientific evidence demonstrating that they improve physiological function or are otherwise safe and effective. In fact, the long-term use of opioids to treat chronic pain is antithetical to the purposes of Workers' Compensation: long-term use can cause hyperalgesia (increased sensitivity to pain) and cognitive impairment without improving physiological function.

569. In addition to these prescription costs, the State has paid for medical care and prescriptions necessitated by long-term opioid use and abuse including addiction treatment.

(2) Lost wages and disability

570. A growing body of research shows that long-term opioid use to treat chronic pain is associated with slower returns to work. The State has paid claims for lost wages attributable, in whole or in part, to opioid-related disability.

(3) The false claims against the State's Workers' Compensation fund

571. The following is a representative sample of claims submitted to the State's Workers' Compensation program:

- (a) New Jersey Workers' Compensation Patient I was diagnosed with lumbago in October 2009. This patient received 191 opioid prescriptions between October 2009 and June 2017. The State has paid \$64,242 for Patient I's medical care.
- (b) New Jersey Workers' Compensation Patient J was diagnosed with a lumbar region sprain in April 2008. This patient received 150 opioid prescriptions between April 2008 and June 2017. The State has paid \$15,176 for Patient J's medical care.
- (c) New Jersey Workers' Compensation Patient K was diagnosed with a lumbar region sprain in February 2010. This patient received 132 opioid prescriptions. The State has paid \$7,155 for Patient K's medical care.
- (d) New Jersey Workers' Compensation Patient L received opioid prescriptions for chronic pain arising from a work-related injury. Patient L became addicted to opioids and consequently entered a 33-day residential rehabilitation treatment program for which the State paid an additional \$68,700. While in this rehabilitation treatment program, Patient L claimed and the State paid \$3,754 for lost wages.

572. The State paid these prescription claims believing that they were medically necessary and therefore covered by the State's Workers' Compensation program. Long-term opioid use is generally neither necessary nor the most appropriate treatment for moderate chronic pain. Thus, these claims—and their attendant and consequential costs—were ineligible for payment.

573. Based on a preliminary review, the State spent more than \$6 million for over 12,600 claims for opioid prescriptions submitted to the State's Workers' Compensation Program during the period January 2008 to August 2017. This includes approximately \$886,000 for Purdue opioids, and \$5.2 million for brand name and generic opioids produced by other manufacturers. The State estimates that a substantial percentage of these claims were false claims because they were for opioids prescribed for a period longer than 90 days and were prescribed: (a) at a strength of 90 MME or more; or (b) to treat moderate, rather than severe, pain; or (c) without exploration of alternative therapies like non-opioid medication and physical therapy.

- c. Misrepresentations regarding the medical necessity were material to the State's decision to pay these claims

574. The fact that the State would pay for these ineligible prescriptions was both the foreseeable and intended consequence of the fraudulent marketing scheme Purdue implemented in New Jersey at the direction and under the supervision of the Sacklers. As described above, Purdue set out to change the medical and general consensus supporting chronic opioid therapy so that doctors would prescribe and so that government payors, such as the State, would pay for long-term prescriptions of opioids to treat chronic pain despite the absence of substantial scientific evidence supporting chronic opioid therapy and the contrary evidence regarding the significant risks and limited benefits from long-term use of opioids.

575. Purdue's misrepresentations were material to and influenced the State's decisions to pay claims for opioids for chronic pain and, subsequently, to bear consequential costs in treating overdose, addiction, and other side effects of opioid use. But for the fraudulent and deceptive marketing campaign initiated by Purdue, the State would not have been presented with, or paid, claims for opioids to treat chronic, moderate pain.

576. As laid out above, Purdue's misrepresentations related to the State's requirement that medical treatments be medically necessary—a condition of coverage for any medical treatment under the State's comprehensive health plans and Workers' Compensation program. But for Purdue's fraudulent and deceptive marketing, prescribers would have more accurately understood the risks and benefits of long-term opioid use and would not have prescribed opioids as medically necessary or reasonably required to treat chronic pain. Misrepresentations as to, for example, whether patients were likely to become addicted to the drug, would be able to resume life activities, and would experience long-term relief were not minor or insubstantial matters, but went to the core of a prescriber's decision-making.

577. Since becoming aware of the growing use and abuse of opioids in New Jersey, the State has taken numerous steps to address the problem by educating prescribers and consumers about the risks and benefits of opioids, restricting prescribing, reducing the number of opioids pills in circulation, and increasing the coverage and availability of treatment for opioid overdose and addiction. The State's efforts include:

- launching, and then mandating use of, the Prescription Monitoring Program to help providers determine what other opioids a patient has been prescribed;
- launching the Project Medicine Drop initiative, designed to rid home medicine cabinets of unused opioids;
- publishing a set of best practices for pharmacists for the secure handling and dispensing of prescription drugs in order to reduce diversion;

- launching the “Know Addiction” public awareness campaign, which has distributed information and resources regarding the opioid epidemic, the risks of opioid use, abuse, and addiction, and the particular vulnerability of children, teens, and young adults to dangerous experimentation and misuse;
- setting a new, five-day supply limit on initial prescriptions of opioids for acute pain and authorizing doctors to prescribe only immediate release drugs in the lowest effective dose for this purpose;
- referring prescribers to the CDC Guideline;
- requiring insurers to cover addiction treatment for a period of 180 days—without delays or limits—when prescribed by a licensed provider; and
- passing legislation that provides funding and authority for health care providers to prescribe, and first responders to administer, overdose antidotes.

578. The State has taken concrete steps to limit the prescribing of long-term opioid use for chronic pain. The New Jersey Legislature passed legislation in February 2017 that requires practitioners to take certain affirmative steps before issuing an initial opioid prescription to treat chronic pain. The practitioner is required to prescribe the lowest effective dose and to disclose and discuss:

- risks of addiction and overdose even when the drug is taken precisely as prescribed;
- alternative therapies; and
- the reasons why the prescription is necessary.

Before issuing a third refill prescription, practitioners are required to enter into a “pain management agreement” with patients which, among other things:

- documents a pain management plan;
- identifies other non-opioid medication and modes of treatment that are part of the pain treatment program; and
- specifies measures that will be used to confirm proper prescription use, like toxicology screening and pill-counting.

Where opioid use is continuous and long-term, the practitioners must:

- assess the patient before issuing each renewal prescription;
- document the course of treatment, the patient's progress, and new information about the etiology of the pain every three months;
- assess whether the patient is experiencing problems associated with physical and psychological dependence and document the assessment;
- make periodic efforts to taper the dosage or otherwise reduce or discontinue opioid use; and
- refer the patient to a pain management or addiction specialist for independent evaluation or treatment.

579. The State Board of Medical Examiners' implementing regulations took effect in March 2017 and were consistent with the standards set forth in the 2016 CDC Guideline.

580. The State has also taken steps to limit its own coverage of long-term opioid use for chronic pain. The State presented the CDC Guideline to Medicaid vendors in April 2016. The State has also ratified coverage restrictions proposed by Express Scripts, applicable to the Employee Health Plans, for the purpose of monitoring and creating safer opioids utilization.

F. The Sacklers, Who Knew that Purdue's Marketing of Opioids Was False and Misleading, Instructed the Company to Fraudulently Conceal Its Misconduct and Hid their Own Involvement.

581. Purdue made, promoted, and profited from its misrepresentations about the risks and benefits of opioids for chronic pain even though it knew that its marketing was false and misleading. The history of opioids, as well as research and clinical experience over the last 20 years, established that opioids were highly addictive and responsible for a long list of very serious adverse outcomes. The FDA and other regulators warned Purdue of this, and Purdue entered into settlements in the hundreds of millions of dollars to address similar misconduct that occurred before 2008. Purdue had access to scientific studies, detailed prescription data, and reports of adverse events, including reports of addiction, hospitalization, and deaths—all of which made clear

the harms from long-term opioid use and that patients are suffering from addiction, overdoses, and death in alarming numbers. More recently, the FDA and the CDC have issued pronouncements based on existing medical evidence that conclusively expose the known falsity of Purdue's misrepresentations.

582. The Sacklers knew all of this, too. They were not merely passive overseers who met yearly, approved budgets, and took distributions. The Sacklers were deeply involved in running Purdue, were highly knowledgeable about Purdue products and sales tactics, and were knowledgeable about what types of statements and practices were lawful. As discussed in Section V.B, the Corporate Integrity Agreement they approved in 2007 required them to be trained on marketing rules and report violations. Notwithstanding this knowledge, at all times relevant to this Complaint, the Sacklers directed Purdue to engage in the deceptive and unconscionable practices described herein and then took the additional steps of directing or sanctioning the steps taken by Purdue to fraudulently conceal Purdue's wrongful conduct.

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

584. Purdue further failed to report to authorities illicit or suspicious prescribing of its opioids, even as it has publicly and repeatedly touted its "constructive role in the fight against

opioid abuse” and “strong record of coordination with law enforcement.” The Sacklers received regular updates on just how many “Reports of Concern” had been submitted to the company and how few of those were even investigated, much less reported to law enforcement. The Sacklers also received regular updates of exactly how many calls had been received by Purdue’s compliance hotline, and how many of the calls had been reported to the authorities. In almost every case, the number of calls Purdue reported to the authorities was zero. The Sacklers received reports that Purdue had failed to act on its own employees’ reports of suspicious doctors and pharmacies, but took no action to ensure prompt reporting of abuse and diversion. The Sacklers received reports that Purdue’s corporate policies and the Board’s own compliance policies were below the standards set by other drug companies, but took no action to bring their compliance policies into line with the rest of the industry.

585. Purdue’s public stance long has been that patients who deliberately misuse opioids and the diversion of pills to illicit secondary channels—not overprescribing of OxyContin and other opioids for chronic pain—are to blame for widespread addiction and abuse. Richard Sackler devised this narrative in 2001, and it has been the foundation for Purdue’s approach to the opioid crisis ever since.

586. To address these issues, as framed by Purdue, the company funded various drug abuse prevention programs nationwide and in New Jersey, and, most notably, introduced abuse-deterrent opioids reformulated to make non-oral ingestion more difficult. Purdue also pumped out research, presented at conferences of addiction prevention professionals, stressing the importance of patient selection and touting the efficacy of its “abuse deterrent” opioids. Depicting the opioid crisis as a problem of misuse and diversion, and promoting its pills as solutions, allows Purdue to

present itself as a responsible corporate citizen while continuing to profit from the commonplace prescribing of its drugs, even at high doses for long-term use.

587. At the heart of Purdue's public outreach is the claim that it works hand-in-glove with law enforcement and government agencies to combat opioid abuse and diversion. Purdue has consistently trumpeted this partnership since at least 2008, and the message of close cooperation features in virtually all of Purdue's recent pronouncements in response to public scrutiny of opioid abuse.

588. Touting the benefits of opioids with abuse-deterrent formulations, Purdue's website asserts: "[W]e are acutely aware of the public health risks these powerful medications create That's why we work with health experts, law enforcement, and government agencies on efforts to reduce the risks of opioid abuse and misuse" Purdue's statement on "Opioids Corporate Responsibility" likewise states that "[f]or many years, Purdue has committed substantial resources to combat opioid abuse by partnering with . . . communities, law enforcement, and government." And, responding to criticism of Purdue's failure to report suspicious prescribing to government regulatory and enforcement authorities, the website similarly proclaims that Purdue "ha[s] a long record of close coordination with the DEA and other law enforcement stakeholders to detect and reduce drug diversion."

589. These public pronouncements create the misimpression that Purdue is proactively working with law enforcement and government authorities, nationwide and in New Jersey, to root out drug diversion, including the illicit prescribing that can lead to diversion. They aim to distance Purdue from its past, publicly admonished conduct in deceptively marketing opioids, which gave rise to 2007 criminal pleas, and to make its current marketing seem more trustworthy and truthful. In fact, Purdue has consistently failed to report suspicious prescribing to authorities, despite having

all the necessary tools—detailed prescribing data and the eyes and ears of its sales force—to observe such practices.

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

591. Yet, according to a 2016 investigation by the Los Angeles Times, Purdue failed to cut off these providers’ opioid supply at the pharmacy level—meaning Purdue continued to generate sales revenue from their prescriptions—and failed to report these providers to state medical boards or law enforcement. In an interview with the Times, Purdue’s former senior compliance officer acknowledged that in five years of investigating suspicious pharmacies, Purdue consistently failed to report suspicious dispensing or to stop supplies to the pharmacy, even where Purdue employees personally witnessed the diversion of its drugs. The same was true of prescribers. Despite its knowledge of illicit prescribing, Purdue did not report its suspicions, for example, until years after law enforcement shut down a Los Angeles clinic that Purdue’s district manager described internally as “an organized drug ring” and that had prescribed more than 1.1 million OxyContin tablets. As described in Section V.C, the Sacklers were briefed in detail on Purdue’s efforts to blunt the impact of the Times’ story, including by collaborating on more

favorable reporting by a Times competitor. After receiving that briefing, Richard Sackler went so far as to demand from the Times that it send him all the paper's correspondence with Purdue.

592. The Sacklers requested and received reports on Region Zero as early as 2010. On information and belief, they either knew that Region Zero prescribers were not being referred to law enforcement or elected not to inquire.

593. Purdue thus successfully concealed from the medical community, patients, and the State facts sufficient to arouse suspicion of the claims that the State now asserts. The State did not know of the existence or scope of Purdue's fraud and could not have acquired such knowledge earlier through the exercise of reasonable diligence.

594. The Sacklers sought to hide their role as well. After vacating executive positions within the company in 2007, they served on the Board of Directors. On information and belief, they did so recognizing that it was crucial to install a CEO who would be loyal to the family. The Sacklers also hid behind the façade that they operated as a normal board, approving high-level strategy and budgets but no more. When Richard Sackler announced his plan to accompany sales representative on their prescriber visits in 2011, staff agreed that he needed to be "mum and anonymous." Contemporaneous correspondence indicates that he was warned on this point and further advised that his participation in sales visits constituted a compliance risk under the terms of the federal Corporate Integrity Agreement.

VI. CAUSES OF ACTION

COUNT ONE VIOLATIONS OF THE CONSUMER FRAUD ACT (UNCONSCIONABLE COMMERCIAL PRACTICES)

595. Plaintiffs re-allege and incorporate by reference each of the allegations contained in the preceding paragraphs of this Complaint as though fully alleged herein.

596. The CFA defines "advertisement" as:

. . . the attempt directly or indirectly by publication, dissemination, solicitation, indorsement or circulation or in any other way to induce directly or indirectly any person to enter or not enter into any obligation or acquire any title or interest in any merchandise or to increase the consumption thereof

[N.J.S.A. 56:8-1(a).]

597. The CFA defines “merchandise” as including “any objects, wares, goods, commodities, services or anything offered, directly or indirectly to the public for sale.” N.J.S.A. 56:8-1(c).

598. The CFA defines “sale” as “any sale, rental or distribution, offer for sale, rental or distribution or attempt directly or indirectly to sell, rent or distribute.” N.J.S.A. 56:8-1(e).

599. Defendants are “persons” as defined by the CFA and have advertised, offered for sale, and sold “merchandise” also as defined by the CFA.

600. The CFA makes it unlawful for a business to engage in any unconscionable commercial practice in connection with the sale or advertisement of pharmaceutical products. N.J.S.A. 56:8-2.

601. At all times relevant to this Complaint, Defendants violated N.J.S.A. 56:8-2 by directing, approving, and participating in the following unconscionable commercial practices:

- (a) Engaging in deceptive, fraudulent, false, and misleading marketing that was unsupported by substantial scientific evidence to support its product claims in violation of 21 C.F.R. § 202.1(e);
- (b) Engaging in a marketing campaign that failed, despite the known, serious risks of addiction and adverse effects posed by opioids, to present a fair balance of benefit and risk information in its promotion of opioids, in violation of FDA regulations, including 21 C.F.R. § 202.1(e);
- (c) Promoting the purported advantages of opioids over other pain relief products, including but not limited to the risks and/or benefits of opioids in comparison to NSAIDs or acetaminophen, without substantial scientific evidence to support those claims, in violation of FDA regulations, including 21 C.F.R. § 202.1(e);

- (d) Promoting high doses for extended periods of time, in contravention of longstanding public policy to avoid and minimize the risk of addiction and abuse of controlled substances;
- (e) Targeting a vulnerable population—the elderly—for promotion of opioids to treat chronic pain in the face of the known, heightened risks of opioid use to that population, including risks of addiction, adverse effects, hospitalization, and death;
- (f) Targeting opioid naïve patients for conversion to Purdue’s ER/LA opioid products; and
- (g) Offering consumer savings cards to prescribers and pharmacies with the surreptitious goal of inducing long-term use of opioids, despite knowing the serious risks and unproven benefits of long-term use.

602. These acts or practices may be deemed unconscionable and unfair in that they offend public policy reflected in (a) federal law, which requires the truthful and balanced marketing of prescription drugs, 21 C.F.R. § 202.1(e); (b) the CFA, which protects consumers and competitors from deceptive marketing and to ensure an honest marketplace; and (b) State legislation and standards of practice related to controlled substances—including, but not limited to, the prescribing and dispensing standards set forth in N.J.A.C. 13:35-7.6—which seek to minimize the risk of addiction to and abuse of controlled substances.

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

604. Defendants purposely directed the unconscionable conduct alleged above to prescribers and patients in New Jersey. These acts or practices were either undertaken at Defendants’ direction or known to and sanctioned by Defendants. Defendants continually

approved the hiring of sales representatives, targets for volume of sales representative activity, and sales objectives with the knowledge that Purdue would engage in these acts or practices.

605. As a direct result of the foregoing unconscionable commercial acts and practices, Defendants obtained income, profits, and other benefits that they would not otherwise have obtained.

COUNT TWO
VIOLATIONS OF THE CONSUMER FRAUD ACT
(DECEPTIONS, MISREPRESENTATIONS, AND OMISSIONS OF MATERIAL FACTS)

606. Plaintiffs re-allege and incorporate by reference each of the allegations contained in the preceding paragraphs of this Complaint as though fully alleged herein.

607. The CFA makes it unlawful for a business to engage in “deception, fraud, false pretense, false promise, misrepresentation, or the knowing concealment, suppression or omission of any material fact with intent that others may rely upon such concealment, suppression or omission” in connection with the sale or advertisement of pharmaceutical products. N.J.S.A. 56:8-1, 56:8-2.

608. Defendants were required to comply with the provisions of the CFA in their conduct directing the marketing, promotion, sale, and distribution of prescription drugs.

609. At all times relevant to this Complaint, Defendants violated N.J.S.A. 56:8-2 by directing and engaging in the deceptive marketing and promotion of Purdue’s products by:

- (a) causing false or misleading statements about the use of opioids to treat chronic pain to be made and disseminated;
- (b) causing false or misleading statements about opioids to be made and disseminated;
- (c) causing statements to promote the use of opioids to treat chronic pain that omitted or concealed material facts to be made and disseminated; and
- (d) failing to correct prior misrepresentations and omissions about the risks and benefits of opioids.

610. Defendants purposely directed the deceptive marketing and promotion alleged above to prescribers and patients in New Jersey.

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

612. At all times relevant to this Complaint, Defendants violated N.J.S.A. 56:8-2 by directing, approving, and participating in Purdue misrepresentations, including, but not limited to, the following:

- (a) Misrepresenting that opioids were effective for long-term use of months and years, including that they would improve patients' function and quality of life;
- (b) Mischaracterizing the risk of opioid addiction and abuse;
- (c) Misrepresenting that addiction can be avoided or successfully managed through the use of screening and other tools;
- (d) Promoting the misleading concept of pseudoaddiction and emphasizing the prevalence of dependence, thus concealing the true risk of addiction;
- (e) Misrepresenting that increasing the dose of opioids (titrating up) poses no significant additional risk;
- (f) Misleadingly depicting the safety profile of opioids by minimizing their risks and adverse effects while emphasizing the risks of competing products, including NSAIDs and acetaminophen; and

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

613. Defendants purposely directed the deceptive marketing and misrepresentations alleged above to prescribers and patients in New Jersey. Purdue's misrepresentations were either undertaken at Defendants' direction or known to and sanctioned by Defendants. Defendants continually approved the hiring of sales representatives, targets for volume of sales representative activity, and sales objectives with the knowledge that Purdue would engage in these misrepresentations.

614. As a direct result of the foregoing deceptions, misrepresentations, and omissions of material fact, Defendants obtained income, profits and other benefits that they would not otherwise have obtained.

COUNT THREE
VIOLATIONS OF THE CONSUMER FRAUD ACT
(UNCONSCIONABLE AND DECEPTIVE PRACTICES AGAINST SENIOR CITIZENS)

615. Plaintiffs re-allege and incorporate by reference each of the allegations contained in the preceding paragraphs of this Complaint as though fully alleged herein.

616. The CFA, N.J.S.A. 56:8-14.3, provides for additional penalties for pecuniary injury to a senior citizen. Specifically, "In addition to any other penalty authorized by law, a person who violates the provisions of [the CFA] shall be subject to additional penalties as follows: (1) A penalty of not more than \$10,000 if the violation caused the victim of the violation pecuniary injury and the person knew or should have known that the victim is a senior citizen[;] (2) or [a] penalty of not more than \$30,000 if the violation was part of a scheme, plan, or course of conduct directed at senior citizens . . . in connection with sales or advertisements."

617. Each instance in which Defendants engaged in deceptive practices in connection with its marketing and sale of opioids to senior citizens falls within the scope of additional penalties provided by N.J.S.A. 56:8-14.3.

618. At varying times, Defendants have directed, approved, and participated in targeting senior citizens, as defined by N.J.S.A. 56:8-14.2, as part of their strategy to continue increasing Purdue's revenues from the sale of opioids.

619. Among other things, Purdue sales representatives focused on the nursing home market in New Jersey and educating physicians in New Jersey about Medicare Part D coverage for opioids.

620. Elderly patients taking opioids are at a greater risk for fractures and hospitalization and have increased vulnerability to adverse drug effects, such as respiratory depression.

621. Defendants purposely directed the conduct alleged above to prescribers and patients in New Jersey. Each of these practices was either undertaken at Defendants' direction or known to and sanctioned by Defendants. Defendants continually approved the hiring of sales representatives, targets for volume of sales representative activity, and sales objectives with the knowledge that Purdue would engage in these practices.

622. As a direct result of the foregoing deceptive and unconscionable acts and practices, Defendants obtained income, profits, and other benefits that they would not otherwise have obtained.

COUNT FOUR
VIOLATIONS OF THE NEW JERSEY FALSE CLAIMS ACT, N.J.S.A. 2A:32C-1
(FALSE CLAIMS)

623. Plaintiffs re-allege and incorporate herein by reference each of the allegations contained in the preceding paragraphs of this Complaint as though fully alleged herein.

624. A person is liable under the New Jersey False Claims Act, N.J.S.A. 2A:32C-3, when that person:

(1) knowingly presents or causes to be presented to an employee, officer, or agent of the State, or to any contractor, grantee, or other recipient of State funds, a false or fraudulent claim for payment or approval;

(2) knowingly makes, uses, or causes to be made or used, a false record or statement to get a false or fraudulent claim paid or approved by the State.

N.J.S.A. 2A:32C-2 defines a "claim" as:

a request or demand, under a contract or otherwise, for money, property, or services that is made to any employee, officer, or agent of the State, or to any contractor, grantee, or other recipient if the State provides any portion of the money, property, or services requested or demanded, or if the State will reimburse the contractor, grantee, or other recipient for any portion of the money, property, or services requested or demanded.

625. Defendants' conduct, as described in the Complaint, violated N.J.S.A. 2A:32C-3. By directing, approving, and participating in Purdue's deceptive marketing of opioids for chronic pain, Defendants caused to be presented false or fraudulent claims and knowingly used or caused to be used false statements to get false or fraudulent claims paid or approved by the State.

626. Defendants knew, deliberately ignored, or recklessly disregarded, at the time the marketing occurred, that the marketing statements were untrue, false, misleading, or unsupported by substantial scientific evidence, and were made for the purpose of inducing the State, through its employees and contractors, to pay for opioids for long-term treatment of chronic pain. In addition, Defendants knew or should have known that Purdue's marketing and promotional efforts created an untrue, false, and misleading impression about the risks, benefits, and superiority of opioids for chronic pain.

627. Purdue's marketing and promotion, as directed, approved, and participated in by Defendants, caused doctors and other prescribers to write prescriptions for opioids to treat chronic pain that were presented to the State's Medicaid, Employee Health, and Workers' Compensation plans for payment. Doctors, pharmacists, other health care providers, and/or other agents of the health plans and Workers' Compensation program expressly or impliedly certified to the State that opioids were medically necessary and reasonably required to treat chronic pain because they were influenced by the false and misleading statements disseminated by Purdue. To the extent that such prescribing was considered customary or consistent with generally accepted medical standards, those standards were influenced and ultimately corrupted by Purdue's deceptive marketing as well.

628. Defendants purposely directed the conduct alleged above to prescribers and patients in New Jersey. This conduct was either undertaken at Defendants' direction or known to and sanctioned by Defendants. Defendants continually approved the hiring of sales representatives, targets for volume of sales representative activity, and sales objectives with the knowledge that Purdue would engage in these acts or practices.

629. Defendants knew or should have known that, as a natural consequence of their actions, which were purposely directed at New Jersey, governments such as the State would necessarily be paying for long-term prescriptions of opioids to treat chronic pain, which were dispensed as a consequence of their deceptive and fraudulent campaign. The misrepresentations Defendants caused to be made were material to the State's decisions to pay the costs of long-term opioid use because they falsely suggested that such treatment was medically necessary.

630. The State has paid millions of dollars for opioid prescriptions that were represented to the State as medically necessary. These prescriptions would not have been prescribed or covered

and reimbursed by State insurance plans but for Defendants' deceptive, fraudulent, and unlawful marketing practices.

631. The State has paid and will continue to pay consequential health care costs necessitated by Defendants' deceptive, fraudulent, and unlawful marketing practices: drugs for persons dependent upon and addicted to opioids and treatment costs for those dealing with addiction, overdose, and other adverse effects.

VII. PRAYER FOR RELIEF

WHEREFORE, based on the foregoing allegations, Plaintiffs respectfully request that the Court enter judgment against Defendants:

- (a) Finding that the acts and practices of Defendants constitute multiple instances of unlawful practices in violation of the CFA, N.J.S.A. 56:8-1 et seq.;
- (b) Permanently enjoining Defendants from engaging in, continuing to engage in or doing any acts and practices in violation of the CFA, N.J.S.A. 56:8-1 et seq., including, but not limited to, the acts and practices alleged in this Complaint, as authorized by the CFA, N.J.S.A. 56:8-8;
- (c) Directing Defendants to disgorge all profits unlawfully acquired or retained, as authorized by the CFA, N.J.S.A. 56:8-8;
- (d) Directing Defendants to pay the maximum statutory civil penalties for each and every violation of the CFA, in accordance with N.J.S.A. 56:8-13 and 56:8-14.3, and the FCA in accordance with N.J.S.A. 2A:32C-3;
- (e) Assessing treble damages for payments made by or on behalf of the State for medically unnecessary opioid prescriptions and related claims covered by the State's Medicaid, Employee Health and Workers' Compensation programs, in accordance with N.J.S.A. 2A:32C-3;
- (f) Directing Defendants to pay costs and fees including attorneys' fees for the use of the State of New Jersey, as authorized by the CFA, N.J.S.A. 56:8-11 and N.J.S.A. 56:8-19, and the FCA, N.J.S.A. 2A:32C-8; and
- (g) Granting such other relief as the interests of justice may require.

Dated: May 30, 2019
Newark, New Jersey

GURBIR S. GREWAL
ATTORNEY GENERAL OF NEW JERSEY
Attorney for Plaintiffs

By: Patricia Schiripo

Patricia Schiripo
Deputy Attorney General, Assistant Chief
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RULE 4:5-1 CERTIFICATION

I certify, to the best of my information and belief, that the matter in controversy in this action is not the subject of any other action pending in any other court of this State, other than Grewal, et al. v. Purdue Pharma, et al., ESX-C-245-17, Camden County v. Purdue Pharma L.P., et al., Dckt. No. 18cv11983 (D.N.J. filed July 23, 2018), Cape May County v. Purdue Pharma L.P., et al., Dckt. No. L-000621-18 (Cape May County, filed July 3, 2018). I further certify, to the best of my information and belief, that the matter in controversy in this action is not the subject of a pending arbitration proceeding in this State, nor is any other action or arbitration proceeding contemplated.

Dated: May 30, 2019
Newark, New Jersey

GURBIR S. GREWAL
ATTORNEY GENERAL OF NEW JERSEY
Attorney for Plaintiffs

By: Patricia Schiripo

Patricia Schiripo
Deputy Attorney General, Assistant Chief
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RULE 1:38-7(c) CERTIFICATION OF COMPLIANCE

I certify that confidential personal identifiers have been redacted from documents now submitted to the Court, and will be redacted from all documents submitted in the future in accordance with R. 1:38-7(b).

Dated: May 31, 2019
Newark, New Jersey

GURBIR S. GREWAL
ATTORNEY GENERAL OF NEW JERSEY
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DESIGNATION OF TRIAL COUNSEL

Pursuant to R. 4:25-4, Patricia Schiripo is hereby designated as trial counsel for the Plaintiffs in this action.

Dated: May 30, 2019
Newark, New Jersey

GURBIR S. GREWAL
ATTORNEY GENERAL OF NEW JERSEY
Attorney for Plaintiffs

By: Patricia Schiripo

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